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Health and Welfare / Mandatory Health Insurance Coverage for Cancer Clinical Trials

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Code Sections Affected

Health and Safety Code § 1370.6 (new); Insurance Code § 10145.4 (new); Welfare and Institutions Code §§ 14087.11, 14132.98, and 14132.99 (new).
SB 37 (Speier); 2001 STAT. Ch. 172.

I. INTRODUCTION

After diagnosing Ms. Judith Harris with advanced-stage breast cancer, her physician recommended that she consider High Dosage Chemotherapy with Autologous Bone Marrow Transplant (HDC-ABMT).[1] This procedure involves the extraction of the patient's bone marrow, which is frozen and stored.[2] The patient then receives near-lethal doses of chemotherapy.[3] The chemotherapy kills not only the cancer cells, but also the patient's healthy bone marrow.[4] The previously extracted bone marrow is returned to the patient where it rapidly duplicates and replaces the bone marrow damaged by the chemotherapy.[5] The cost of HDC-ABMT ranges between $75,000 and $150,000.[6]

HDC-ABMT is used on patients who have not responded to traditional chemotherapy.[7] Without this treatment, Ms. Harris' chance of survival was grim.[8] Ms. Harris' physician referred her to Indiana University Medical Center, where

1. *See* Harris v. Mut. of Omaha, 992 F.2d 706, 707 (7th Cir. 1993) (describing Ms. Harris' medical condition).

2. Melody L. Harness, *What is "Experimental" Medical Treatment?: A Legislative Definition is Needed,* 44 CLEV. ST. L. REV. 67, 74 (1996).

3. *Id.*

4. *Id.*

5. *Id.*

6. *See Harris,* 992 F.2d at 708 (stating HDC-ABMT costs between $100,000 to $150,000); Adams v. Blue Cross/Blue Shield, 757 F. Supp. 661, 662 (D. Md. 1991) (stating HDC-ABMT costs approximately $100,000); Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131, 132 (D.N.J. 1989) (stating HDC-ABMT costs range between $75,000 to $125,000).

7. *See* Emily Smayda, *Current Legal Intervention Regarding "Experimental" Treatments Must be Changed: An Analysis of High Doses of Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer Patients,* 13 J.L. & HEALTH 257, 257-58 (1998) (describing a young woman with late-stage breast cancer who endured nine months of chemotherapy and radiation but whose disease still progressed; her doctor told her without HDC-ABMT she would die).

8. *See Harris,* 992 F.2d at 708 (according to Ms. Harris' doctor, she had "very little" chance of surviving five years without HDC-ABMT).

she sought treatment as part of a Phase II clinical trial.[9] Ms. Harris requested authorization for the procedure from her insurance carrier.[10] The authorization was denied because her insurance policy did not cover experimental treatments.[11]

Ms. Harris' insurance carrier, Mutual of Omaha, defined Phase I, II, and III clinical trials[12] as experimental or investigational.[13] Before any new treatment becomes acceptable medical practice, clinical trials must indicate that the treatment is safe and effective for the specific condition.[14] Until a procedure or drug is considered standard medical practice, insurance companies typically deem the treatment investigational and experimental.[15]

Whether an insurer should cover experimental medical treatment is a difficult problem to remedy because determining whether an insurance company covers treatment is usually a matter of contract law.[16] Often times, there is a conflict between the social policy of promoting new effective treatments through clinical trials and insurance carriers' reluctance to pay for an unproven treatment.[17]

This Legislative Note discusses the nature of clinical trials,[18] how they are conducted, and the costs of such trials.[19] Next, an analysis of the current law relating to insurance coverage of cancer clinical trials is presented.[20] Finally, this Note discusses the mandates of Chapter 172 and its likely effect on insurance coverage of cancer clinical trials.[21]

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9. *See id.* at 707; *infra* Part II.A (describing the different stages of clinical trials).

10. *Harris*, 992 F.2d at 710.

11. *Id.*

12. *Infra* Part II.A.

13. *Harris*, 992 F.2d at 710.

14. *See* Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131, 135 (D.N.J. 1989) (quoting David W. Plocher, M.D., the Vice President of Medical Services at Prudential, when asked how Prudential determines if a novel treatment is covered); Letter from Nancy Davenport-Ennis, CEO, National Patient Advocate Foundation, to the Health Care Financing Administration (July 17, 2000) [hereinafter Davenport-Ennis Letter] (on file with the *McGeorge Law Review*) (stating that reimbursement of new therapies aided the progress of the treatment of pediatric cancer over many decades).

15. *See* Nancy A. Wynstra, *Breast Cancer: Selected Legal Issues*, 74 CANCER 491 (1994) (explaining the "hotly contested" legal issue of reimbursement of unproven treatments, such as clinical trials).

16. *See Harris*, 992 F.2d at 711 (stating that Ms. Harris' suit against her insurance failed). Under the Administrative Procedures Act 5 U.S.C.A. § 706(2)(a), the Office of Personnel Management's (OPM) determination was final, unless the decision was "arbitrary and capricious." Therefore, whether or not the clinical trial was experimental or standard medical practice was not at issue. *Id.*

17. Wynstra, *supra* note 15, at 491-92 (noting that society and health plans each have an interest in not paying for unproven treatments because it is not cost effective).

18. *See infra* Part II.A-C (noting the structure and costs of clinical trials).

19. *Infra* Part II.A-C.

20. *See infra* Part III (discussing the existing law).

21. *See infra* Part V (analyzing the possible effects of Chapter 172).

II. BACKGROUND

A. *Clinical Trials*

Prescription drugs go through a more rigorous process than medical devices, while medical procedures are not put through the regulatory process at all.[22] For instance, a new drug may not be marketed unless the Food and Drug Administration (FDA) approves it as safe and effective.[23] Clinical trials are another prerequisite for determination of safety and effectiveness.[24]

Organizations or individuals marketing a drug, device, or product sponsor clinical trials, and it is the sponsor who must ensure that the trial is conducted both legally and ethically.[25] Each clinical trial is based on a set of rules called a protocol.[26] A protocol sets forth who may participate in the trial and determines the appropriate procedures, medications, and dosages to be used in the clinical trials.[27] All protocols must be approved by the sponsor of the study and by the Institutional Review Board (IRB) at the facility where the trial is conducted.[28] There are IRB groups at every facility conducting clinical trials.[29] IRBs are groups of doctors, clergy members, and consumers who review protocols to ensure patient safety.[30] In fact, IRBs must review and approve protocols for all clinical trials funded by the federal government.[31]

Clinical trials are conducted in four phases. Phase I studies are almost exclusively conducted at specialized research centers which evaluate a treatment's safety and typically involve twenty to eighty patients.[32] In Phase II studies, the new treatment is generally administered to a larger group of people, between one hundred to three hundred, to further evaluate its safety.[33] Phase III studies are typically conducted on an even larger group of people, between one to three thousand.[34] This phase monitors side effects, compares the new treatment to currently used treatments, and collects more data on its safety.[35] To compare data

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22. Harness, *supra* note 2, at 70.

23. 21 U.S.C.A § 355(a) (West 1999).

24. *Id.* § 355(d) (giving guidelines for approval, specifically requiring "substantial evidence").

25. *See* National Institute of Health, *What is a Clinical Trial?* (July 22, 2001), *at* http://www.clinicaltrials.gov (giving a detailed description of the structure of clinical trials).

26. *Id.*

27. *Id.*

28. *See Taking Part in Clinical Trials: What Cancer Patients Need to Know*, CancerNet (Nat'l Cancer Inst., Bethesda, Md.), revised May 1998 at 1, 3-4, http://cancernet.nci.nih.gov/peb/taking_part_treatment/index.html [hereinafter *Taking Part*] (discussing IRBs and structure of clinical trials).

29. *Id.*

30. *Id.* at 10.

31. National Institute of Health, *supra* note 25, at 5.

32. *Id.* at 2.

33. *Id.*

34. *Id.*

35. *Id.*

between Phase II and Phase III trials, participants in Phase III trials are randomly assigned to receive either the new treatment or the standard treatment, to avoid any bias in the study.[36] In fact, some studies do not inform patients whether or not they are in the control group.[37] Finally, Phase IV studies consist of continued investigations after the drug, treatment, or procedure is marketed, to determine the effects on various populations including long-term side effects.[38]

B. Costs of Clinical Trials

There are two types of costs associated with clinical trials: patient care and research costs.[39] Patient care costs include items such as doctor visits, x-rays, and hospital stays.[40] Research costs include the costs associated with data collection.[41]

One study compared costs of 135 patients in 22 Phase II cancer clinical trials, to 135 matched control subjects.[42] This research found that the clinical trial enrollees, on average, had a higher one-year medical care cost.[43] The increase is largely due to costs associated with receiving Bone Marrow Transplant (BMT), as the costs of patients participating without BMT were no higher than those in the control group.[44]

C. Participation in Clinical Trials

Less than four percent of adults with cancer are enrolled in clinical trials.[45] One reason for low participation in clinical trials is a lack of consistency in insurance coverage.[46] Some scholars argue that covering costs of clinical trials is the "first step" in increasing participation in cancer clinical trials.[47]

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36. *Taking Part*, *supra* note 28, at 5.

37. *See id.* (defining a control group as those patients receiving the "standard treatment" rather than the new treatment).

38. *Id.* at 2.

39. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 7-8 (June 19, 2001).

40. *Id.*

41. *Id.*

42. *See* Bruce H. Fireman et al., *Cost of Care for Patients in Cancer Clinical Trials*, 92 J. NAT'L CANCER INST. 136, 136 (Jan. 19, 2000) (defining matched control subjects as "comparison subjects").

43. *See id.* at 142 (stating that enrollees had higher one-year costs by $1,487, or about ten percent).

44. *Id.*

45. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 6 (June 19, 2001); Letter from Arlyne Draper, President/Co-Founder, California Breast Cancer Organizations, to Jackie Speier, Senator (Feb. 14, 2001) (on file with the *McGeorge Law Review*).

46. Harness, *supra* note 2, at 71.

47. Draper, *supra* note 45.

III. EXISTING LAW

Existing California law requires health insurance plans to provide only "basic health care services."[48] Provided those basic services are included, an insurance policy contract can include or exclude any other types of benefits.

Contract language therefore controls whether a treatment is covered by the health insurance plan.[49] When a person is denied treatment that is specifically excluded from the policy, the policyholder has no contractual remedy available.[50] Courts only review the contract provisions to which both parties agreed.[51] When examining a contract, the denial of benefits is never addressed; rather, only the contract language is reviewed.[52]

Case law on the denial of coverage for clinical trials as experimental is remarkably inconsistent.[53] To complicate the matter further, one insurance carrier may cover clinical trials while another may not.[54] This inconsistency reveals that there is no universal definition of what constitutes experimental treatment in either the legal or in the health care industry.[55]

IV. CHAPTER 172

Chapter 172 requires health service plans, disability insurers, and Medi-Cal to provide coverage for all "routine patient care costs" associated with clinical trials, for patients who are diagnosed with cancer and accepted into a Phase I, II,

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48. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 4 (June 19, 2001) (giving examples of basic services: physician, hospital, diagnostic, home health, preventative, emergency, and hospice care).

49. *See* Thomas v. Gulf Health Plan, Inc., 688 F. Supp. 590, 595 (S.D. Ala. 1988) (stating that a court must uphold the plan administrator's decision regarding the contract unless a court determines that it was "arbitrary and capricious"); Bechtold v. Physicians Health Plan, 19 F.3d 322, 327 (7th Cir. 1994) (asserting that courts can only interpret language of the insurance contract in question).

50. Smayda, *supra* note 7, at 266.

51. *Id.*

52. *Id.* at 267.

53. *See, e.g.*, DiDomenico v. Employers Coop. Indus. Trust, 676 F. Supp. 903, 907-08 (N.D. Ind. 1987) (ordering treatment because the contract was not clear as to whether the liver transplant procedure or the patient's age made the treatment experimental); Adams v. Blue Cross/Blue Shield, 757 F. Supp. 661, 666 (D. Md. 1991) (deeming a treatment experimental if the treatment was not the accepted practice in the area); Fassio v. Mont. Physicians' Serv., 553 P.2d 998, 1002 (Mont. 1976) (ordering payment for treatment of Mongolism because the denial was based on an exclusion that was a change in policy and because the beneficiaries did not receive notice of the change); Jacob v. Blue Cross/Blue Shield, P.2d 382, 384 (Or. 1988) (holding there is no ambiguity in the exclusionary provision of an "experimental procedure"); Harris v. Mut. of Omaha 992 F.2d 706, 707-08 (7th Cir. 1993) (holding contract language specifically excluded experimental treatment, including clinical trials, unless efficacy was proven with reliable evidence as determined by the Plan).

54. William B. Farrar, *Clinical Trials: Access and Reimbursement*, 67 CANCER 1779, 1781 (1991).

55. Richard S. Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1098 (1992).

III, or IV clinical trial.[56] "Routine patient care costs" are services that would normally be covered by the plan if treatment was not part of a clinical trial.[57] Services for reasonable and necessary care for an investigational treatment and any complications arising from the investigational treatment are also included.[58] The patient's normal co-payments and deductibles will apply to services rendered in the clinical trial.[59] Specifically excluded from "routine patient care costs" are drugs or devices not approved by the FDA, although part of the clinical trial; travel expenses; pure data collection services; services normally performed at no charge; and services specifically excluded under the policy.[60]

A condition of coverage of the clinical trial is that the treating physician, providing services under the enrollee's health plan, must determine that the clinical trial has "meaningful potential" to benefit the patient before recommending participation in the clinical trial.[61] Interestingly, the statute does not define "meaningful potential" or provide any specific criteria for meeting this requirement.[62]

V. EFFECTS OF CHAPTER 172

Currently, the level of participation in cancer clinical trials is extremely low.[63] Increased participation is needed because clinical trials refine new treatments into the most efficacious treatment possible.[64] However, improvements

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56. *See* CAL. HEALTH & SAFETY CODE § 1370.6(a) (enacted by Chapter 172) (requiring managed care organizations to cover cancer clinical trials); CAL. INS. CODE § 10145.4(a) (enacted by Chapter 172) (requiring all disability insurances including indemnity plans and preferred provider organizations, to cover cancer clinical trials); CAL. WELF. & INST. CODE § 14087.11(b) (enacted by Chapter 172) (requiring County Organized Health System contracts to cover cancer clinical trials). This program is similar to the state Medi-Cal program but is administered at the county level. *Id.*; CAL. WELF. & INST. CODE § 14132.98(a) (enacted by Chapter 172) (requiring Medi-Cal to cover cancer clinical trials).

57. CAL. HEALTH & SAFETY CODE § 1370.6(b)(1) (enacted by Chapter 172); CAL. INS. CODE § 10145.4(b)(1) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14087.11(c)(1) (enacted by Chapter 172); CAL WELF. & INST. CODE § 14132.98(b)(1) (enacted by Chapter 172).

58. CAL. HEALTH & SAFETY CODE §§ 1370.6(b)(1)(B)-(E) (enacted by Chapter 172); CAL INS. CODE §§ 10145.4(b)(1)(B)-(E) (enacted by Chapter 172); CAL. WELF. & INST. CODE §§ 14087.11(c)(1)(B)-(E) (enacted by Chapter 172).

59. CAL. HEALTH & SAFETY CODE § 1370.6(i) (enacted by Chapter 172); CAL. INS. CODE § 10145.4(i) (enacted by Chapter 172); CAL. WELF. & INST. CODE §§ 14087.11(c)(1)(B)-(C) (enacted by Chapter 172).

60. CAL. HEALTH & SAFETY CODE §§ 1370.6(b)(2)(A)-(E) (enacted by Chapter 172); CAL. INS. CODE §§ 10145.4(b)(2)(A)-(E) (enacted by Chapter 172); CAL. WELF. & INST. CODE §§ 14087.11(c)(2)(A)-(E) (enacted by Chapter 172); CAL. WELF. & INST. CODE §§ 14132.98(b)(2)(A)-(E) (enacted by Chapter 172).

61. CAL. HEALTH & SAFETY CODE § 1370.6(a) (enacted by Chapter 172); CAL. INS. CODE § 10145.4(a) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14087.11(b) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14132.98(a) (enacted by Chapter 172).

62. CAL. HEALTH & SAFETY CODE § 1370.6(a) (enacted by Chapter 172); CAL. INS. CODE § 10145.4(a) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14087.11(b) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14132.98(a) (enacted by Chapter 172).

63. *See supra* Part II.C (discussing clinical trial participation).

64. *See* Letter from Theresa M. Renken, Legislative Advocate, American Cancer Society, to Sam Aanestad, Assemblymember (July 12, 2001) (on file with the *McGeorge Law Review*) (stating that increased

in treatment usually occur very slowly.[65] Therefore, it follows that, if more health insurance plans cover costs associated with cancer clinical trials, more people with cancer will participate in clinical trials, resulting in an increase in the rate of cancer treatment improvements. The drafters of Chapter 172 have such a hope.[66]

Proponents of Chapter 172 justify broad mandatory coverage of clinical trials by relying on research that indicates the costs of treating people in a clinical trial are not significantly greater than the costs of treating people not enrolled in the clinical trials.[67] However, the statistics used are misleading because the study analyzed data from clinical trials that were not a "representative sample" of all cancer clinical trials.[68] Rather, the study was exclusively based on clinical trials performed at Kaiser Permanente.[69] The authors of that study concede that costs of clinical trials vary with the type of treatment being evaluated.[70] Thus, the financial impact on health plans remains uncertain.

For instance, Chapter 172 requires coverage for all stages of clinical trials.[71] Before the adoption of Chapter 172, Medi-Cal typically covered Phase III and IV, but not Phase I and II.[72] The Assembly Appropriations Committee estimates costs to the Medi-Cal program will increase approximately $300,000 annually.[73] Rising costs will not be exclusive to Medi-Cal. Any health insurance plan that does not cover routine costs associated with clinical trials, which Chapter 172 now requires, will incur new costs.[74] This increase in costs could reasonably be passed down to enrollees in the form of increased premium prices.[75] The increase

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enrollment helps make treatments available); Draper, *supra* note 45 (indicating that clinical trials are necessary to learn how to effectively treat illnesses like cancer).

65. *See* Davenport-Ennis Letter, *supra* note 14 (on file with the *McGeorge Law Review*) (explaining that progress in the treatment of pediatric cancer came from decades of "incremental improvements").

66. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 6 (June 19, 2001) (stating the purpose of the Bill is to increase participation in cancer clinical trials in hope of finding cures for various cancers).

67. *See supra* Part II.B (comparing the costs of treating patients in clinical trials with the costs of treating patients receiving standard treatment).

68. *See* Cary A. Presant, *Correspondence: Patient Costs on Clinical Trials*, 92 J. NAT'L CANCER INST. 1441, 1442 (Sept. 6, 2000) (summarizing a response to Presant by Bruce Fireman, Louis Fehrenbacher, and G. Thomas Ray).

69. *Id.*

70. *Id.*

71. *See supra* Part IV (detailing what CHAPTER 172 covers); CAL. HEALTH & SAFETY CODE § 1370.6(a) (enacted by Chapter 172); CAL. INS. CODE § 10145.4(a) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14087.11(b) (enacted by Chapter 172); CAL. WELF. & INST. CODE § 14132.98(a) (enacted by Chapter 172).

72. ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 37, at 2 (July 11, 2001).

73. *See id.* (stating that there are currently fifteen thousand people participating in Phase I and II clinical trials in California). If Chapter 172 increases participation in those phases by ten percent, the estimated number of Medi-Cal participants would be approximately two hundred. This figure multiplied by the average cost increase of $1,487 per person will increase total costs to the program by approximately $297,400. *Id.*

74. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 6 (June 19, 2001) (noting that early opposition to SB 37 warned that mandating coverage of clinical trials would increase health insurance premiums and possibly the number of those uninsured).

75. *Id.*

in premiums could put health coverage out of reach for some, thereby raising the number of California's uninsured patients.[76]

Additional concerns exist about the effectiveness of Chapter 172 in increasing participation in clinical trials and health plans paying for the corresponding routine costs. Chapter 172 explicitly defines what is considered routine costs and what is not.[77] However, Chapter 172 does not define the phrases "meaningful potential" or "reasonable and necessary."[78]

Ambiguous language such as "reasonable and necessary" is precisely what gave rise to inconsistent coverage of clinical trials (allowing companies to include clinical trials as an investigational or experimental treatment), and such ambiguous language is the obstacle this legislation is designed to remedy.[79] One clue as to how "meaningful potential" and "reasonable and necessary" might be interpreted is to analogize to the proposed Medicare standard of review for access to new technologies.[80] The proposed Medicare rule provides criteria for determining "reasonable and necessary."[81] For instance, "breakthrough technology" and treatments that are "medically beneficial" are criteria that have been proposed.[82] The Health Care Financing Administration stated that the Medicare standard of "medically beneficial" is met when objective scientific evidence establishes that the new procedure will produce a better outcome than if the patient received no treatment or the customary medical management of symptoms.[83]

The proposed standard by Medicare will likely not help increase participation in clinical trials because most progress in the treatment of cancer is attributable to small refinements in treatment over many years, rather than "breakthroughs" in treatments.[84] Therefore, if the "meaningful potential" or "reasonable and necessary" conditions of Chapter 172 are interpreted as a standard similar to Medicare's proposed rules, Chapter 172 may actually fall short of its purpose—promoting clinical trials to help find a cure for cancer.

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76. *Id.*

77. *See supra* Part IV (defining "routine patient care costs").

78. *See supra* Part IV (discussing "meaningful potential" and "reasonable and necessary").

79. *See supra* Part III (detailing inconsistent judicial treatment of ambiguous contract language, such as the term "medical necessity").

80. Proposed Medicare Program Rules from Department of Health and Human Services and Health Care Financing Administration, 65 Fed. Reg. 31,124 (proposed May 16, 2000) (to be codified at 42 C.F.R. pt. 405).

81. *Id.* at 31,126.

82. *Id.* at 31,125.

83. *See* Davenport-Ennis Letter, *supra* note 14 (commenting on the Medicare standard).

84. Proposed Medicare Program Rules from Department of Health and Human Services and Health Care Financing Administration, 2 Fed. Reg. 31,125 (proposed May 16, 2000) (to be codified at 42 C.F.R. pt. 405).

VI. CONCLUSION

Chapter 172 attempts to increase participation in cancer clinical trials by mandating that health plans cover routine costs associated with cancer clinical trials which, in turn, will improve treatment and ultimately help find a cure for cancer.[85] It is not clear whether Chapter 172 will actually increase clinical trial participation. Quarrels over ambiguity in the statute's language may continue to exclude candidates from participation.[86] At the very least, Chapter 172 will give people like Ms. Harris some assurance that their health insurance plans are now more likely to cover cancer clinical trials.[87]

85. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 37, at 6 (June 19, 2001) (summarizing the purpose of the Bill as increasing participation in cancer clinical trials to find a cure for cancer).

86. *See supra* Part IV (discussing previous problems with ambiguous language such as "reasonable and necessary").

87. *See supra* Part I (discussing the problems Ms. Harris encountered when trying to persuade her insurance carrier to cover the costs of her participation in a cancer clinical trial).