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ARTICLES

THIRD PARTY REIMBURSEMENT FOR PARTICIPATION IN CANCER CLINICAL TRIALS: A PROPOSAL FOR LEGISLATION

*Gina Mazzariello Plaue**

Each year, approximately one million Americans are diagnosed with cancer,¹ and although about half are cured, much remains unknown about this disease.² Clinical trials for new treatments are the primary method of testing new cancer drugs for efficacy and toxicity.³ Indeed, in 1991, the American Medical Association (AMA) estimated that broader participation in clinical trials could raise the cancer cure rate to seventy-five percent by the year 2000.⁴ However, currently less than three percent of Americans diagnosed with cancer are enrolled in a clinical trial, while the remaining ninety-seven percent continue to receive standard treatment.⁵

Two primary reasons for lack of enrollment into clinical trials are the unwillingness of doctors to refer their patients to these trials and

* J.D., Harvard Law School, 1999; B.S., Syracuse University, 1993. The author would like to dedicate this Article to its inspiration, the late Rudy Plaue.

1. See American Medical Ass'n Council on Scientific Affairs, *Viability of Cancer Clinical Research: Patient Accrual, Coverage, and Reimbursement*, 83 J. NAT'L. CANCER INST. 254, 254 (1991) [hereinafter AMA on Scientific Affairs].

2. See *id.*

3. See Dwight Kaufman, *Cancer Therapy and the Randomized Clinical Trial: Good Medicine?* 72 CANCER SUPPLEMENT 2801, 2801 (1993); Robert J. Levine, *Ethics of Clinical Trials: Do They Help the Patient?* 72 CANCER SUPPLEMENT 2805, 2806 (1993).

4. See Melody L. Harness, *What Is "Experimental" Medical Treatment?: A Legislative Definition Is Needed*, 44 CLEV. ST. L. REV. 67, 71 (1996).

5. See AMA on Scientific Affairs, *supra* note 1, at 254.

the unwillingness of patients to participate.⁶ The National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH), has attempted to increase enrollment in clinical trials by initiating educational programs for the general public, community programs to involve more physicians in clinical trials, and informational programs to give patients and doctors the information necessary to consider enrollment in clinical trials.⁷ In 1997, the Food and Drug Administration (FDA) aided NIH in this effort by requiring the establishment of an easily-accessible data bank of all clinical trials conducted for life-threatening diseases.⁸ These efforts are commendable, but do not resolve the fundamental problem confronting low enrollment in clinical trials, namely, third party reimbursement for the costs of the trials.

Two types of costs are associated with clinical trials: research costs and patient care costs.⁹ Although research costs are paid by the sponsor of the trial, usually a pharmaceutical company or the federal government through the NIH, patients are responsible for general patient care costs.¹⁰ Historically, third parties reimbursed patients for these costs,¹¹ but over the past ten years the increase in managed care dramatically reduced this reimbursement.¹² Unless third parties reverse course and willingly pay for these costs, patient access to clinical trials will continue to diminish.

Most third parties, including private insurers and federal programs such as Medicare, do not currently reimburse patients for basic patient costs associated with participation in clinical trials.¹³ These parties believe that the trials are "experimental" or not "medically necessary" and, therefore, fall outside the scope of coverage.¹⁴ Recently, how-

6. See *id.* at 254-55.

7. See *infra*, text accompanying notes 116-124.

8. See *infra*, text accompanying notes 125-129.

9. See Robert E. Wittes, *Paying for Patient Care in Treatment Research - Who is Responsible?* 71 *CANCER TREATMENT REP.* 107, 109 (1987).

10. See Michael A. Friedman & Mary S. McCabe, *Assigning Care Costs Associated with Therapeutic Oncology Research: A Modest Proposal*, 84 *J. NAT'L. CANCER INST.* 760, 760 (1992). See also *infra*, text accompanying notes 57-65.

11. See Wittes, *supra* note 9, at 109.

12. See AMA on Scientific Affairs, *supra* note 1, at 256.

13. See *id.*

14. See *id.*

ever, there is a push to convince third-parties to pay for these costs.¹⁵ In response, the federal government, through the Department of Defense (DoD) and the Department of Veterans Affairs (VA), agreed to cover patient care costs for participation in clinical trials.¹⁶ Several private insurance carriers are following the lead of the DoD and the VA and are initiating the same policy.¹⁷ Even more recently, the American Association of Health Plans, a managed care trade association, formed an agreement with the NIH to encourage managed care organizations to cover patient care costs associated with clinical trials.¹⁸

These efforts, though, do not guarantee access to clinical trials for all Americans and, importantly, their continued vitality may depend upon maintaining equal or lower costs for participation in clinical trials as compared to the costs of standard treatment.¹⁹ While general cost equality is one reason that reimbursing patients for participation in clinical trials makes sense for third party payors, many other reasons for such reimbursement also exist. First, participation in clinical trials may constitute the best treatment alternative for seriously ill patients.²⁰ Second, many long-term benefits are available to both society and third party payors from such reimbursement such as increased patient enrollment and the possibility for development of cheaper and/or more effective treatment.²¹ However, because individual insurers are primarily motivated by short-term cost²² and are unlikely to respond to long-term incentives without a guarantee that others will do the same,²³ a legislative solution is necessary.

Six states statutorily mandate coverage of patient care costs associated with participation in clinical trials,²⁴ and thirteen others are considering passage of similar legislation.²⁵ Yet, even if all fifty states

15. See *infra*, text accompanying notes 213-220.

16. See *infra*, text accompanying notes 222-241.

17. See *infra*, text accompanying notes 251-257.

18. See *infra*, text accompanying notes 258-265.

19. See *id.*

20. See Levine, *supra* note 3, at 2806.

21. See *infra*, text accompanying notes 208-211.

22. See Walter Lawrence, Jr. et al., *The Impact of Clinical Trial Protocols on Patient Care Systems*, 72 CANCER SUPPLEMENT 2839, 2840 (1993).

23. See *infra*, text accompanying notes 153-154.

24. See *infra*, text accompanying notes 269-285.

25. See sources cited *infra* note 285.

were to follow suit, enormous gaps in coverage would remain because of the large percentage of the population covered by Medicare and Medicaid, which are not subject to state regulation,²⁶ and because the Employee Retirement Insurance Security Act of 1974 (ERISA) pre-empts state law as applied to employer self-insured plans.²⁷ Thus, federal legislation mandating coverage of patient care costs associated with participation in clinical trials by all third parties is needed.²⁸ Congress should pass such a law to ensure that seriously ill patients are not denied what may be the best alternative treatment and to realize all the other long-term benefits associated with widespread participation in clinical trials.

Part I of this Article describes the aspects of a clinical trial. Part II examines the problems of patient enrollment in clinical trials, including the various efforts underway to increase this enrollment. Part III describes the particular problem of third party failures to reimburse for patient care costs associated with participation in clinical trials while Part IV explores efforts being made by health benefits providers, including the federal government and private insurance carriers, to combat this problem. Parts V and VI examine legislative efforts by the states and Congress to require insurers to pay or reimburse for these costs. Finally, Part VII summarizes the argument for action at the federal level in the form of comprehensive legislation to require all health insurers to reimburse patients for these costs.

I. WHAT IS A CLINICAL TRIAL?

Clinical trials are part of the process by which a drug is tested to insure that it meets the FDA's approval as "safe and effective."²⁹ To test whether the drug is "safe and effective," the trials serve as the primary method for determining efficacy and side effects of the drug on humans.³⁰ Any sponsor wishing to conduct a clinical trial is first required

26. See *infra* note 148.

27. See *infra*, text accompanying notes 292-294.

28. See sources cited *infra* note 285.

29. 42 U.S.C. § 355 (1998). See also The Food and Drug Administration's Process For Approving New Drugs, Report of the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong. (1980), in PETER BARTON HUTT AND RICHARD A. MERRILL, *FOOD AND DRUG LAW CASES AND MATERIALS* 514-516 (2nd ed. 1991) [hereinafter Subcommittee Report].

30. See *id.*

to file a "Claimed Exemption for an Investigational New Drug" (IND),³¹ which includes all pre-clinical research data and a scientific design of the human studies to be conducted. In addition, a sponsor must gain approval of its plan by an Institutional Review Board (IRB) in the institution where the drug will be tested.³² Typically, these clinical trials are conducted in three phases,³³ which span four to six years.³⁴

A. The Three Phases of Clinical Trials

In Phase I, the purpose of the trial is to ensure the drug is safe for humans³⁵ and to determine the appropriate dosage.³⁶ Phase I consists of testing the drug on a small number of volunteers and/or patients,³⁷ usually numbering twenty to 100,³⁸ over a period of several months.³⁹ If no problems in human toleration of the drug surface, the trial moves on to Phase II; however, if any testing subjects exhibit adverse effects, which would limit the use of the drug, the trial is concluded and the drug abandoned at this stage.⁴⁰ Presently, approximately seventy percent of drugs tested successfully complete Phase I.⁴¹

Phase II involves the evaluation of the drug's efficacy by testing it on those whom the drug is designed to treat.⁴² For example, in cancer trials, Phase II studies focus on a particular type of cancer.⁴³ Up to

31. 21 C.F.R. § 312.23 (1998) (outlining contents of an IND application).

32. *See id.*

33. *See* 21 C.F.R. § 312.21 (1998) (describing the three phases of clinical trials). There are also "Phase IV" trials to continue evaluation of a drug after it has been approved for market use. *See* 21 C.F.R. § 314.80 (1998).

34. *See* Subcommittee Report, *supra* note 29; Ken Flieger, *Testing Drugs in People*, FDA CONSUMER, July 1, 1994.

35. *See* Flieger, *supra* note 34.

36. *See* James Metz, *OncoTip: Becoming Involved in Clinical Research Trials* (last modified Feb. 14, 1999) <<http://cancer.med.upenn.edu/support/tips/tip10.html>>.

37. *See* Flieger, *supra* note 34.

38. Participants in Phase I clinical trials may or may not have the disease which the drug is designed to treat. *See* Subcommittee Report, *supra* note 29.

39. *See id.*

40. *See id.*

41. *See* Flieger, *supra* note 34.

42. *See id.*; Subcommittee Report, *supra* note 29.

43. *See Understanding Clinical Trials – An Introduction* (visited October 15, 1999) <<http://cancertrials.nci.nih.gov/>>.

several hundred patients participate in these studies, which can last from several months to two years.⁴⁴ If during this phase the drug appears to render the desired therapeutic effect, it continues to Phase III.⁴⁵ About thirty-three percent of drugs successfully complete Phase II.⁴⁶

The final phase, Phase III, is designed to compare the experimental treatment against the standard treatment⁴⁷ to evaluate all aspects of human consumption of the drug: its safety, dosage, and effectiveness.⁴⁸ The tests are conducted in a clinical setting⁴⁹ as random, blind studies, where patients receive either the standard treatment or the new treatment.⁵⁰ To be effective, Phase III studies require participation from a large number of patients, usually several hundred to several thousand,⁵¹ and can last anywhere from one to four years.⁵² Once a drug has completed at least one adequate and well-controlled Phase III clinical trial, a New Drug Application (NDA) may be submitted to the FDA for approval.⁵³ About twenty-five to thirty-three percent of drugs successfully complete Phase III, with one in five drugs eventually receiving marketing approval by the FDA.⁵⁴

Clinical trials are generally sponsored by the pharmaceutical company that manufactures the drug under testing,⁵⁵ but clinical trials may

44. See Flieger, *supra* note 34.

45. See Subcommittee Report, *supra* note 29.

46. See Flieger, *supra* note 34.

47. See Metz, *supra* note 36.

48. See Flieger, *supra* note 34.

49. Phase III clinical studies can successfully be conducted in cancer centers, university hospitals or community hospitals. See Lawrence, *supra* note 22, at 2840.

50. Placebos are also sometimes used as a control. See Subcommittee Report, *supra* note 29. However, placebos are rarely used in the field of oncology. See Levine, *supra* note 3, at 2809.

51. See Flieger, *supra* note 34.

52. See *id.*

53. Before 1997, a drug was usually expected to complete at least two clinical studies. See Subcommittee Report, *supra* note 29. However, the Food and Drug Modernization Act, Pub. L. No. 105-115, 111 Stat. 2310, § 115 (a) (codified as amended at 21 U.S.C. § 355 (d) (1997)), clarified that completion of one clinical study could be sufficient to establish "substantial evidence" of a drug's effectiveness and thus qualify the drug for approval.

54. See Flieger, *supra* note 34.

55. See *Understanding Clinical Research: From Promise to Practice* (vis-

also be sponsored by the federal government, through the NIH or some other federal agency.⁵⁶ There are two types of costs associated with participation in clinical trials: (1) the costs of doing the research itself and (2) the costs of caring for the patient.⁵⁷ Research costs generally include costs for "data collection and management, research physician and nurse time, analysis of results, and tests purely performed for research purposes."⁵⁸ The sponsor of the clinical trial generally pays for these research costs.⁵⁹ Patient care costs fall into two categories: (1) usual care costs and (2) extra care costs.⁶⁰ Usual care costs include doctor visits, hospital stays, clinical laboratory tests, x-rays, and other similar costs, which would occur during cancer treatment whether or not the patient is participating in a clinical trial.⁶¹ Extra care costs are costs directly attributable to participation in the clinical trial,⁶² which include, for example, hospitalization due to unexpected side effects of an investigational drug.⁶³ Patients are, for the most part, responsible for paying all patient care costs.⁶⁴ Thus, these are the costs for which patients seek reimbursement from third party payors.⁶⁵

ited Oct. 15, 1999) <<http://cancertrials.nci.nih.gov/>> for information on clinical trials sponsored by the NCI.

56. See *id.*

57. See Wittes, *supra* note 9, at 109.

58. *Clinical Trials and Insurance Coverage* (visited Oct. 15, 1999) <<http://cancertrials.nci.nih.gov/>> [hereinafter *Insurance Coverage*].

59. See Friedman & McCabe, *supra* note 10, at 760.

60. See *Insurance Coverage*, *supra* note 58.

61. See *id.*

62. See *id.*

63. See Jane Erickson, *Getting Managed Care to Pay for Clinical Trials*, ONCOLOGY TIMES, March 1996, at 1, 17.

64. See Friedman & McCabe, *supra* note 10, at 760.

65. Note that, although NCI states on its webpage that usual patient care costs are "usually" covered by third parties, there is strong evidence to the contrary. See *Insurance Coverage*, *supra* note 47. First, much of the legislation concerning reimbursement of patient care costs for participation in clinical trials defines the patient care costs to be covered as those costs that would be covered if the patient were not participating in a clinical trial. See, e.g., GA. CODE ANN. § 33-24-59.1 (1998); MD. CODE ANN., Insurance § 15-827 (1998); H.R. 61, 106th Cong. (1999). This indicates that these costs are not currently covered. In addition, commentators who have documented the decline in third party reimbursement of patient care costs for participation in clinical trials and argued for coverage have not distinguished between usual care costs and extra care costs. See *infra* notes 203-220 and accompanying text.

B. The Ethics of Clinical Trials

The ethics of clinical trials, particularly Phase III randomized trials, is often debated.⁶⁶ Although third party payors cite cost, not ethical considerations, when denying payment,⁶⁷ examining the ethical considerations of clinical trials is essential to understanding why paying for them makes sense. There are two primary criticisms levied against clinical trials: (1) randomized clinical trials are unethical because one of the two therapies is superior to the other, thus unfairly injuring one-half of the patients in the study by administering to them sub-standard treatment; and (2) researchers encounter a conflict of interest between the research aims of the study and the best interests of the individual patients.⁶⁸ Both criticisms stem from a basic misunderstanding of the assumptions underlying clinical trials.⁶⁹

The key to refuting these criticisms is in recognizing that Phase III clinical trials are based on the assumption that, although it is hoped that the new treatment will turn out to be more effective than the standard treatment, both treatments are equally effective. One commentator, Dwight Kaufman, notes

A new therapy always should have some putative or theoretical advantage over standard therapy, and there should be some reason to believe that the new therapy might be more effective or less toxic than standard therapy. The purpose of the Phase III trial is to prove or disprove an advantage of the experimental therapy using some objective end point, such as a prolonged survival or disease-free interval, or lower toxicity with no sacrifice in survival. The starting premise of any such trial must be the recognition and honest declaration by the investigators who design it and all reviewers of the trial before its implementation, that the answer to the question being posed is unknown.⁷⁰

This "null hypothesis" is termed " equipoise " by researchers.⁷¹ Equipoise essentially guarantees that patients will receive one of the

66. See generally Kaufman, *supra* note 3.

67. See Lawrence, *supra* note 22, at 2840.

68. See Kaufman, *supra* note 3, at 2802. See also Levine, *supra* note 3, at 2808.

69. See Kaufman, *supra* note 3, at 2802.

70. *Id.*

71. See Levine, *supra* note 3, at 2806.

best-known therapies for their condition by enrolling in a Phase III clinical trial.⁷² In fact, the oncology community generally views enrollment in research protocols as the best available medical care and "state-of-the-art" treatment.⁷³ Thus, the underlying assumption of equipoise directly contradicts the first ethical criticism of clinical trials and severely undermines the second. As long as the care the patient receives is considered state-of-the-art, the research aims of the study do not create a conflict of interest for the researcher.

Kaufman recognizes at least two criteria that must be fulfilled for a clinical trial to be considered ethical: (1) an assumption that each arm of the study is of equal effectiveness and (2) a promise the experiment will be modified based on new information to the contrary.⁷⁴ In addition, a third criterion required to insure the clinical trial is ethical is that the potential statistical difference in therapeutic outcomes must be "important."⁷⁵ This third criterion is not a significant obstacle in cancer clinical trials because "moderate benefits of a particular therapy may have great significance for cancer patients for whom no alternative therapy exists."⁷⁶ These foregoing criteria are all required by the NCI before approving any drug for cancer clinical trials.⁷⁷ Consequently, as a result of meeting these stringent criteria, patients enrolled in NCI-approved Phase III clinical trials are guaranteed to receive state-of-the-art treatment provided in an ethical fashion.

C. Costs and Benefits of Participating in Clinical Trials

In addition to the consideration that patients enrolled in clinical trials receive the best treatment available, which is mostly applicable to participation in Phase III trials, several other benefits to patients are associated with participation in all phases of clinical trials. Most im-

72. See *id.* at 2807.

73. See AMA on Scientific Affairs, *supra* note 1, at 257. See also Walter Lawrence, *Patient Selection for Clinical Trials: Risks Versus Benefits and Quality of Life Issues*, 72 CANCER SUPPLEMENT 2798, 2798 (1993) ("the majority of investigators believe that the well-designed and properly implemented clinical trial is the optimal treatment approach.").

74. See Kaufman, *supra* note 3, at 2803.

75. See *id.* The author suggests that "importance" should be measured by whether the outcome will "make a meaningful difference in clinical practice or in patient outcome[.]" *Id.*

76. See AMA on Scientific Affairs, *supra* note 1, at 254.

77. See Kaufman, *supra* note 3, at 2804.

portantly, in clinical trials involving life-threatening diseases, the treatment may prolong or even save patients' lives.⁷⁸ An added benefit of clinical trials is that adherence to rigid treatment protocols tends to result in optimal outcomes from the treatment.⁷⁹ Patients may derive great personal satisfaction from being a "teammate" in studies designed to improve the management of their disease.⁸⁰ For some poorer patients, participation in these clinical trials may be the only way to receive any medical care.⁸¹ In sum, evidence appears to show that patients enrolled in clinical trials do better than those receiving non-controlled treatment.⁸² However, these benefits are not limited purely to individuals. In fact, society as a whole benefits from participation in clinical trials. "Clinical research is currently the only method for demonstrating the safety and efficacy of new drugs and new technology and for determining whether new therapies offer advantages over existing, 'standard' therap[ies]."⁸³ For example, clinical trials are particularly important in oncology, where they "are so integral to the fabric of much cancer medicine."⁸⁴

Of course, there are both economic and non-economic costs associated with participation in a trial. The rigid protocol that may result in optimal treatment is sometimes very difficult to follow.⁸⁵ There may be an increased toxicity or a side effect from the treatment that is un-

78. Although, admittedly, drugs usually "reduce the risk of death, but don't entirely eliminate it. They usually accomplish this by relieving the symptoms of the illness[.]" Flieger, *supra* note 34.

79. See Lawrence, *supra* note 22, at 2799.

80. See *id.* See also Metz, *supra* note 34.

81. See Levine, *supra* note 3, at 2808.

82. See Kaufman, *supra* note 3, at 2804.

83. Kaufman, *supra* note 3, at 2801. See also AMA on Scientific Affairs, *supra* note 1, at 255 (noting that "[c]ontrolled clinical trials are the definitive mechanism for evaluating the therapeutic effectiveness of new modalities.").

84. Wittes, *supra* note 9, at 112. One doctor has noted that clinical trials are "how we essentially cured patients of leukemias and lymphomas. And all the therapeutic advances that have been made in cancer were made through clinical trials." Erickson, *supra* note 63, at 20. Finally, many people in the research community feel that "oncology is different from other specialties in that oncology depends on novel therapies to a greater extent than other diseases, except perhaps AIDS." Susan Jenks, *Does Managed Care Jeopardize Cancer Research*, 87 J. NAT'L. CANCER INST. 1102, 1103 (1995).

85. See Lawrence, *supra* note 22, at 2800.

known at the time of the trial.⁸⁶ The hope that the new treatment is more effective or less toxic may not be realized; the logical conclusion of equipoise is that sometimes the new treatment will actually be worse than the standard treatment.⁸⁷ Other costs to participation in clinical trials also include practical considerations, such as the amount of travel and time required and the concern over reimbursement for the patient care costs associated with participation in the trial. Therefore, before a patient enrolls in a clinical trial, these benefits and costs should be thoroughly discussed with the patient's physician.⁸⁸

II. PROBLEMS AND SOLUTIONS IN PATIENT ENROLLMENT

A. Problems with Patient Enrollment

The success of clinical trials depends on the enrollment of a sufficient number of patients within a reasonable amount of time. "The Phase III comparison trials must be designed to minimize the probability of erroneous conclusions by . . . minimizing all potential sources of bias. This requires . . . sufficiently large numbers of patients in each arm[.]"⁸⁹ Success also depends on designing a trial that "balance[s] all possible prognostic factors for natural history of the disease and response[s] to therapy. . . . Such factors may include age, performance status, gender, race and socioeconomic status of the patients[.]"⁹⁰

Despite the benefits described above, less than three percent of the nearly one million cancer patients in the United States annually participate in clinical trials.⁹¹ This low percentage of enrollment "impedes timely completion of many cancer drug trials, has a negative impact on the cancer cure rate, and exacerbates the problem of cover-

86. *See id.*

87. *See id.*

88. *See Levine, supra* note 3, at 2807. *See also infra* notes 99-102 and accompanying text, discussing the burdens managed care places on physicians' abilities to thoroughly discuss treatment options with their patients.

89. Kaufman, *supra* note 3, at 2802.

90. *Id.* at 2803.

91. *See* AMA on Scientific Affairs, *supra* note 1, at 254 (Breaking down accrual statistics: 1-1.5 percent of breast cancer patients, 1 percent of colon cancer patients and .5 percent of rectal cancer patients are enrolled in clinical trials. Three major clinical trial sponsor groups recently analyzed by the NCI were operating at accrual rates slower than planned.).

age disputes."⁹² In fact, in 1991, it was estimated that "if 10% of patients with common tumors participated in clinical trials, most trials could be completed within 1 year instead of the current 3 to 5 years."⁹³

There are two primary reasons for the lack of patient enrollment in clinical trials: (1) unwillingness of physicians to recommend patients to clinical trials and; (2) unwillingness of the patients to participate.⁹⁴ Several studies attempted to determine reasons why physicians are reluctant to refer patients into clinical trials. The results of these studies varied,⁹⁵ but each had a recurring theme: the physicians' belief that their obligation of caring for the individual patient supersedes the societal need to evaluate therapies that might be used more widely.⁹⁶ Several commentators suggest that the solution to this problem is to educate physicians on the underlying assumptions of clinical research, namely, that at all times the patient receives one of the best-known treatments available.⁹⁷

92. Harness, *supra* note 4, at 70-71. See also AMA on Scientific Affairs, *supra* note 1, at 254 ("it is critical that the predetermined sample size be attained by entering eligible patients in cancer clinical trials in sufficient numbers and in a timely fashion. Presently, clinical research in cancer is being threatened by inadequacies in the accrual of patients for the clinical trials.").

93. William B. Farrar, *Clinical Trials: Access and Reimbursement*, 67 CANCER 1779, 1780 (1991).

94. See AMA on Scientific Affairs, *supra* note 1, at 254-55. See also Kaufman, *supra* note 3, at 2804.

95. See Farrar, *supra* note 93, at 1780 (finding the top three reasons for physician reluctance to enroll patients in clinical trials to be: (1) fear of losing contact with the patient, (2) physician's belief that answers to a specific trial are already known, and (3) the time required to discuss and implement a clinical trial). See also AMA on Scientific Affairs, *supra* note 1, at 255 (summarizing the results of two major studies on physician reluctance to enroll patients in clinical trials. The first study, conducted by the National Surgical Adjuvant Breast and Bowel Project, found the following reasons: (1) concern with the doctor-patient relationship (73 percent), (2) trouble with informed consent (38 percent), (3) dislike of open discussions about uncertainty (23 percent), (4) conflict within the physician as a clinician and as a scientist (18 percent), (5) practical difficulties in trial procedures (9 percent), and (6) feelings of personal responsibility if treatments are unequal (8 percent). *Id.* The second study found that the primary reason for non-entry in 50 percent of the eligible patients was preference by the physician for a specific or alternate form of treatment.). *Id.*

96. See AMA on Scientific Affairs, *supra* note 1, at 255.

97. See Farrar, *supra* note 93, at 1781. Another suggestion is to not only

Another concern of physicians is that managed care places greater limitations on physicians' ability to refer patients to clinical trials.⁹⁸ Some physicians believe that discussing the costs and benefits of participation in a clinical trial with a particular patient is too time-consuming,⁹⁹ because managed care grants incentives to physicians for spending less and less time with their patients.¹⁰⁰ Managed care is also criticized as affecting physicians' choice of treatment for other reasons, namely, lack of third party reimbursement. "In cases where obtaining approval for a particular treatment is time-consuming, or where the patient is left wholly responsible for the bill, the physician may think twice before offering the same treatment to another patient, no matter what its advantages may be."¹⁰¹

Until recently, even if physicians wanted to refer their patients for participation in a clinical trial, managed care could prevent them from doing so through "gag" rules. A gag clause is one way that managed care organizations (MCOs) attempt to contain costs by preventing physicians from disclosing certain information to patients.¹⁰² Such information includes the existence of treatment options not covered by the MCO, such as participation in clinical trials.¹⁰³ Recently, however, gag clauses have come under fire for interfering with the fundamental doctor/patient relationship and interference with a physician's obligation to obtain informed consent from a patient to administer treatment.¹⁰⁴ Such "informed consent" requires that the patient be

educate physicians, but to involve them in clinical trials. See AMA on Scientific Affairs, *supra* note 1, at 255. See also *infra* notes 116-20 and accompanying text, discussing efforts to educate and involve physicians.

98. See *infra* notes 145 and 149 and accompanying text, discussing the prevalence of managed care.

99. See Farrar, *supra* note 93, at 1780-81.

100. See Michael Misocky, *The Patients' Bill of Rights: Managed Care Under Siege*, 15 J. CONTEMP. HEALTH L. & POL'Y 57, 69 (1998). One doctor has complained "People in the [medical] community are trying so hard to survive, seeing twice as many patients and making half as much money, that they don't enter people into clinical trials anymore." Erickson, *supra* note 63, at 17.

101. Karen Antman, *Reimbursement Issues Facing Patients, Providers, and Payers*, 72 CANCER SUPPLEMENT 2842, 2843 (1993).

102. See Misocky, *supra* note 100, at 72.

103. See *id.* See also Bethany J. Spielman, *After the Gag Episode: Physician Communication in Managed Care Organizations*, 22 SETON HALL LEGIS. J. 437, 441 (1998).

104. See Misocky, *supra* note 100, at 74.

aware of all relevant treatment alternatives.¹⁰⁵

Over one-half of the states ban the use of gag clauses in managed care contracts.¹⁰⁶ The Health Care Financing Administration (HCFA), which administers the Medicare and Medicaid programs, also bans the use of such clauses by MCOs that contract with Medicare and Medicaid.¹⁰⁷ Today, the general view regarding gag clauses is that their presence in physician contracts with managed care organizations¹⁰⁸ is overridden by the physician's ethical duty to disclose information regarding treatment options.¹⁰⁹ Thus, this particular managed care problem should not pose a threat to communication about clinical trials. In fact, the ensuing controversy suggests that physicians should be ethically obligated to discuss participation in clinical trials, at least in cases where the physician believes that the treatment would be beneficial.¹¹⁰

The most common reasons cited for patients' refusal to participate in clinical trials are the concerns about experimentation, toxicity, and certain costs.¹¹¹ The first two of these concerns can only be addressed through further patient education.¹¹² The concern about costs, however, is a more global and complex problem. As discussed above, patients are responsible for the patient care costs associated with their

105. *See id.*

106. *See* Spielman, *supra* note 103, at 439 (listing states). Note, however, that these laws are pre-empted by ERISA as applied to employer self-insured plans. *See infra* notes 284-86 and accompanying text.

107. *See* Spielman, *supra* note 102, at 451-52.

108. The actual prevalence of these clauses is unclear. Studies on the subject have conflicting results. *See, e.g.,* GENERAL ACCOUNTING OFFICE, MANAGED CARE: EXPLICIT GAG CLAUSES NOT FOUND IN HMO CONTRACT, BUT PHYSICIAN CONCERNS REMAIN (1997) (finding gag clauses rare in managed care contracts); Diane S. Swanson, *Physician Gag Clauses – The Hypocrisy of the Hippocratic Oath*, 21 S. ILL. U. L. J. 313, 314 (1997) (reaching opposite result).

109. *See* CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY 1242 (2nd ed. 1998).

110. *See id.* (suggesting that a federal statute be enacted to codify this duty).

111. *See* Farrar, *supra* note 93, at 1781; AMA on Scientific Affairs, *supra* note 1, at 255.

112. *See* Farrar, *supra* note 93, at 1781. *See also infra*, text and accompanying notes 120-22 (discussing efforts to increase patient education.).

participation in a clinical trial.¹¹³ In order to meet these costs, most patients rely on their health insurance, but find that the insurance providers do not provide this coverage.¹¹⁴ Thus, this lack of insurance coverage is a "major contributing factor" to low enrollment in clinical trials.¹¹⁵

B. Solutions to Enrollment Problems

In the early 1980s, the NCI took a first step toward improving patient enrollment in clinical trials by initiating community clinical oncology programs (CCOPs).¹¹⁶ Realizing that community physician involvement in clinical trial research¹¹⁷ would lead to increased physician referrals of patients into clinical trials, the NCI established CCOPs to extend research to the community level.¹¹⁸ At the time of the NCI's initiative, approximately eighty-five percent of all cancer patients received treatment at the community level.¹¹⁹ Now operating over fifty programs nationwide, CCOPs currently account for approximately fifty percent of all patients entered into formal NCI clinical research protocols.¹²⁰

In 1988, the NCI initiated further action to increase patient enrollment into clinical trials¹²¹ by adopting a promotional campaign that involved conducting seminars, placing feature stories in national and local news media, and assisting in making information on clinical trials available to physicians and patients.¹²² To assist in disseminating information on clinical trials, the NCI developed the Physician Data Query (PDQ), a database designed to provide information on available NCI-sponsored clinical trials.¹²³ NCI has expanded this effort via the

113. See *supra* notes 60-65 and accompanying text.

114. See *infra* notes 142-50 and accompanying text (discussing the distribution of insurers).

115. Laurent Castellucci, *Maryland Bill Proposes Mandated Clinical Trial Coverage*, 90 J. NAT'L CANCER INST. 423, 423 (1998).

116. See AMA on Scientific Affairs, *supra* note 1, at 255.

117. Seventy-two percent of physicians surveyed indicated that they would be willing to be a clinical investigator. See *id.* at 256.

118. See *id.* at 255.

119. See *id.*

120. See *id.*

121. See Farrar, *supra* note 93, at 1780.

122. See *id.*

123. See *id.*

Internet, where it employs an expansive website covering all major topics of interest to providers and patients on clinical trials.¹²⁴

The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides another initiative, guaranteeing patients and providers access to information on all clinical drug trials being conducted for "serious or life-threatening diseases."¹²⁵ The legislation mandates that the Secretary of Health and Human Services, acting through the Director of the NIH, establish and maintain a data bank of all clinical trials, regardless of the funding source, for experimental treatments of serious or life-threatening diseases and conditions. The Secretary must disseminate the information through information systems "which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers."¹²⁶ The data bank must include the following information: (1) a description of the purpose of each experimental drug, (2) eligibility criteria for participation in the clinical trial, (3) a description of the location of trial sites, and (4) a point of contact for those wanting to enroll in the trial.¹²⁷ The information must be forwarded to the data bank by the sponsor of the trial not more than twenty-one days after approval of the protocol.¹²⁸ A sponsor can gain exemption from the law's requirements only after providing a "detailed certification" to the Secretary ensuring that disclosure of the information "would substantially interfere with the timely enrollment of subjects in the investigation."¹²⁹

The impetus for this legislation began during testimony at a hearing of the Senate Cancer Coalition in 1996, during which a constituent described the difficulties cancer patients face in trying to find information on experimental treatments.¹³⁰ Although the constituent acknowledged that the existing NCI's Cancer Information Service was helpful, she also testified that the system was incomplete because it did not in-

124. *See generally Cancer Trials* (visited Oct. 15, 1999) <<http://cancertrials.nci.nih.gov>>.

125. Pub. L. No. 105-115, 111 Stat. 2310 § 113 (codified as amended at 42 U.S.C. § 282 (1997)).

126. *Id.*

127. *See id.*

128. *See id.*

129. *Id.*

130. *See* 142 Cong. Rec. S9555 (Aug. 2, 1996) (testimony of Senators Snowe and Feinstein) [hereinafter Snowe/Feinstein testimony].

clude the 300-plus clinical trials sponsored by private pharmaceutical companies.¹³¹ She compared the difficulty cancer patients face to the ease with which AIDS patients can obtain information about clinical trials due to the existing national databank of AIDS clinical trials.¹³²

Inspired by this constituent's testimony, an independent Senate bill,¹³³ modeled after the 1988 AIDS legislation, was subsequently incorporated into FDAMA.¹³⁴ The independent bill's sponsors, Senators Olympia Snowe and Dianne Feinstein, recognized the many benefits of establishing such a data bank, including increased patient enrollment into clinical trials:

All parties will benefit from this legislation. First and foremost, it encourages patient choice and informed decisions. But pharmaceutical companies will also benefit, because this legislation will allow for easier and quicker recruitment of individuals willing to participate in experimental trials, expediting the approval process for investigational new drugs. . . . But most importantly, it will help save lives and reduce the suffering of Americans who are stricken by serious or life-threatening illnesses.¹³⁵

These Senators also recognized the problem of third party reimbursement for costs associated with participation in these trials. "Providing people with information about clinical trials is only the first step in increasing access to experimental treatments – we must also ensure that they have adequate insurance coverage to cover costs associated with clinical trials."¹³⁶ Although separate bills were introduced at the time to remedy the insurance companies' failure to cover the costs of clinical trials,¹³⁷ the FDAMA itself did not comment on third

131. *See id.*

132. *See id.* In 1988, Congress established a national data bank of all clinical trials for AIDS drugs, both publicly and privately funded, which AIDS patients can access through a toll free number. *See* 42 U.S.C. § 300cc-17 (1988).

133. *See* S. 2024, 104th Cong. (1996).

134. *See* 143 Cong. Rec. S12241-02 (Nov. 9, 1997) (testimony of Senator Jeffords).

135. Snowe/Feinstein testimony, *supra* note 130.

136. 143 Cong. Rec. S379-01 (Jan. 21, 1997) (testimony of Senator Snowe).

137. *See* Improved Patient Access to Clinical Studies Act of 1997, S. 88, 105th Cong. (1997) (providing for reimbursement by most third parties of pa-

party reimbursement for participation in clinical trials.

The Congressional Budget Office (CBO) estimated that a system meeting the FDAMA's minimum requirements could be created in two years.¹³⁸ The estimated cost for the system totaled \$215 million over the 1998-2002 period, appropriating \$20 million in 1998, \$45 million in 1999 and \$50 million per year thereafter for maintenance and quality improvement.¹³⁹ The maintenance estimates were based on the cost of maintaining the current data banks and information networks already established by the NIH.¹⁴⁰

III. THE PROBLEM OF REIMBURSEMENT

Historically, patient care costs for participation in clinical trials were paid by third party insurers.¹⁴¹ However, with the advent of managed care and escalating health care costs, third parties are forced to "retrench support for patients enrolled in clinical related trials."¹⁴² Specifically, a dramatic decline in reimbursement for all patient care costs related to clinical trials occurred between 1987 and 1988.¹⁴³ Since 1988, the steady decline in reimbursement has continued,¹⁴⁴ and

tient care costs associated with participation in federally-approved clinical trials).

138. See H.R. Rep. No. 105-310, at 46 (1997).

139. See *id.*

140. See *id.* Donald Ralbovsky, Information Specialist for the NIH, stated in an interview on February 25, 1999 that the data bank is still under construction and not yet currently available. Mr. Ralbovsky anticipates that the databases currently existing on the NCI web page will be incorporated into the data bank upon its release to the public. See *id.*

141. See Wittes, *supra* note 9, at 109.

142. Antman, *supra* note 101, at 2844. See also Katie J. Smeltz, *Bill Promotes Medicare Coverage of Clinical Trials*, 89 J. NAT'L CANCER INST. 546, 547 (1997) ("[B]asic care costs such as hospital stays, laboratory tests, and physician charges used to be a routine part of health coverage for patients undergoing cancer treatments. But with the advent of managed care, 'many private health insurers are now denying coverage for routine care costs when a patient enters a clinical trial for treatment.'" (quoting Seth Rudnick, M.D.)). The retrenchment of support for patient care costs associated with participation in clinical trials seemingly encompasses "usual" patient care costs that would otherwise be covered. See *supra* note 65.

143. See AMA on Scientific Affairs, *supra* note 1, at 256.

144. See Nancy Nelson, *Physicians and Insurers Debate the Future of Clinical Trials*, 88 J. NAT'L CANCER INST. 1186, 1186 (1996).

Oliver W. Press, M.D., Ph.D., professor of medicine and

currently, reimbursement for these costs is extremely inconsistent. "One company may approve a patient for a clinical trial and another carrier may not. Some pay for laboratory studies but not hospitalization. Some pay for outpatient chemotherapy but will not pay for hospitalization for complications from investigational therapy."¹⁴⁵ Costs are sometimes reimbursed for Phase III clinical trials, however, Phase I and II costs are rarely reimbursed.¹⁴⁶

While the efforts described above certainly address many of the problems in patient enrollment into clinical trials, they do not address the major issue of who will ultimately pay for the patient care costs associated with participation in a clinical trial. Approximately eighty-eight percent of non-elderly Americans have private health care insurance through their employer.¹⁴⁷ Most of these health plans, issued through private employers, are governed by ERISA.¹⁴⁸ Alternatively, approximately nine million Americans are employees of the federal government and are insured under plans issued by private carriers but governed by the Federal Employee Health Benefits Act (FEHBA).¹⁴⁹ These carriers contract with the Office of Personnel Management (OPM), which administers the program.¹⁵⁰ Approximately seventy-three percent of those Americans who obtain health insurance through

biological structure at the University of Washington Medical Center in Seattle . . . reported a change in insurance coverage of patients in protocols in 1996 compared with 1988. In the earlier trials . . . 95% of patients were covered by insurers, compared with 65% this year, despite the fact that in the intervening years two papers showed an increased survival with the experimental treatment." *Id.*

145. Farrar, *supra* note 93, at 1781. One study estimate states that about one-third of HMOs are clearly interested in funding research, another third are not, and the remaining group is occasionally interested. See Nelson, *supra* note 144, at 1188. A principal investigator for several NCI-funded bone marrow transplantation studies noted recently that between 15 percent and 40 percent of patients recommended for transplantation were not treated because of the refusal of third party insurers to pay for the treatment. See *id.* at 1186.

146. See Antman, *supra* note 101, at 2844.

147. See Nicole Weisenborn, *ERISA Preemption and its Effect on State Health Reform*, 5 KAN. J. L. & PUB. POL'Y 147, 155 (1995).

148. See Edward G. Connette, *Challenging Insurance Coverage Denials Under ERISA*, 34 TRIAL 20, 24 (May 1998). See also ERISA, 29 U.S.C. § 1001 *et seq.*

149. See Connette, *supra* note 148, at 24. See also 5 U.S.C. § 8901 *et seq.*

150. See *id.*

their employer are enrolled in some type of managed care.¹⁵¹ The remaining portion of Americans are covered by the federal government through either the Medicare or the Medicaid program,¹⁵² the VA,¹⁵³ or the Department of Defense.¹⁵⁴ A growing number of Medicare and Medicaid beneficiaries are also enrolled in managed care plans.¹⁵⁵

All third party payors cite the same reason, in one form or another, for refusing to reimburse for these costs. The providers consider the treatment "investigational" or "experimental" and thus not cost effective.¹⁵⁶ The following section outlines litigation that has developed over third party reimbursement of patient care costs in clinical trials, then concludes by discussing the arguments in favor of third party reimbursement of all phases of clinical trials.

A. Litigation

Most of the litigation challenging denial of coverage for participation in a clinical trial is brought under ERISA,¹⁵⁷ although there have also been several cases against private non-ERISA plans, brought under state law, and several cases against the OPM, brought under the FEHBA.¹⁵⁸ Plaintiffs usually seek coverage for participation in Phase

151. See Misocky, *supra* note 100, at 64.

152. Thirty million and twenty million respectively. See Charles D. Weller, *The Secret Life of the Dominant Form of Managed Care: Self-Insured ERISA Networks*, 6 HEALTH MATRIX 305, 311 (1996).

153. See *infra* note 223 and accompanying text.

154. See *infra* note 229 and accompanying text.

155. See John K. Iglehart, *The Struggle to Reform Medicare*, 334 NEW ENG. J. MED. 1071, 1072 (1996) (stating that in 1996, four million Medicare recipients – approximately 10 percent of all Medicare recipients – were enrolled in managed care plans); see also John K. Iglehart, *Medicaid and Managed Care*, 332 NEW ENG. J. MED. 1727, 1728 (1995) (stating that in 1994, 7.8 million Medicaid recipients – approximately 35 percent of all Medicaid recipients – were enrolled in managed care plans).

156. See AMA on Scientific Affairs, *supra* note 1, at 256. See also *infra* notes 244-48 and accompanying text, discussing exclusions by private insurers, and notes 299-300 and accompanying text, discussing exclusions under Medicare.

157. ERISA preempts any state law claims based on denial of coverage. See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 56 (1987) (holding that state lawsuit asserting improper benefit denial under ERISA-regulated plan was preempted by ERISA); see also Weisenborn, *supra* note 147, at 153.

158. Before the agreement between the Department of Defense and the

II clinical trials,¹⁵⁹ seeking one of three remedies: (1) reimbursement for treatment already rendered, (2) a permanent injunction to prevent the insurer from denying coverage, or (3) a preliminary injunction to prevent the insurer from denying coverage in the period before a final determination can be made.¹⁶⁰ Plaintiffs who bring claims under state law may also seek compensatory damages for emotional distress or pain and suffering.¹⁶¹ Largely, however, defendants have escaped li-

NCI, there was at least one suit brought against the Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). *See infra* notes 234-40 and accompanying text; *Wilson v. CHAMPUS*, 65 F.3d 361 (4th Cir. 1995). In *Wilson*, the court found that CHAMPUS had abused its discretion in denying coverage for plaintiff's participation in a pre-phase III clinical study of HDC/PSCR, because it relied on an unwritten agency policy mandating the completion of Phase III trials before a treatment is covered, when the coverage regulations provided only that the treatment had to be "generally accepted." *Id.* at 366.

There have also been a growing number of cases brought under the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101 *et seq.* (1994), which prohibits employers from discriminating against an employee on the basis of a disability with regard to health care benefits. *See Harness, supra* note 4, at 90-91. Plaintiffs in these cases claim that their employers are discriminating against them by denying certain treatment for their disease, usually HDC/AMBT for breast cancer, while covering the same treatment for a different disease. *See id.* These cases are not fully applicable to the discussion here because it focuses on denial of coverage because the treatment is administered in a clinical trial, not because it is for a particular disease.

159. Twelve of the seventeen cases surveyed in this section involved coverage for participation in a Phase II study.

160. To obtain a preliminary injunction, a plaintiff must show: (a) that he or she will suffer irreparable harm in the absence of the injunction, and (b) either (i) a likelihood of success on the merits or (ii) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the plaintiffs favor. *See Velez v. Prudential Health Care Plan of New York, Inc.*, 943 F. Supp. 332, 338 (S.D.N.Y. 1996). Although this burden is slightly lower than having to actually succeed on the merits, the standard has not worked to plaintiffs' advantage, because in order to determine the likelihood of success in such a fact specific inquiry, courts generally go through a thorough analysis of the claim.

161. *See Lehman v. Mutual of Omaha Insurance Co.*, 806 F. Supp. 859, 860 (D. Ariz. 1992) (bringing state law bad faith claim and claim for emotional distress against non-ERISA covered plan). ERISA does not allow for recovery of extra-contractual damages, but may allow for recovery of attorneys' fees. *See Connette, supra* note 148, at 24. *See also* Massachusetts Mut. Life Ins. Co.

ability for denial of coverage for participation in clinical trials.¹⁶² The success of the plaintiff in these cases depends primarily on two factors: (1) the standard of review utilized by the court to evaluate the denial of coverage and (2) the specific language of the coverage agreement.

1. Standard of Review

The standard of review refers to the degree of deference a court allows the plan administrator when reviewing the decision to deny treatment. Typically, actions against ERISA plans are reviewed under a *de novo* standard, which affords the plan administrator no particular deference in evaluating the denial.¹⁶³ However, in *Firestone Tire & Rubber Co. v. Burch*, the Supreme Court held that if an ERISA plan grants discretionary authority to decide coverage to the plan administrator, courts must review the plan administrator's decision under the more deferential "arbitrary and capricious" standard.¹⁶⁴ A court will only overturn the coverage decision upon finding that the decision was rendered in an arbitrary and capricious manner, given the plan's language.¹⁶⁵

The *Firestone* decision creates two obstacles for plaintiffs. First, it is easy for a plan to avail itself of the heightened standard by simply drafting a plan granting discretionary authority to the plan administrator. Indeed, courts have found that a simple sentence granting discretion to the administrator will suffice.¹⁶⁶ Second, once the plan is

v. Russell, 473 U.S. 134, 144 (1985) (finding that punitive damages or extra-contractual damages are not available under ERISA). In addition, most circuits have found that FEHBA pre-empts any claims for extra-contractual damages. See Brian Harr, *FEHBA's Preemption Clause: Is It A Model For Private Employers' Subsidized Health Care?*, 22 J. LEGIS. 267, 269 (1996).

162. Only four of the seventeen cases surveyed resulted in a favorable ruling for the plaintiff. And in some cases, the favorable ruling meant only that the plaintiff survived a motion for summary judgment – thus, there is no guarantee the plaintiff will ultimately prevail. See *Wolf v. Prudential Insurance Co. of Am.*, 50 F.3d 793, 806 (10 Cir. 1995).

163. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 109 (1989).

164. See *id.*

165. See *id.*

166. See, e.g., *Goldstein v. Fortis Benefits Co.*, 1996 WL 18977, at *3 (N.D. Ill. 1996) (finding discretionary authority granted when plan stated "Our Medical Board will make the determination as to the effectiveness of a treatment"); *Edens v. Central Benefits Nat'l Life Ins. Co.*, 900 F. Supp. 928, 933

insulated by the heightened standard, it is difficult for plaintiffs to prove a denial of coverage for participation in a clinical trial is "arbitrary and capricious," where the insurance plan contains any language excluding "experimental" treatment.¹⁶⁷ *Firestone*, however, does provide a plaintiff the opportunity to modify the arbitrary and capricious standard in its holding that if the plan administrator is "operating under a conflict of interest, that conflict must be weighed as a factor in determining whether there is an abuse of discretion."¹⁶⁸ Courts find such conflicts of interest when a plan administrator serves the dual roles of decision-maker, with regard to the granting or denial of claims, and insurer, whose incentives are to keep costs down.¹⁶⁹ Although courts differ in the ways they "weigh" the conflict of interest,

(W.D. Tenn. 1995) (plan defines experimental as "any treatment . . . which Central Benefits does not recognize as accepted medical practice."); *Jenkins v. Blue Cross Blue Shield of Michigan*, 1994 WL 901184, at *4 (N.D. Ohio 1994) (plan states that "the Blue Cross Medical Director is responsible for determining whether the use of any service is experimental."); *Schnitker v. Blue Cross Blue Shield of Nebraska*, 787 F. Supp. 903, 906 (D. Neb. 1991) (plan states that "we shall determine whether a service . . . is investigative.").

167. See, e.g., *Goldstein*, 1996 WL 18977 at *6 (finding defendant's denial of coverage for participation in Phase II cancer clinical trial not "arbitrary and capricious" where plan contained a general exclusion of "experimental" or "investigative" treatments); *Edens*, 900 F. Supp. at 934 (same); *Kost v. Prudential Ins. Co. of Am.*, 1995 WL 359934, *5 (N.D. Ill. 1995) (same, but plan did contain explicit exclusion of "all phases of clinical trials"); but see *Jenkins*, 1994 WL 901184, at *11 (finding where plaintiff sought coverage for participation in a Phase II study, that it is "arbitrary and capricious to conclude that merely by use of the term 'study,' a treatment is rendered experimental," even though plan listed ongoing clinical trials as a factor appropriate for consideration when determining whether a treatment was experimental).

Note, however, that even *de novo* review might pose similar problems for plaintiffs if they reach an appellate court. When reviewing a lower court's judgment on denial of coverage, the appellate court will defer to the trial court's finding of whether a medical procedure is covered by the agreement unless that finding is "clearly erroneous." See *Hendricks v. Central Reserve Life Ins. Co.*, 39 F.3d 507, 513 (4th Cir. 1994) (affirming trial court's finding that coverage for participation in Phase II cancer clinical trial was excluded under plan's general exclusion of "experimental" treatment). Some courts have also noted in dicta that the outcome, favorable to the insurer, would have been the same under *de novo* review. See *Harris v. Mutual of Omaha Co.*, 992 F.2d 706, 713 (7th Cir. 1993); *Schnitker*, 787 F. Supp. at 906.

168. *Firestone*, 489 U.S. at 115.

169. See *Velez*, 943 F. Supp. at 339.

certain conflicts can lead to a favorable result for the plaintiff.¹⁷⁰

Under OPM regulations, an individual insured under the FEHBA may appeal to the OPM for review of the insurance company's denial of coverage.¹⁷¹ Actions against the OPM, similar to some brought under ERISA, are reviewed under the "arbitrary and capricious" standard.¹⁷² However, before seeking judicial review of the decision, the insured must first exhaust any administrative remedies.¹⁷³ Under the Administrative Procedure Act, once the OPM issues its ruling, a court can only overturn the decision if the ruling is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."¹⁷⁴

The applicable state law determines the standard of review for actions brought under state law. Usually, because state actions involve breach of contract or allegations of bad faith, a court will review an insurance company's decision using a "reasonableness" standard.¹⁷⁵

2. Policy Language

Once a court settles upon the appropriate standard of review, it looks to the language of the policy to determine whether the denial of coverage for participation in a clinical trial is warranted. One important, but not determinative, factor is whether the plan specifically excludes participation in clinical trials.

For example, in *Wolf v. Prudential Insurance Co. of Am.*,¹⁷⁶ the plaintiff brought state claims of breach of contract and bad faith against a non-ERISA private plan for denying coverage for participation in a Phase II clinical trial. The plaintiff received treatment in a clinical trial from 1990-91, during which time the plan sponsor implemented a new health plan.¹⁷⁷ When the plaintiff sought coverage for the treatment in 1991, the insurer denied coverage as "experimental."¹⁷⁸ The district court granted summary judgment to the defendant insurer on the basis that the plaintiff was not a third party beneficiary

170. See *id.* at 343.

171. See *Harris*, 992 F.2d at 707.

172. See *id.* at 712. See also 5 C.F.R. § 890.105 (1992).

173. See *Harness*, *supra* note 4, at 78.

174. *Harris*, 992 F.2d at 712. See also 5 U.S.C. § 706(2)(A).

175. See *Wolf*, 50 F.3d at 799; *Lehman*, 806 F. Supp. at 860.

176. 50 F.3d at 796.

177. See *id.*

178. See *id.*

of the plan, but left unanswered the question of whether the denial of coverage was warranted by the plan's language.¹⁷⁹ On appeal, the Court of Appeals for the Tenth Circuit reversed on the third party beneficiary issue and proceeded to analyze the denial of coverage under a "reasonableness" standard.¹⁸⁰ The court found the denial of coverage reasonable under the new plan, which specifically excluded as experimental "all phases of clinical trials," and granted summary judgment to the defendant on that issue.¹⁸¹ However, the court did rule that because the old plan contained only a general exclusion for "experimental" treatment, a genuine issue of material fact existed as to whether the plan unjustifiably excluded the treatment, sufficient to withstand defendant's motion for summary judgment.¹⁸²

Similarly, in *Harris v. Mutual of Omaha Co.*, the Seventh Circuit found that the OPM's denial of coverage for participation in a Phase II clinical trial, where the plan's definition of "experimental" included Phase I, II, or III trials, was not "arbitrary and capricious."¹⁸³ Also, in *Martin v. Blue Cross/Blue Shield of Va.*,¹⁸⁴ the Fourth Circuit also found that it was not "arbitrary and capricious" for an ERISA plan to deny coverage for participation in a Phase II clinical trial, where the definition of "experimental" included "drugs that haven't received final FDA approval."¹⁸⁵ District courts have followed suit.¹⁸⁶

Interestingly, however, the reference to clinical trials in the definition of experimental is not always fatal to plaintiffs challenging denial

179. *See id.*

180. *See id.* at 798.

181. 50 F.3d at 799.

182. *See id.*

183. 992 F.2d at 713.

184. 115 F.3d 1201 (4th Cir. 1997).

185. *Id.* at 1209.

186. *See Kost*, 1995 WL 359934 at *5 (finding denial of coverage for participation in a Phase II clinical trial not arbitrary and capricious where plan's definition of experimental included all phases of clinical trials); *Bushman v. State Mutual Life Assurance Co.*, 915 F. Supp. 945, 953 (N.D. Ill. 1996) (same but plan excluded only Phase I and Phase II trials); *Edens*, 900 F.Supp. at 934 (same, but plan excluded treatments that were not "accepted medical practice" or which did not have the required governmental approval); *Watts v. Massachusetts Mutual Life Ins. Co.*, 892 F.Supp. 737, 738 (W.D.N.C. 1995) (same, but plan excluded treatments that did not have governmental approval); *Schnitker*, 787 F.Supp. at 906 (same).

of coverage. In *Jenkins v. Blue Cross/Blue Shield of Mich.*,¹⁸⁷ the plaintiff sought coverage from her ERISA plan for treatment administered as part of a Phase II clinical trial. Although the plan's language provided that "[t]he service may be determined to be experimental or investigational when there is . . . an ongoing clinical trial," the court held it arbitrary and capricious to deny this coverage.¹⁸⁸ The court based its decision on expert testimony, which stated:

All patients undergoing [ABMT] at the Cleveland Clinic Foundation are part of a "study." We believe it is vitally important that we continue to accrue data in a logical and uniform way, in an effort [to] analyze the current results, and hopefully improve upon our results in the future. The only way to do this is through well thought out, prospective trials. The fact that we are accumulating data on patients such as [the plaintiff] does not mean that the procedure itself is experimental.¹⁸⁹

Thus, the court relied more on its own determination as to whether the treatment was experimental than on the specific plan's language.

In *Velez v. Prudential Health Care Plan of N.Y.*, the plaintiff sought a preliminary injunction to prevent Prudential from denying coverage of treatment administered as part of a "research protocol."¹⁹⁰ Although the plan's language provided for exclusion of treatment that "is under study or in a clinical trial," the court held the denial of coverage to be arbitrary and capricious.¹⁹¹ First, the court found the plan operated under a conflict of interest, thus slightly modifying the standard of review.¹⁹² The court then noted that, despite the plan's language, Prudential previously stated that it would fund single-dose treatment described in research protocols.¹⁹³ Here, the court concluded Prudential's varying application of the exclusion supported the allegation that Prudential abused its discretion in denying coverage.¹⁹⁴ In addition, the court noted in sympathetic dicta that "the equities weigh in favor of plaintiff. The urgency of plaintiff's request for relief and the fact

187. 1994 WL 901184, at *1.

188. *Id.* at *11.

189. *Id.*

190. 943 F.Supp. at 336.

191. *Id.*

192. *See id.* at 340. *See also supra* notes 169-71 and accompanying text.

193. *See* 943 F. Supp. at 343.

194. *See id.*

that any delay in granting relief will diminish the treatment's chance of success gravitate in favor of the relief sought."¹⁹⁵ Thus, rather than relying on the experimental status of the treatment, the court based its decision on the behavior of the insurer itself.

Despite the sympathetic outcomes in *Wolf*, *Jenkins*, and *Velez*, courts have found less specific language sufficient to uphold a denial of coverage. In *Fuja v. Benefit Trust Life Ins. Co.*, the Seventh Circuit found a contract which defined "medically necessary" as not including treatment provided "in connection with medical or other research," unambiguous as a matter of law in reversing the district court's finding that the contract did not exclude plaintiff's request for coverage for participation in a Phase II trial.¹⁹⁶ Similarly, in *Hendricks v. Central Reserve Life Ins. Co.*,¹⁹⁷ the Fourth Circuit found the district court not clearly erroneous in concluding that a plan which excluded treatment "experimental in nature, which is not necessary to the treatment of the illness and not generally accepted medical practice" properly denied coverage for plaintiff's participation in a clinical trial.¹⁹⁸

Although guided by law in making their decisions favoring defendants, some judges have noted what they perceive as unfairness in the outcome. One judge, after finding a denial of coverage for participation in a Phase II clinical trial not arbitrary and capricious, stated:

[T]he court cannot help but note that this result appears to be unjust, unwise and unreasonable. . . . There are two facts in this case that are brutally shocking to this court. First, the procedure at issue is not some type of voodoo or alternative medicine prescribed by someone outside the mainstream of medical practice. To the contrary, it is being prescribed by the head of a major department of a highly respected medical institution. Second, defendant's policy will pay large amounts of money for conventional chemotherapy treatment, which

195. *Id.*

196. 18 F.3d 1405, 1411 (7th Cir. 1993)

197. 39 F.3d at 514.

198. A number of district courts have followed this rationale. See *Goldstein*, 1996 WL 18977, at *6 (finding defendant's denial of coverage for participation in Phase II cancer clinical trial not "arbitrary and capricious" where plan contained a general exclusion of "experimental" or "investigative" treatments); *Lehman*, 806 F. Supp. at 865 (finding defendant's denial of coverage for participation in a Phase II study reasonable where plan contained a general exclusion of "experimental" treatments);

according to the evidence will ultimately prove to be futile. It will not, however, pay for [this treatment] which apparently holds the only hope – however slim – for plaintiff's long term survival. This paradox is non-sensical, shortsighted, and cruel.¹⁹⁹

Another judge offered a personal message after finding for the defendant. "While the Plaintiff did not prevail on the legal issues, the admiration and hope for [the plaintiff] by all involved in this case, including the Court, is heartfelt."²⁰⁰

In addition to the fairness concerns cited above, this case-by-case fact specific analysis method takes up precious judicial time and resources.²⁰¹ Routinely, judges are placed in the position of essentially making decisions about the experimental status of medical procedures about which the judge possesses no specialized expertise.²⁰² Thus, if coverage for participation in clinical trials is the optimal outcome, the justice system is not the optimal place to achieve it. The next section outlines why coverage for participation in clinical trials is the optimal outcome and suggests that the optimal means to achieve consistent coverage is through legislation.

3. *The Necessity for Reimbursement*

The problems associated with excluding coverage for patient care costs in clinical trials are widely cited in medical literature. With respect to Phase III trials, a primary criticism is that the "investigational" exclusion is not properly applied when the theory of equipoise is accepted with regard to a clinical trial. "In the appropriate clinical setting (scientifically and ethically sound trials), investigational treatment should be equated with 'state-of-the-art' care. Certainly the 'best' patient care should be covered by third party payors."²⁰³ Along the same lines, at least one commentator equates the problem, which applies to refusal to reimburse for all phases of clinical trials, with applying the exclusion in situations involving terminal diseases. "Seri-

199. *Bushman*, 915 F.Supp. at 954-55.

200. *Lehman*, 806 F. Supp. at 866.

201. See *Harness*, *supra* note 4, at 90.

202. See *id.*

203. Karen Antman et al., *The Crisis in Clinical Cancer Research*, 319 NEW ENG. J. OF MED. 46, 47 (1988). See also Wittes, *supra* note 9, at 110 ("A reasonable insurance system ought to reimburse all medical care that is effective, whether investigational or not.").

ously ill patients may have exhausted more conventional remedies, and the best treatment for them may be available only through participation in a clinical trial.”²⁰⁴

A second criticism, also applicable for refusals to reimburse for all Phases of clinical trials, is that these decisions may not be logically or economically sound, as patients would incur many of these costs in the course of traditional, yet ineffective, treatment. As such, these costs would ostensibly be covered by third party payors.²⁰⁵ Furthermore, these exclusions often result in the denial of reimbursement for otherwise “legitimate” costs, if incurred in conjunction with “investigational” costs, because insurers are unwilling to undertake the tedious task of itemizing care.²⁰⁶

Even if reimbursing investigational costs is not economical in the short term, reimbursement of all Phases of clinical trials will pay dividends in the long term, both for the insurers and for society as a whole. Clinical trials may lead to treatment that is more effective and

204. AMA on Scientific Affairs, *supra* note 1, at 257. Commentators have additionally recognized that these types of exclusions essentially allow third parties to make treatment decisions. See Farrar, *supra* note 93, at 1781.

205. See *supra* notes 61-65 and accompanying text discussing the distinction between usual patient care costs and extra care costs. See also Kaufman, *supra* note 3, at 2804 (“An insurance carrier or other third party payer clearly would be contractually obligated to pay for the control arm, which is received by half the patients on the trial. The denial of coverage for patients in a randomized trial on the basis of its being ‘experimental’ is an absurd breach of (at least) faith.”). See also Antman et al., *supra* note 203, at 47; AMA on Scientific Affairs, *supra* note 1, at 257.

206. See Wittes, *supra* note 9, at 109. The author provides a useful example:

A patient with metastatic breast cancer, previously treated with standard combination chemotherapy and appropriate hormonal maneuvers, is hospitalized for progressive cancer and hypercalcemia. Institution of a saline diuresis and glucocorticoids fails to control the serum calcium adequately, so on Day 10 her physicians begin cytotoxic therapy with an investigational agent that has shown promising initial evidence of activity in breast cancer during the early phase II trials. This agent must be given by continuous infusion over 5 days. The serum calcium normalizes, and the patient is discharged 8 days after start of therapy.

Id. Clearly, the first nine days of hospitalization are attributable to conventional care, but the remaining eight are unclear. Most insurers would deny all coverage because of the treatment’s “experimental” nature. See *id.* This is unjustified if the treatment happens to be the most promising treatment available or if there is no good alternative conventional therapy. See *id.*

cheaper than the current standard treatment.²⁰⁷ Even if the result is not cheaper treatment, third parties will obtain data to evaluate the effectiveness of the therapy, which is what insurers claim they want when applying these “investigational” exclusions.²⁰⁸ Furthermore, if effective, the treatment could return a cured cancer patient to the work force more quickly, thereby placing the patient back in a position to contribute to society.²⁰⁹ Finally, such reimbursement will insure that clinical research is conducted effectively and efficiently by increasing patient enrollment to clinical trials.²¹⁰

While these arguments appear persuasive, a further problem lurks in the background. Unfortunately, a long-term analysis by an individual insurer would only lead the insurer to reimburse these costs if it could be assured that others would do the same. In other words, this presents a classic collective action problem.²¹¹ Thus, while patient and physician education may alleviate some accrual concerns, reimbursement concerns require further action in the form of regulation to achieve optimal behavior on the part of insurers, at least until short term cost comparisons can be developed.

Since the severe reduction in reimbursement for patient care costs of clinical trials in the late 1980s,²¹² several industry leaders and commentators have argued that third party payors should bear responsibility for these costs. In 1989, the NCI issued a formal statement recommending that third party coverage be allowed for patient care costs of all nationally approved cancer treatment research protocols.²¹³ The

207. See *id.* at 110. Sometimes trials will result in more effective, but more expensive treatment. See *id.*

208. See AMA on Scientific Affairs, *supra* note 1, at 257.

209. See Wittes, *supra* note 9, at 110.

210. One commentator points out that when third parties deny payment, only affluent people will have access to the care. See Antman et al., *supra* note 202, at 48. This could seriously undermine the need for a wide range of socioeconomic and racial participants. See *supra* note 90 and accompanying text. There is also further support for why Phase I and Phase II trials should also be reimbursed – without them, there would be no Phase III trials. See Farrar, *supra* note 92, at 1782. In addition, “patients in these studies are receiving a therapeutic approach that, in the judgment of the treating physician and his peers on the local IRB and at the sponsoring organization, is appropriate medical care under the circumstances.” Wittes, *supra* note 9, at 112.

211. See Wittes, *supra* note 9, at 112.

212. See *id.*

213. *Impact of Third party Reimbursement on Cancer Clinical Investiga-*

statement also urged third party coverage be allowed for all cancer treatment research protocols not subject to national approval, provided that the protocol has been approved by "established peer-review mechanisms."²¹⁴ The NCI issued this statement after reasoning that the denial of payment for patient care costs on clinical trials "threatens to impede the development of effective new therapies and severely limits access of severely ill patients to the most promising therapies."²¹⁵

Some commentators similarly recognizing this problem argue that third parties should pay these patient care costs, but do not focus on ways in which to effectuate this change. The recommendations range from the narrow, such as third parties should reimburse only for Phase III randomized clinical trials,²¹⁶ or third parties should reimburse only for nationally approved clinical trials,²¹⁷ to the broad, such as third-parties should pay for all Phases of clinical trials approved by an IRB.²¹⁸ Other commentators focus on the federal government as the solution to the problem, both as an employer and as a regulator.²¹⁹ For example, one commentator suggests that Congress require Medicare to cover patient care costs associated with clinical trials.²²⁰ In comparison, at least one commentator suggests that legislation take place at both the state and federal level to provide universal coverage for all patients.²²¹

As the first part of this section highlighted, judicial time and resources are unnecessarily used to solve these problems on a case-by-case basis.²²² In addition, patients are losing precious time as they wage these legal battles with their insurers. As the second part has

tion: *A Consensus Statement Coordinated by the National Cancer Institute*, reprinted in 81 J. NAT'L. CANCER INST. 1585, 1585 (1989).

214. *Id.*

215. *Id.*

216. See Kaufman, *supra* note 3, at 2804; see also Levine, *supra* note 3, at 2810.

217. See AMA on Scientific Affairs, *supra* note 1, at 258; Friedman and McCabe, *supra* note 10, at 761-62.

218. See Wittes, *supra* note 9, at 112.

219. See Antman et al., *supra* note 203, at 48; see also Wittes, *supra* note 9, at 112.; Erickson, *supra* note 63, at 17.

220. See Antman et al., *supra* note 203, at 48.

221. See Erickson, *supra* note 63, at 19.

222. See Harness, *supra* note 4, at 90.

shown, reimbursement for clinical trials is a logical step for insurance companies to take and, thus, should not be left to inconsistent coverage as is currently the case. Action must be taken at the federal level to guarantee patient access to the important treatments provided through clinical trials.

IV. INSURER EFFORTS AT REIMBURSEMENT

A. The Federal Government's Response

The VA provides health care benefits to veterans of the U.S. armed forces.²²³ It operates an extensive health care delivery system that includes 173 medical centers and more than 400 clinics, serving approximately 2.9 million veterans annually.²²⁴ The VA and the NCI have a longstanding working relationship in the battle against cancer: "[t]he VA has long recognized its responsibility to participate in national efforts to lessen the burden of cancer, which is a particularly important threat to the VA patient population."²²⁵

In 1997, the VA and the NCI entered into a formal agreement "to expand the already productive relationship between the VA and the NCI into a more formal and extensive partnership."²²⁶ The fundamental features of the agreement are to increase the access of eligible veterans to NCI-sponsored clinical trials and to provide VA clinical investigators with expanded opportunities to participate in clinical cancer research.²²⁷ Specifically, the VA now reimburses beneficiaries for previously uncovered patient care costs for eligible veterans' participation in NCI-sponsored clinical trials, either at VA sites, or in some circumstances, at non-VA sites.²²⁸ Over the three years the agreement is in effect, the VA and the NCI will collect information to evaluate the project, including information on clinical trial enrollment,

223. See *Interagency Agreement Between the Department of Veterans Affairs and the National Cancer Institute for a Partnership in Clinical Trials for Cancer* (visited Oct. 15, 1999) <<http://www.va.gov>> [hereinafter *VA Interagency Agreement*].

224. See *id.*

225. *Id.*

226. *Id.*

227. See *id.*

228. See *VA Interagency Agreement*, *supra* note 223.

resource utilization and relative costs.²²⁹

The DoD provides medical services and support to members of the armed forces and their families.²³⁰ The program, called TRICARE, provides these services to approximately 8.3 million beneficiaries, either through a direct care system, comprised of 120 military medical treatment facilities (MTFs), or through care purchased from civilian providers who are reimbursed by the DoD through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).²³¹ In 1994, the DoD established a demonstration project, which provided CHAMPUS reimbursement for eligible beneficiaries who received previously uncovered treatment for breast cancer under approved NCI trials for high dose chemotherapy with stem cell rescue (HDC/SCR).²³² The purpose of the trial was to "improve beneficiary access to promising new therapies, assist in meeting the NCI's clinical trials goals, and arrival at conclusions regarding the safety and efficacy of HDC/SCR in the treatment of breast cancer."²³³ In 1996, the DoD signed an interagency agreement with the NCI²³⁴ to expand the demonstration project to include all NCI-sponsored Phase II and III clinical trials.²³⁵ Beneficiaries can participate in trials either through NCI-approved MTFs or through CHAMPUS-reimbursed civilian care.²³⁶ The DoD stated its purpose for entering the agreement as follows:

DoD shares public and scientific concern about disappointing cure rates under standard cancer therapies and has an interest and a responsibility to participate in the appropriate evaluation of improved therapeutic approaches for DoD patients. Through this agreement, DoD will have access to clinical research and patients can receive state-of-art care through NCI-sponsored clinical trials throughout the country by participating in

229. *See id.*

230. *See Interagency Agreement Between the Department of Defense and National Cancer Institute For Partnership in Clinical Trials for Cancer* (last modified Dec. 22, 1988) <<http://www.tricare.osd.mil/>> [hereinafter *DoD Interagency Agreement*].

231. *See id.*

232. *See id.*

233. *Id.*

234. Pursuant to 10 U.S.C. § 1092.

235. *See DoD Interagency Agreement, supra* note 230.

236. *See id.*

the evaluation of emerging new therapies that have significant promise for the successful treatment of cancers.²³⁷

The demonstration project began on January 1, 1996, and was scheduled to last one year.²³⁸ The DoD extended the project until December 31, 1999,²³⁹ because the Department hypothesized that this "increased access to innovative cancer therapies will occur at a cost comparable to that. . . experienced in paying for conventional therapies under the standard CHAMPUS program. Results of this demonstration will provide a framework for determining the scope of DoD's continued participation in the NCI's research efforts."²⁴⁰ As of January 1998, approximately ninety-one cases had been funded under this agreement, including care for solid tumors, hematologic malignancies, and other tumors.²⁴¹ Based on these results, certain comments have hailed this agreement as a turning point in spurring managed care into providing reimbursement for clinical trials.²⁴²

B. Private Insurance Carriers

Reimbursement policies of private insurers are inconsistent.²⁴³ Virtually all plans exclude coverage for experimental treatment, but the specific policy language differs among the many insurers.²⁴⁴ Some plans list the treatments they consider experimental or list the treatment they cover, implying that treatments not listed are not covered.²⁴⁵ Other policies defer to approval by government agencies, usually the FDA, to determine whether a treatment is experimental,²⁴⁶ while some

237. *Id.*

238. *See id.*

239. *See Notice of Extension of Cancer Treatment Clinical Trials Demonstration Project* (last modified Dec. 18, 1998) < <http://www.tricare.osd.mil/>>.

240. *Id.*

241. *See* Doris Browne, et al., *Oncology Services: The Department of Defense Perspective*, 82 CANCER SUPPLEMENT 2010, 2013 (1998).

242. *See* Erickson, *supra* note 63, at 17.

243. *See* Troy Parkins, *Clinical Trial Reimbursement Reform Sought*, 85 J. NAT'L CANCER INST. 1549, 1550 (1993).

244. *See* Connette, *supra* note 148, at 22.

245. *See id.* *See also* Jenkins, 1994 WL 901184 at *5.

246. *See* Connette, *supra* note 148, at 22. *See also* Martin, 115 F.3d at 1205. At least one commentator has suggested that reliance on FDA approval "is really most unsuitable for reimbursement decision-making." Wittes, *supra* note 9, at 108. This is because a pharmaceutical company's decision to seek

plans reserve discretion to determine which treatments are experimental.²⁴⁷ The latter type of clause is usually accompanied by a variety of factors the plan will use in making its determinations.²⁴⁸

The overwhelming reason for denying this coverage is the perceived additional costs.²⁴⁹ Some insurers argue that they fear litigation not from people enrolled in trials but from those wanting to receive the treatment.²⁵⁰ However, at least one case holds that a contractual agreement to cover costs associated with a clinical trial does not create an obligation to cover the same treatment when not administered in a clinical trial.²⁵¹ Thus, it appears that if insurers could be convinced that costs for participation in clinical trials are not significantly higher than costs for standard treatment, they might agree to pay for the "experimental" treatment.

Some insurers have at least expressed willingness to test the cost comparison of clinical trial treatments versus standard treatments. Specifically, Ohio Med, one of five health plans covering approximately 100,000 Ohio state employees, recently announced a new three-year demonstration project based upon the agreement between the DoD and the NIH.²⁵² The project covers all previously uncovered patient care costs that are associated with participation in an NCI-approved Phase II or Phase III cancer clinical trial.²⁵³ On a larger scale, pursuant to a groundbreaking agreement, United HealthCare, a large MCO based in Minnetonka, Minnesota, now covers the costs of its members enrolled in NCI-sponsored clinical trials.²⁵⁴ More spe-

FDA approval of a drug "is a complex business decision that depends on many factors other than the scientific evidence supporting the claim." *Id.*

247. See Connette, *supra* note 148, at 22. See also Schnitker, 787 F.Supp. at 904. Note that this can affect the standard of review used to evaluate a plan's denial of benefits. See *supra* notes 165-66 and accompanying text.

248. See Schnitker, 787 F. Supp. at 904.

249. See Lawrence, *supra* note 21, at 2840.

250. See Parkins, *supra* note 243, at 1550. See Jenks, *supra* note 83, at 1104.

251. See *Dodd v. Blue Cross and Blue Shield Assoc.*, 835 F. Supp. 888, 890 (E.D.Va. 1993) (finding that notice of demonstration project for desired treatment did not obligate plan to provide coverage for treatment outside project).

252. See *Ohio State Employee Health Plan to Cover NCI-Sponsored Trials* (visited Oct. 15, 1999) <<http://cancertrials.nci.nih.gov/>>.

253. See *id.*

254. See *Cancer Clinical Trials Pilot Program Launched by United*

cifically, in late 1998, United and the Coalition of National Cancer Cooperative Groups, Inc., created the Clinical Trials Pilot Program, in which United members can enroll in clinical trials sponsored by members of the Coalition.²⁵⁵ Formed in November 1997, the Coalition is a non-profit foundation comprised of six of the twelve Cooperative Groups sponsored by NCI²⁵⁶ and boasts 12,000 cancer researchers nationwide.²⁵⁷ Through this unique agreement, United, with thirteen million members in thirty-two states, will provide thousands of patients with access to clinical trials while setting an example for other members in the managed care industry.²⁵⁸

Finally, a recent agreement with a trade group of the managed care industry offers some promise that managed care will pay for patient care costs associated with clinical trials. In February 1999, the NIH and the AAHP reached an agreement to work together to increase patient participation in NIH-sponsored clinical trials.²⁵⁹ The AAHP, organized in 1997, serves as the official trade group of the managed care industry²⁶⁰ and presently has more than 1,000 members that provide care for 100 million Americans nationwide.²⁶¹ Under this agreement, the AAHP is encouraging its members to "reimburse the routine patient-care costs associated with NIH-sponsored clinical trials, provided these costs are not substantially higher than the costs a plan would incur in the course of standard treatment."²⁶² One function of this agreement will be to study the costs of participation in clinical trials

HealthCare and Cooperative Coalition to Pay Patient Care Costs (last modified Nov. 25, 1998) <<http://cancertrials.nci.nih.gov/>>.

255. *See id.*

256. *See id.* The Coalition members are: Eastern Cooperative Oncology Group, Cancer and Leukemia Group B, North Central Cancer Treatment Group, National Surgical Adjuvant Breast and Bowel Program, Radiation Treatment Oncology Group, and Pediatric Oncology Group. *See id.*

257. *See* Robert Pear, *Managed-Care Plans Agree to Help Pay the Costs of Their Members in Clinical Trials*, N.Y. TIMES, Feb. 9, 1999, at A21.

258. *See id.*

259. *See Agreement between the National Institutes of Health and the American Association of Health Plans in Support of Clinical Trials* (last modified Feb. 23, 1999) <<http://cancertrials.nci.nih.gov/>> [hereinafter *AAHP Agreement*].

260. *See AAHP Membership Information* (visited Oct. 15, 1999) <<http://www.aahp.org>>.

261. *See id.*

262. Pear, *supra* note 257, at A21.

compared to standard treatment.²⁶³ The agreement is expected to lead to more programs like the United Healthcare project described *supra*.²⁶⁴

According to the NIH, this agreement is based on a “set of jointly held principles:”

- clinical trials are the most effective means of generating reliable evidence relating to medical interventions;
- NIH is committed to supporting the conduct of this research as the means of identifying therapeutic advances that are then translated into standards of patient care;
- health plans have the potential to create new opportunities to increase patient enrollment, conduct clinical research, disseminate research findings, and incorporate research advances into routine medical practice;
- AAHP is committed to increasing the participation of plan members in well-designed, high quality clinical trials;
- and plans are more likely to facilitate and encourage clinical trials participation if it is not markedly more expensive to the plan than standard clinical care.²⁶⁵

Importantly, these principles indicate that MCOs recognize the critical role they play in cancer research. To evaluate the elements of the agreement, a steering committee consisting of five NIH representatives, five AAHP representatives and three patient advocates will report on the agreement’s progress on a yearly basis.²⁶⁶

The efforts discussed in this section are certainly commendable. The reliance on comparable costs in most of these efforts, however, suggests that insurers are mostly focusing on the short term. Given this view, regulation again appears as the most effective medium to ensure consistent reimbursement until the nature of clinical trials costs in relation to standard treatment is established.

V. STATE LEGISLATIVE EFFORTS

Some states have enacted legislation mandating that insurance com-

263. See *AAHP Agreement*, *supra* note 259.

264. See *id.*

265. *Id.*

266. See *id.*

panies provide coverage for routine medical costs associated with enrollment in cancer clinical trials. For example, in Rhode Island, coverage is mandated for Phase II, III and IV cancer clinical trials²⁶⁷ under the following circumstances: (1) the clinical trial has been approved by the NIH, Community Clinical Oncology Programs, the FDA, the Department of Veterans' Affairs, or otherwise meets NCI guidelines; (2) the trial is approved by an IRB; (3) the 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 patient meets all protocol requirements; (5) there is no clearly superior, non-investigational treatment available; and (6) the available data provide a reasonable expectation that the treatment will be at least as efficacious as its alternative.²⁶⁸ Georgia mandates coverage for "routine patient care costs" of dependent children enrolled in Phase II or Phase III clinical trials that are approved by the FDA or the NCI for the treatment of cancer that generally first manifests itself in children under nineteen.²⁶⁹ "Routine patient care costs" include "blood tests, X-rays, bone scans, magnetic resonance images, patient visits, hospital stays, or other similar costs" that would normally be covered if the beneficiary were not enrolled in a clinical trial.²⁷⁰ The statute clarifies, however, that "[i]t is specifically the intent of this Code section not to relieve the sponsor of a clinical trial program of financial responsibility for accepted costs of such program."²⁷¹

In Virginia, coverage is mandated for "patient costs incurred during participation in clinical trials for treatment studies on cancer" if the treatment is being conducted in a federally-approved Phase II, III, or IV clinical trial.²⁷² However, this law only applies if: (1) "There is no clearly superior, non-investigational treatment alternative;" (2) there is a "reasonable expectation" that the treatment will be at least as effective as the non-investigational treatment alternative, and (3) the patient and the health care provider both deem that the patient's participation

267. But coverage for Phase II clinical trials expired on December 31, 1999. See R.I. GEN. LAWS § 27-18-36.2 (1998) (insurance policies); R.I. GEN. LAWS § 27-41-41.2 (1998) (HMOs).

268. See R.I. GEN. LAWS § 27-18-36.2 (1998) (insurance policies); R.I. GEN. LAWS § 27-41-41.2 (1998) (HMOs).

269. See GA. CODE ANN. § 33-24-59.1 (1998).

270. *Id.*

271. *Id.*

272. VA. CODE ANN. § 38.2-3418.8 (1999).

in the clinical trial is "appropriate."²⁷³ Similar to Virginia, Louisiana mandates coverage for patient costs if treatment is being provided in a Phase II, III or IV clinical trial for cancer.²⁷⁴ The law further defines "patient costs" as costs that "are incurred as part of the protocol treatment being provided to the patient for purposes of clinical trial."²⁷⁵ Such costs do not include: (1) non-health care service costs; (2) costs associated with managing the research data associated with the clinical trial and; (3) the cost of investigational devices or drugs.²⁷⁶ Additionally, beginning January 1, 2000, coverage is mandated in Illinois for routine patient care costs incurred during treatment in a federally-approved Phase II, III or IV cancer clinical trial.²⁷⁷ However, coverage is limited to trials conducted in Illinois, with an annual benefit limit of \$10,000,²⁷⁸ and terminates on January 1, 2003. The purpose of the mandate is to generate data to study the costs and benefits derived from coverage of these costs.²⁷⁹

In by far the most expansive legislation, Maryland enacted a statute in 1998 mandating coverage of routine patient care costs incurred during Phase I, II, III and IV clinical trials for cancer treatment and Phase II, III and IV clinical trials for treatment of other life-threatening diseases.²⁸⁰ Coverage is required if: (1) the clinical trial is approved by the NIH, the FDA, the VA, or an IRB of an institution in Maryland which has a multiple project assurance contract approved by the NIH; (2) the personnel providing the treatment are "capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;" (3) there is no clearly superior non-investigational alternative; and (4) the available data provide a reasonable expectation the treatment will be at least as effective as its alternative.²⁸¹ The statute requires any entity seeking coverage to post information electronically and keep an up-to-date list of all clinical trials

273. *Id.*

274. *See* Act of July 12, 1999, 1999 LA. SESS. LAW SERV. 1357 (S.B. 761) (West) (to be codified at LA. REV. STAT. ANN. § 22:230.3).

275. *Id.*

276. *See id.*

277. *See* Act of August 3, 1999, 1999 ILL. LEGIS. SERV. 91-406 (H.B. 1622) (West) (to be codified at 20 ILL. COMP. STAT. 1405/56.3).

278. *See id.*

279. *See id.*

280. *See* MD. CODE ANN., Insurance § 15-827 (1998).

281. *See id.*

meeting the statute's requirements.²⁸²

The Maryland legislation is hailed as a much-needed first step toward breaking down the barriers to clinical trial participation. Dr. Barry Meisenberg, Director of Hematology and Oncology at the University of Maryland Hospital, Baltimore, states, "[i]f insurers in Maryland, home of the NIH and the FDA, don't go out of business . . . others will be less likely to oppose such legislation in the future."²⁸³ This type of legislation "signal[s] a major change in how clinical trials are perceived – by the public and payors alike,"²⁸⁴ because it will help eliminate the myth that patients in clinical trials are just "guinea pigs." The ultimate result is that patients, as well as payors, will be more likely to see the benefits of clinical trials.²⁸⁵

Following the lead of these states, legislation is being considered in thirteen other states to require insurers to reimburse patients for patient care costs associated with participation in various types of clinical trials.²⁸⁶ In addition, some states require reimbursement for a particular treatment, ostensibly including when it is conducted as part of a clinical trial, most notably high-dose chemotherapy supported by autologous bone marrow transplantation for breast cancer.²⁸⁷

282. See *id.*

283. Castellucci, *supra* note 115, at 423.

284. Diane Naughton, *Paying the Price for Progress; New Maryland Law Requires Insurers to Cover Patients' Costs in Clinical Trials*, WASH. POST, Sept. 22, 1998, available in 1998 WL 16557582, at 139.

285. See *id.*

286. See H.C.R. 2004, 44th Leg., 1st Reg. Sess. (Ariz. 1999); A.B. 591, Reg. Sess. (Ca. 1999); S.B. 132, Reg. Sess. (Conn. 1999); S.B. 396, 111th Leg., 1st Reg. Sess. (Ind. 1999); S.B. 668, 119th Leg., 1st Reg. Sess. (Me. 1999); H.B. 2916, 181st Gen. Ct. (Mass. 1999); S.B. 953, 81st Leg., Reg. Sess. (Minn. 1999); S.B. 311, 90th Leg., 1st Reg. Sess. (Mo. 1999); A.B. 6257, 222nd Leg., Reg. Sess. (N.Y. 1999); S.B. 982, Gen. Assem. (N.C. 1999); H.B. 1681, 47th Leg., 1st Sess. (Okla. 1999); S.B. 658, 183rd Leg., Reg. Sess. (Pa. 1999); H.B. 372, 65th Leg. (Vt. 1999).

287. Over the past few years, there has been an ongoing controversy over the efficacy of HDC/ABMT in the treatment of breast cancer and a barrage of litigation involving insurance companies' denial of coverage for the treatment because it is experimental. For an excellent discussion of the HDC/ABMT controversy and the resulting state legislation mandating its coverage, see Denise S. Wolf, *Who Should Pay for Experimental Treatments? Breast Cancer Patients v. Their Insurers*, 44 AM. U. L. REV. 2029 (1995). See also U.S. General Accounting Office, *Health Insurance – Coverage of Autologous Bone*

Although state initiatives to mandate coverage of participation in clinical trials are certainly steps in the right direction, they have many limitations. First, they do not cover Medicare and Medicaid beneficiaries.²⁸⁸ Second, they do not cover the uninsured. Third, and perhaps most importantly from a legislative perspective, employer self-insured health plans are exempt from state regulation mandating benefits under the ERISA.²⁸⁹ Nearly sixty-five percent of Americans are covered

Marrow Transplantation for Breast Cancer (April 24, 1996), available in 1996 WL 441066. Several commentators have noted, however, that state mandated coverage may actually impede a determination of the treatment's true efficacy, because patients' incentives to enroll in clinical trials will be greatly diminished if coverage outside trials is available. *See, e.g.,* Harness, *supra* note 4, at 95. At least one insurer has recognized this problem. In 1991, the Blue Cross Blue Shield Association, the trade association representing the Blue Cross/Blue Shield plans nationwide, began a demonstration project to fund patient participation in randomized clinical trials of HDC/AMBT for breast cancer. *See Blue Cross and Blue Shield Association Setting Precedent by Funding Clinical Trials for Women with Advanced Breast Cancer*, TRANSPLANT NEWS (Nov. 17, 1995), available in 1995 WL 10121002 [hereinafter TRANSPLANT NEWS]. Over the course of the five-year demonstration project, the Blue Cross/Blue Shield Plans were expected to contribute about \$40 million dollars to a series of NCI-approved Phase III randomized clinical trials, which were expected to include about 1,500 women. *See* Mary Ader, *Access to Investigational Treatments*, 6 HEALTH MATRIX 187, 197 (1996). One of the reasons for the establishment of the demonstration project was the recognition that simply providing coverage for the treatment, as many other insurers did and as some were required to do, would impede research on the actual efficacy of the treatment. *See* TRANSPLANT NEWS, *supra* note 287. As of this writing, no results of the demonstration project have been published. However, not all states and/or insurers will necessarily acknowledge and react to this problem. Thus, legislation focused on coverage for participation in clinical trials, rather than coverage for a particular treatment, will be more effective in achieving the short term goal of increased patient access to promising treatments and the long term goal of development of efficacy information. *See* Harness, *supra* note 4, at 95.

288. *But see infra* notes 305-09 and accompanying text, discussing proposed legislation to cover Medicare beneficiaries.

289. *See* Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 739 (1985). In Metropolitan Life, the Supreme Court held that a Massachusetts statute, requiring health plans to provide a certain minimum of mental health coverage, "regulated insurance" as specified in 29 U.S.C. § 1144(b)(2)(A) (known as the "Savings Clause"), and thus was not pre-empted by ERISA as it applied to purchased insurance plans. 471 U.S. at 379. However, the Court noted that ERISA pre-empted the statute as applied to self-insured employers,

by ERISA self-insured plans.²⁹⁰ Self-insured plans of all types cover about 100 million people and pay over \$100 billion a year in benefits.²⁹¹ These numbers will only continue to grow as employers recognize the benefits of being self-insured, namely, insulation from state regulation.²⁹² Accordingly, federal legislation is necessary to prevent self-insured employers from circumventing state legislation to provide coverage for clinical trials.

VI. FEDERAL LEGISLATIVE EFFORTS

A. Regulation of Medicare

While over half of the people who have cancer are over sixty-five,²⁹³ Medicare does not cover the patient care costs associated with participation in clinical trials.²⁹⁴ The federal law governing Medicare excludes services from coverage when they are not "reasonable and necessary for . . . treatment of illness."²⁹⁵ More specifically, Medicare regulations specifically exclude participation in clinical trials from coverage.²⁹⁶ Despite this policy, a recent GAO report concluded that Medicare actually does reimburse for certain costs associated with clinical trials, up to as much as fifty percent of claims made under Part

because, pursuant to 29 U.S.C. § 1144(b)(2)(B) (known as the "Deemer Clause"), such employers could not be deemed to practice in the business of insurance and thus could not be saved from preemption under the Savings Clause. For a thorough discussion of the mechanics of ERISA pre-emption, see generally Weisenborn, *supra* note 147.

290. See Weisenborn, *supra* note 147, at 155. "Self-insurance" includes a number of financial arrangements: (1) No Insurance, where the employee plan is totally at risk for all health claims, (2) Stop-Loss Insurance, where the employer or health and welfare plan is insured for catastrophic cases above a certain stop-loss amount. There is no insurance below these stop-loss limits, which is where the vast majority of claims fall. (3) Minimum Premium Insurance, which is similar to stop-loss insurance and (4) HMO Prepayment. See Weller, *supra* note 152, at 312.

291. See Weller, *supra* note 152, at 308.

292. See *id.* at 309.

293. See 145 Cong. Rec. E37-03 (1999) (testimony of Representative Bentsen) [hereinafter Bentsen testimony].

294. See *id.*; Smeltz, *supra* note 142, at 546.

295. 42 U.S.C. § 1395 (1998).

296. See 42 C.F.R. § 411.15(o)(2) (1998).

B and fifteen percent of claims made under Part A.²⁹⁷ However, Medicare coverage decisions do not follow pre-established guidelines, but instead turn on physicians' and hospitals' abilities to convince HCFA to cover such costs.²⁹⁸ Medicare-covered patients are thus taking a gamble when enrolling in a clinical trial. This lack of Medicare reimbursement of these costs, therefore, severely impedes the goal of ensuring cancer patients access to clinical trials.

Presently, a bill is pending in Congress which would require Medicare to reimburse patients for "routine patient care costs" associated with participation in a federally approved clinical trial.²⁹⁹ The proposed legislation, entitled "The Medicare Clinical Trial Coverage Act of 1999," defines "routine patient care costs" as "items and services that . . . would otherwise be covered under [Medicare] if such items and services were not provided in connection with a Federally approved clinical trial and . . . are furnished according to the design of a Federally approved clinical trial."³⁰⁰ Under the present version of this bill, a patient would not be denied coverage of routine medical care costs simply because she enters a clinical trial. The legislation would apply to all types of Medicare plans, including Medicare managed care plans, and importantly, to all three phases of clinical trials.³⁰¹ To ensure coverage, a clinical trial needs approval from any of the following: the Secretary of Health and Human Services, the NIH, the FDA, the Secretary of Veterans Affairs, the Secretary of Defense, the Secretary of Energy, a non-governmental research entity as defined by the NIH or a peer-review and approved research program as defined by the Secretary of Health and Human Services.³⁰² The legislation would also require the Secretary of Health and Human Services and the Secretary of Labor to jointly prepare a report on the costs associated with requiring health plans to reimburse patients for routine medical care costs associated with participation in clinical trials.³⁰³

The bill's sponsor, Representative Ken Bentsen (D-Tx.), believes the legislation would increase participation in clinical trials and lead

297. See Bentsen testimony, *supra* note 293.

298. See *id.*

299. See H.R. 61, 106th Cong. (1999).

300. *Id.*

301. See *id.*

302. See *id.*

303. See *id.*

to faster development of therapies for life-threatening diseases.³⁰⁴ He argues that Medicare reimbursement of routine patient care costs associated with clinical trials would encourage other health plans to provide coverage.³⁰⁵ Representative Bentsen also believes the reports required by the legislation on the costs associated with reimbursement will likely reveal that covering clinical trial costs is actually cost-effective, thereby ensuring that all health plans will provide access to clinical trials.³⁰⁶

This is not the first time Representative Bentsen has introduced this legislation. He introduced the exact same bill in 1998, although no action took place.³⁰⁷ In addition, it is not the only proposal for Medicare coverage of patient care costs associated with clinical trials. Bills are currently pending in both the Senate and the House that would establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries enrolled in approved cancer clinical trials.³⁰⁸ The definitions for "routine patient care costs" and approved clinical trials in these bills mirror those included in Representative Bentsen's bill.³⁰⁹ The legislation, entitled the "Medicare Cancer Clinical Trial Coverage Act of 1999," would mandate Medicare coverage of costs associated with cancer clinical trials for a five-year period.³¹⁰ At the conclusion of the five-year demonstration period, the legislation would require the Secretary to submit a report to Congress outlining any incremental costs to the Medicare program as a result of coverage of costs associated with cancer clinical trials. The report must also include a projection of expenditures if coverage of such costs were extended to individuals with a diagnosis other than cancer.³¹¹ This legislation is narrower than Representative Bentsen's proposal because it would limit coverage to cancer clinical trials and expire after five years. The goals of the two bills, however, are very similar and either would be a step in the direction of ensuring

304. See Bentsen testimony, *supra* note 293.

305. See *id.* See also *Fuja*, 18 F.3d at 1408, (examined plan including availability of HCFA reimbursement as a factor in determining whether a treatment was experimental.).

306. See Bentsen testimony, *supra* note 293.

307. See H.R. 3283, 105th Cong. (1997).

308. See S. 784, 106th Cong. (1999); H.R. 1388, 106th Cong. (1999).

309. See *id.*

310. See *id.*

311. See *id.*

older Americans access to clinical trials.

Finally, the Clinton Administration recognizes the problems caused by lack of reimbursement for clinical trial costs and proposed a demonstration project of its own.³¹² The Clinton proposal would be a three-year demonstration project, similar to the one proposed in Congress' bill.³¹³ The project, estimated to cost \$750 million, would be supported by funds from the comprehensive tobacco legislation.³¹⁴ The project would coincide with an increase in funding of sixty-five percent over five years for cancer research at the NIH.³¹⁵

B. Regulation of Private Insurance Carriers

As discussed *supra*, employer self-insured health plans are exempt from any state regulation mandating coverage of participation in clinical trials.³¹⁶ To counter self-insurers exemption from regulation, action must be taken at the federal level to require these plans to cover such costs. Congress could achieve this goal either by exempting health plans from ERISA altogether, thus leaving all health plans open to state regulation, or by amending ERISA to require ERISA-covered plans to reimburse beneficiaries for patient care costs associated with clinical trials.

The first alternative does not have much support in Congress and is probably not the most efficient way to guarantee access to clinical trials. The purpose of ERISA was to achieve uniformity in employment law,³¹⁷ which is why Congress "has been reluctant to restructure the ERISA preemption to allow states to implement health care reform because of the perceived need for such uniformity."³¹⁸ Congress does not seek to burden companies operating in more than one state by subjecting them to each state's regulation.³¹⁹ One commentator suggests a solution to this problem, which would require a major overhaul

312. See Laurent Castellucci, *Gore Champions Major New Cancer Initiative*, 90 J. NAT'L CANCER INST. 270, 270 (1998).

313. See *id.*

314. See *id.*

315. See *id.*

316. See *supra* notes 285-86 and accompanying text.

317. See Scott D. Litman, *Health Care Reform for the Twenty-First Century: The Need for a Federal and State Partnership*, 7 CORNELL J. L. & PUB. POL'Y 871, 882 (1998).

318. *Id.*

319. See *id.*

of health care regulation.³²⁰ Specifically, the proposal would require: (1) a federal law mandating that all states provide a minimum benefits package, (2) a federal ERISA exemption for health care, which would allow the states' minimum benefits packages to apply to all insurers, and (3) a federal law mandating that all self-insuring employers with operations in five or more states respect the minimum benefit laws of either their state of incorporation or their principle place of business.³²¹ Under this scenario, total coverage of patient costs associated with clinical trials would require all fifty states to include such coverage in their minimum benefits package.³²² This legislation appears more cumbersome than the legislative changes discussed in the next section. At any rate, no other legislation is currently pending that would have such broad implications.³²³

The second alternative, however, is supported in Congress and has become part of the great debate on health care reform. In March 1997, President Clinton appointed the Advisory Commission on Consumer Protection and Quality in the Health Care Industry and asked it to draft a "Consumer Bill of Rights."³²⁴ The Commission presented the bill to the President in November of 1997.³²⁵ The bill consisted of seven major areas of consumer rights including: Information Disclosure, Choice of Provider and Plans, Access to Emergency Services, Participation in Treatment Decisions, Respect and Nondiscrimination,

320. *See id.* at 911.

321. *See id.*

322. There are, of course, federalism arguments that this is the more appropriate way to regulate health care benefits. *See generally* James E. Holloway, ERISA, Preemption and Comprehensive Federal Health Care: A Call for "Cooperative Federalism" to Preserve the States' Role in Formulating Health Care Policy, 16 CAMPBELL L. REV. 405 (1994) (arguing that the dominance of federal regulation in the field of medical care . . . "accelerate[s] the decline of federalism by restricting states' ability to concern themselves with local medical care needs and to use local employment-based resources in formulating a comprehensive state health care policy.").

323. The closest proposed legislation that has come to this alternative is to exempt from ERISA pre-emption state tort and breach of contract claims. *See generally* sources cited *infra* notes 337, 339, 344, 346 and 351.

324. *See Advisory Commission on Consumer Protection and Quality in the Health Care Industry, Consumer Bill of Rights and Responsibilities, Report to the President of the United States* (Nov. 1997), reprinted in Havighurst, *supra* note 109, at 1277.

325. *See id.*

Confidentiality of Health Information, and Complaints and Appeals.³²⁶ Under the heading of "Participation in Treatment Decisions," the Commission recommended that patients receive the right to be advised of all treatment options, ostensibly including participation in clinical trials.³²⁷

The Commission's work quickly translated into many bills introduced during the 105th Congress, none of which were passed into law.³²⁸ Most of these bills recommended amending ERISA to require ERISA-covered plans to adhere to the patient rights established, thus eliminating the ERISA preemption problem.³²⁹ In addition, these bills recommended amending the Public Health Service Act, which would subject all non-ERISA state-regulated health plans to the proposed law's requirements, thereby establishing a national minimum floor of patients' rights.³³⁰ At least one bill has even suggested amending the Medicaid statute.³³¹ Some type of health reform to address patient

326. *See id.*

327. *See id.*

328. *See id.* at 1276.

329. *See* sources cited *infra* notes 337, 339, 344, 346 and 351.

330. *See id.* In 1996, Congress passed and President Clinton signed into law the Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 104-191, 110 Stat. 1936 (1996) [hereinafter HIPAA]. In furtherance of the statute's goal to guarantee continued availability of health care coverage to employees and their spouses and dependents who have group health insurance, it added a new title to the Public Health Service Act, 42 U.S.C. §§ 201-299 (1994) [hereinafter PHSA], which brings federal regulation to private health insurance issuers that before had been primarily subject to state regulatory control. *See* Jack A. Rovner, *Federal Regulation Comes to Private Health Care Financing: The Group Health Insurance Provisions of the Health Insurance Portability and Accountability Act of 1996*, 7 ANNALS HEALTH L. 183, 185 (1998). The addition has been used to create federal minimum health insurance benefits, such as minimum hospital lengths of stay after childbirth. *See* The Newborns' and Mothers' Health Protection Act of 1996, Pub. L. No. 104-204, §§ 601-606, Stat. 2874, 2935 (1996), and financial parity of mental health benefits with medical benefits. *See* The Mental Health Parity Act of 1996, Pub. L. No. 104-204, §§ 701-703, 110 Stat. 2874, 2944 (1996). Note that amendments to the PHSA do not prevent states from legislating requirements that are more stringent. *See* Rovner, at 211-12. *See also* the bills discussed in this section, which all provide for state legislation which is stricter than the proposed requirements.

331. *See* S. 1499, 105th Cong. (1997).

rights in managed care had broad bipartisan support,³³² however, specific proposals differed along party lines. In general, the Democratic bills provided for broader protection of patients' rights, including mandated coverage of participation in clinical trials.

For example, in the House of Representatives, Representative Dingell (D-MI) introduced the "Patients' Bill of Rights Act of 1998."³³³ The bill would have required health plans to cover "routine patient costs" of individuals participating in "approved clinical trials" if: (1) the individual has a life-threatening or serious illness for which no standard treatment is effective, (2) the individual is eligible to participate in an approved clinical trial, (3) the individual's participation in the trial "offers meaningful potential for significant clinical benefit for the individual," and (4) either the individual's referring physician has concluded that the individual's participation in the trial would be appropriate or the individual provides medical and scientific information establishing that her participation would be appropriate.³³⁴ Under this proposed bill, an "approved clinical trial" was defined as one approved and funded by either the NIH, a cooperative group or center of the NIH, the VA or the DoD.³³⁵ The bill would have allowed managed care organizations to require patient participation in a trial conducted by a provider that participates in the plan as opposed to a trial conducted by a non-participating provider, as long as the participating provider accepts the patient into the trial.³³⁶

Although some of the bill's language appeared ambiguous,³³⁷ this legislation clearly required private health plans to cover costs of at least some of their patients participating in clinical trials. A similar bill, containing identical language and also entitled the "Patients' Bill of Rights," was introduced in the Senate.³³⁸ Senator Edward Kennedy (D-MA) described the reasoning behind this portion of the bill as follows:

Access to quality clinical trials is particularly important. These trials are often the only hope for patients

332. See Misocky, *supra* note 100, at 60.

333. H.R. 3605, 105th Cong. (1998)

334. See *id.*

335. See *id.*

336. See *id.*

337. See *id.* For example, it is not clear what is meant by "meaningful potential for significant clinical benefit for the individual?"

338. See S. 1890, 105th Cong. (1998)

with incurable cancer or other diseases where conventional treatments are ineffective. They are the best hope for curing these dreaded [sic] diseases Too often, managed care is locking patients out of clinical trials that offer potential benefit - in effect, passing a death sentence.³³⁹

The Republican bills, by contrast, were significantly less protective of patients' rights, especially with regard to clinical trial participation. For example, in the House of Representatives, Newt Gingrich (R-GA) introduced the "Patient Protection Act of 1998."³⁴⁰ This bill did not mandate coverage of participation in clinical trials, but merely required a plan to disclose information about experimental treatments that are not covered, such as clinical trial participation.³⁴¹ A similar bill was also introduced in the Senate.³⁴²

In July of 1998, the House passed the Gingrich bill described above,³⁴³ however, the Dingell bill was defeated by just five votes.³⁴⁴ No further action was taken by the 105th Congress. However, many bills similar or identical to these have already been introduced in the 106th Congress³⁴⁵ and on October 7, 1999, the House passed a bill identical to the 1998 Dingell bill entitled the "Bipartisan Consensus Managed Care Improvement Act of 1999."³⁴⁶

339. 144 Cong. Rec. S11155-01 (Sept. 30, 1998) (testimony of Senator Kennedy).

340. H.R. 4250, 105th Cong. (1998).

341. *See id.*

342. *See* S. 2230, 105th Cong. (1998).

343. *See House Passes GOP Managed Care Bill: Clinton Administration Threatens Veto*, 6 Health Care Policy Report (BNA) (July 27, 1998).

344. *See id.*

345. *See, e.g.*, H.R. 719, 106th Cong. (1999) (Managed Care Reform Act of 1999) (providing for coverage of clinical trials); S. 374, 106th Cong. (1999) (Promoting Responsibility in Managed Care Act of 1999); H.R. 358, 106th Cong. (1999) (Patients Bill of Rights Act of 1999); S. 240, 106th Cong. (1999) (Patients Bill of Rights Act of 1999); H.R. 448, 106th Cong. (1999) (Patient Protection Act of 1999) (not providing coverage for participation in clinical trials); S. 326, 106th Cong. (1999) (Patients Bill of Rights Act of 1999).

346. *See* H.R. 2723, 106th Cong. (1999). *See also Clinical Trial Costs Covered, The Blue Sheet*, Vol. 42 Issue 41 (Wednesday, Oct. 13, 1999), available in 1999 WL 10784129.

VIII. CONCLUSION

In order to expand patient access to clinical trials, Congress should pass legislation, like the Dingell bill, which substantively regulates health plans, rather than just imposes disclosure requirements on them, requiring reimbursement to patients for costs associated with clinical trials. It makes sense in the short and long term for third parties to reimburse for basic patient care costs associated with participation in all Phases of clinical trials. Recent efforts on the part of the federal government and private insurance carriers to improve patient access to clinical trials indicate that these parties are at least willing to explore some of the benefits of such reimbursement. However, because of the short term emphasis on costs of participation in clinical trials and because of the collective action problem plaguing insurers' reliance on long term benefits, this coverage choice should not be left in the hands of the individual insurer. Not only will reliance on individual insurers result in inconsistent coverage for this important treatment, it will also result, as it already has to some extent, in costly, time-consuming litigation.

Relying on states to mandate coverage is also inefficient, because of the time it will take for all fifty states to pass legislation and because of the enormous gap left by ERISA pre-emption, Medicare, and Medicaid coverage. Therefore, the best solution is for Congress to pass legislation establishing mandated coverage of these costs by all insurers, including ERISA-covered plans, Medicare, and Medicaid. This can be achieved by amending ERISA, the PHSA, and the Social Security Act, all of which has already been suggested in Congress. By passing such legislation, Congress will ensure access of seriously ill patients to treatment that may be their best alternative. In addition, it will ensure the advancement of clinical research for life-threatening diseases. Congress should not pass up this opportunity to take a large step in the battle against cancer and other killers.