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COMMENTARY

WHAT IS THE METHOD TO THEIR "MADNESS?" EXPERIMENTAL TREATMENT EXCLUSIONS IN HEALTH INSURANCE POLICIES

I. INTRODUCTION

A dilemma that many employers and insurance companies find themselves mired in when it comes to providing coverage for employees and insureds is seen in the dispute over experimental treatments. Tensions ensue as insurers attempt to limit reimbursement for only treatments proven safe and effective, while patients demand more access to promising treatments; the employer, if involved, desires to have the appearance of just being the "good guy" caught in the middle. But with juries awarding up to \$89.3 million judgments against providers who deny coverage,¹ "nervous tremors [are being sent] through the health insurance industry which is struggling to define limits on coverage of therapies that are experimental or have only a slight chance of success."² Insurance companies claim they have legitimate concerns when it comes to experimental treatment, but some argue experimental is "just [the insurance companies'] euphemism for too expensive."³

There are various effects of increasing insurance litigation and its result on public perception. Many health maintenance organizations ("HMOs") are establishing more formal decision-making procedures for

1. In a legal battle that received national attention, attorney Mark Hiepler won an \$89 million verdict against Health Net, the second largest health maintenance organization in California. Hiepler argued that Health Net wrongfully denied a bone marrow transplant to his sister, Nelene Fox, a breast cancer victim who died at age 40 in April, 1993. Health Net filed a motion for a new trial before reaching a settlement in April, 1994 with the Fox family for an unstated, but presumably large sum. Greg Miller, *Lawyer Makes it His Business to Fight HMOs*, L.A. TIMES, August 16, 1994, (Valley Edition, Business Section), at 3.

2. Erik Eckholm, *\$89.3 Million Judgment Worries Health Industry HMO declined to pay for Bone-Marrow Transplant*, SACRAMENTO BEE Dec. 30, 1993, at A3.

3. Edmund Sanders, *Cancer Victim's Family Wins Suit*, DAILY NEWS OF L.A., Dec. 29, 1993, at N1.

determining coverage of experimental procedures.⁴ An increasing number of health insurers now require approval from a medical association and/or an independent board of physicians⁵ before they agree to provide coverage for an experimental procedure.⁶ Also, some insurers are allowing employers to choose between two plans—one that covers controversial new treatments and one in which they are specifically excluded.⁷ Coinciding with these effects are the prevailing opinions of medical experts, insurance industry representatives, and politicians⁸ as to how to solve the problem of funding experimental treatment.⁹

Cancer treatment is one particularly bitter battlefield.¹⁰ The debate surrounding experimental treatment transcends cancer, however, and involves many forms of unproven treatments, as well as alternative treatments,¹¹ along with the research that is involved in proving the effectiveness of a procedure. "For years, medical researchers have been frustrated and confused by refusals of insurance companies to pay some or all of the charges relating to the care of a patient who has been involved, however peripherally, in a clinical trial or other study."¹² Because of this frustration and confusion, it is appropriate to examine

4. Jane Baird, *Life, Death, Money: Insurers Balk at "Experimental" Health Treatment*, HOUSTON CHRON., July 10, 1994, at 1.

5. Over the past nine years, Blue Cross & Blue Shield Association has put together a top-notch team of methodologists who have evaluated for local "Blues" plans some 200 new treatment and diagnostic approaches. Now Kaiser Permanente is joining in the enterprise, and the results of the evaluations are going to be sold to other payers - creating a review mechanism that could have a big impact on demand for technology. *Blues Expand Tech Assessment*, HEALTH BUS., Sept. 17, 1993, at 3.

6. Matthew P. Schwartz, "Experimental" Debate is Intensifying, NAT'L. UNDERWRITER LIFE & HEALTH, Apr. 24, 1995, at 5.

7. *Id.*

8. See, e.g., John K. Inglehart, *Health Care Reform, The Labyrinth of Congress*, 329 NEW ENG. J. MED. 1593, 1594-96 (1993).

9. A corresponding debate involves the funding of research to encourage potentially effective treatment.

10. Steven Findlay, *Coverage Denied: Your Treatment Was Expensive*, U.S. NEWS & WORLD REP., Dec. 9, 1991, at 81. Many controversies arise when doctors use chemotherapy drugs, approved for fighting one form of cancer, against other forms of the disease. *Id.*

11. See, e.g., M.A.J. McKenna, *Many Insurers Slow to Cover Alternative Care*, ATLANTA CONST., May 31, 1995, (Health Watch), at C3. Though surveys indicate one in three Americans have used some form of alternative medicine, and one in nine has sought the help of an alternative practitioner, few insurance companies reimburse for those treatments. *Id.* But see Robin Herman, *Therapies Outside the Mainstream*, WASH. POST, August 1, 1995, (Health Tab), at Z10.

12. Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795 (1994).

experimental treatment and how it is managed by the relevant participants.

A. *The Relevant Issues*

As new, high-technology medical procedures advance, insurance companies are in the unenviable position of deciding which procedures will be covered and what procedures are beyond the scope of their policies.¹³ Succeeding these decisions exists much litigation as to whether the treatment in question falls within the exclusionary language in the insurance policy at issue. While courts have attempted to interpret these exclusions to decide whether coverage should be provided, it appears that many, including the public and the courts, do not realize what the dynamics are in fashioning the policy exclusions. "Beyond the bare facts, . . . [little is known] about how insurance companies make their decisions"¹⁴

There are numerous considerations when dealing with experimental exclusions. One side, the insurance companies, argues that rationing new technology is essential for controlling costs.¹⁵ The primary aim of most insurers is to keep costs down;¹⁶ if providers were to pay for everything, "premiums would go through the roof."¹⁷ Insurers claim they are protecting patients from unnecessary medicine and improving the overall quality of care,¹⁸ but many fear that this rationing may "cripple the research and development process and snuff out new treatments before they are even developed."¹⁹ On the other side of the arguments are the insureds who expect their insurers to be there when they need the coverage. Policyholders "don't buy a lottery ticket—[they buy] an insurance policy."²⁰ This matter is a delicate concern—it involves life and death decisions—and the issues involved have become rather muddled. The public's perception of the issues are disparate to those in the health care industry. The central issue often is not whether insurers are justified in

13. Perry C. Papantonis, Note, *Experimental Exclusions: Are Insurance Companies Really Protected?* 9 N.Y.L. SCH. J. HUM. RTS., 217 (1991).

14. Donald W. Light, *Life, Death, and the Insurance Company*, 330 NEW ENG. J. MED. 498 (1994).

15. Harris Meyer, *Reform Debate Skirts Issue of Costly New Technology*, 37 AM. MED. NEWS 1 (1994).

16. Findlay, *supra* note 10, at 80.

17. *Id.*

18. *Id.*

19. *Id.*

20. Mark Holoweiko, *Experimental Treatment: Can You Do the Right Thing Without Going Broke?*, 13 BUS. HEALTH 38 (1995).

refusing to cover experimental procedures when the contract clearly excludes them, but how the conclusion is made as to what is experimental, and who should actually make this determination.²¹

This Commentary examines the procedures surrounding the acceptance of experimental treatment—tracking a treatment's movement into the mainstream of medicine until it becomes considered conventional treatment, if ever. Specifically, it will explore how experimental treatment begins with a protocol and strives to reach the point at which it becomes a generally accepted medical procedure,²² or for some reason continues to maintain its "experimental" status. The Commentary will focus on considerations of the insurance industry as it works with companies in designing health care coverage,²³ and how the resulting policy often is achieved.

While exploring the decisional path of an exclusionary clause, judicial decision making is examined. Because courts are all too often dragged into this debate, a review of the judicial approach is necessary. Identifying defects in the current system, which cause obstacles to settlement, will be accomplished.

Finally, this Commentary will make recommendations regarding how to relieve the burden of these difficult decisions from the court,²⁴ and place them into the hands of people who might be better equipped to make them. Also, a proposal will be made regarding a more efficient approach to experimental treatment and its supporting research.

21. Mark Freedman, *When Insurers Refuse to Pay*. 93 BEST'S REV. - LIFE-HEALTH INS. EDITION 38 (1993).

22. This is the standard that many insurance companies and courts look to in deciding whether treatment has become conventional and should be covered.

23. While this Commentary will peripherally discuss other methods of coverage, the focus is primarily on employer sponsored coverage.

24. District Judge Tinder, in his Memorandum Entry of his Opinion in *Harris v. Mutual of Omaha Cos.*, No. IP 92-1089-C, 1992 WL 421489 (S.D. Ind. Aug. 26, 1992), provides an ideal indication of why judges should be relieved of this burden whenever possible:

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

Id. at *1.

II. THE HEALTH CARE INDUSTRY

“As in other areas of uncertainty, it is often desirable to transfer the financial consequences of loss to some person or group of persons.”²⁵ The usual procedure involves an insured (the person buying the contract) entering into an insurance arrangement with an insurer who assents, in return for the payment of a premium, to pay a fixed amount of money, or to pay expenses up to an amount stated in the contract, in the event an expense is incurred.²⁶

A. Health Care in the United States

The United States Constitution does not guarantee a right to health care, and there is no obligation on the part of the federal government to provide such care.²⁷ For financing health care, the United States has depended largely on employment-related group health insurance, supplemented by individual insurance policies for those who can afford them, and various federal, state, and local programs directed at specific populations. Therefore, health insurance is offered by private or government insurers.²⁸ More specifically, coverage exists²⁹ in private insurance policies,³⁰ employee welfare plans governed by the Employee Retirement In-

25. OSCAR N. SERBEIN, JR., *PAYING FOR MEDICAL CARE IN THE UNITED STATES* 75 (1953).

26. *Id.* Hence, “[i]nsurance has been defined as ‘that social device for making accumulations to meet uncertain losses of capital which is carried out through the transfer of the risks of many individuals to one person or to a group of persons.’” *Id.*

27. *See, e.g., Harris v. McRae*, 448 U.S. 297 (1980).

28. Medical care insurers may also be divided into organizations supplying services or closely associated with suppliers of service (e.g., Blue Cross, Blue Shield, group practice plans with an insurance feature), and organizations that are independent of the medical profession (i.e., commercial insurers engaged primarily in the sale of life, fire, or casualty insurance but also offer medical care insurance through separate contracts or riders on other insurance policies). Serbein, *supra* note 25, at 78.

29. The following are the most prominent means of providing health insurance. However, there exist many funds that supply coverage which will not necessarily be explored in this Commentary. For example, the Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) provides medical and dental benefits to dependents of present and former members of the military. *Smith v. Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)*, 97 F.3d 950 (7th Cir. 1996), *cert. dismissed*, 117 S. Ct. 1027 (1997). However, this Commentary does use the CHAMPUS fund as an excellent example of inconsistent judicial decisions.

30. In 1991, 178 million Americans were covered by some form of private health insurance, including Blue Cross-Blue Shield plans, commercial insurance, self-funded employer plans, or prepaid plans such as HMOs. During that same year, private health insurance paid out \$222.4 billion for health care, accounting for about one-third of national health expenditures. Private insurance paid for nearly 35% of hospital care and over 46% of

come Security Act of 1974 ("ERISA"),³¹ and under the Federal Medicare provisions of the Social Security Act.³²

Today's health care financing system evolved during the past century in response to various incentives and changing circumstances.³³ The factors that had the greatest influence on its development were changes in economic conditions, social trends, government policies, and advances in medical science.³⁴ As the country entered the twentieth century, issues of how to improve public health and extend the new benefits of medical science to all Americans became more important.³⁵ While Americans rejected a tax-financed national health care system, private insurance was not an immediate choice.

The historical dynamics of the health care system have resulted in massive inflation and gaps in coverage, arguably the dominant characteristics of American health care insurance today.³⁶ As health care costs rise, and defects in the system are uncovered, companies and unions continue to agree on insurance coverage for more routine health costs.³⁷ Government and business leaders are becoming alarmed as the cost of private insurance and government health programs balloons.³⁸

Soaring medical costs and gaps in coverage may be the most pressing problems triggered by perverse incentives in the system, [but] they are by no means the only problems in American health care. The design of the system also restricts its ability to take full advantage of the potential of some new technologies for delivering existing services in a more efficient and cost effective manner. At the same time, the system is ill-prepared to

physician services. Almost 96 million people were covered by group policies and nearly 10 million under individual or family policies. In 1990, 81% of employees had health insurance coverage, but only 42% of employers offered health insurance to its employees; many smaller businesses do not offer health insurance as a fringe benefit. HEALTH INSURANCE ASSOCIATION OF AMERICA, SOURCE BOOK OF HEALTH INS. DATA, 1991 & 1993.

31. 29 U.S.C. §§ 1001-1461 (1988).

32. 42 U.S.C. § 1395(y) (1988).

33. Edmund F. Haislmaier, *Why America's Health Care System Is In Trouble*, in A NATIONAL HEALTH SYSTEM FOR AMERICA 4 (Stuart M. Butler and Edmund F. Haislmaier eds., 1989).

34. *Id.*

35. *Id.* at 5.

36. LAURENE A. GRAIG, HEALTH OF NATIONS: AN INTERNATIONAL PERSPECTIVE ON U.S. HEALTH CARE REFORM 17 (1993). Some argue that the background to the health care problem involves medical education, diagnosis, hospitals, specialization, fees, and therapeutic agents. LOUIS HOPEWELL BAUER, PRIVATE ENTERPRISE OR GOVERNMENT IN MEDICINE 3-6 (1948).

37. GRAIG, *supra* note 36.

38. *Id.*

meet the challenge of financing the new demands and new services generated by other technologies.³⁹

It is within this environment that experimental treatment has become a troublesome niche.

B. *Defining Experimental and the Problems with Clinical Trials*

1. *Insurance Providers Determine What Is Experimental*

Insurers and employers routinely deny coverage for medical care deemed experimental, unproven, unnecessary, or inappropriate. Policy-makers in both public and private sectors increasingly find it difficult to determine when new medical services, procedures, and technologies cease to be experimental and become state of the art, and thus accepted.⁴⁰

Currently, thousands of self-insured employers, hundreds of insurers, and various federal and state programs make coverage decisions independently,⁴¹ relying on medical journals and assessments by groups of physicians and scientists, results of technology assessment programs,⁴² and reviews of individual cases by an in-house or outside panel of physicians.⁴³ Some insurers have formal technology review programs in which panels of experts review the medical literature and seek consensus,⁴⁴ while other carriers use a lone medical director to make the decisions. Another approach is a step-by-step process that enables a particular treatment to qualify.⁴⁵ Unfortunately, most of the above methods are used only by major carriers. The other 1,500 insurers and managed care organizations usually decide whether treatment for a particular case

39. Haislmaier, *supra* note 33, at 32.

40. Charles Culhane, *Fight Intensifying Over Paying for New Technology*, AM. MED. NEWS, Dec. 2, 1991, at 8.

41. Meyer, *supra* note 15, at 1. Because of antitrust concerns, each insurer or other third-party payer must make this determination on its own. Freedman, *supra* note 21, at 38.

42. For example, programs are conducted by the American Medical Association and by the HIAA. *Id.*

43. *Id.*

44. *Id.* For example, Aetna utilizes an independent panel of 130 medical experts in different specialties to review contested cases. Three physicians review each case and coverage is approved if at least one reviewer gives the "O.K." *Id.*

45. As a first step toward qualifying for coverage, the "Blues" require that a medical product or technology have final approval from appropriate regulatory bodies, such as the Food and Drug Administration. It also requires scientific evidence to show that the technology can help in diagnosing or effectively changing the health outcome of a disease or injury. Culhane, *supra* note 40, at 8.

should be denied as experimental and investigational based solely on the language of the insurance contract.⁴⁶ The result of the various approaches used is that while one insurer considers treatment experimental, and hence uncoverable, another insurer may allow for the treatment.

2. *How Experimental Becomes Standard: The Trials*⁴⁷

How and when an experimental procedure becomes standard treatment is often the crux of the debate over insurance coverage for any emerging medical treatment.⁴⁸ Therapies are evaluated in clinical trials in which there are three phases, classified according to research objectives and methodology.⁴⁹ The first phase, a Phase I study, starts with a new research treatment being given to a small number of patients.⁵⁰ This involves conducting experiments on animals, as well as humans, to determine whether the treatment can be tolerated, what the appropriate dosage should be, and what side effects may result.⁵¹ While this phase begins with experimentation on animals, it is continued on humans, usually males between the ages of eighteen and forty-five, with the disclaimer that there is no therapeutic intent.⁵² Patients are told this before the procedure is even considered on a human being.

The second phase,⁵³ clinical investigation,⁵⁴ determines if the disease in

46. Freedman, *supra* note 21, at 38. These smaller payers cannot afford to undertake extensive investigations. *Id.*

47. In cancer research, a clinical trial is a study conducted with cancer patients, usually to evaluate a new treatment. Each study is designed to answer scientific questions and to find new and better ways to help cancer patients. OFFICE OF CANCER COMMUNICATIONS, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, WHAT ARE CLINICAL TRIALS ALL ABOUT? 1 (1995). While clinical trials are utilized in research for many illnesses and diseases, the focus here will be on cancer trials.

48. Denise S. Wolf, Comment, *Who Should Pay For Experimental Treatments? Breast Cancer Patients v. Their Insurers*, 44 AM. U. L. REV. 2029, 2041 (1995).

49. Much of the information contained in this section of the article was obtained from an interview with John Cova, an insurance industry consultant. *See also* Smith v. Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), 97 F.3d 950, 953 n.3 (7th Cir. 1996), *cert. dismissed*, 117 S. Ct. 1027 (1997).

50. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 16.

51. Telephone Interview with John Cova, insurance industry consultant (Nov. 3, 1995). The research treatment is well tested in laboratory and animal studies without the knowledge of how patients will react. Phase I studies may involve significant risks for this reason. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 16. The aim of the study at this point is to determine: dosage; how the patient metabolizes the drug; what is the best route of administration (intravenously or orally or both); and, what side effects are involved.

52. Interview, *supra* note 51.

53. Phase II studies determine the effect of a research treatment on various types of

the human being responds to treatment.⁵⁵ Usually what is looked for is "shrinkage" or some other clinical criteria.⁵⁶ This phase can be divided into two phases with the latter phase emphasizing adverse side effects not apparent in earlier phases.⁵⁷ It usually involves a larger number of patients but is not necessarily a representative, cross-section of the disease patients.⁵⁸

The third phase⁵⁹ is the randomized trial phase⁶⁰ which ascertains whether the treatment is as good as or better than the existing conventional treatment.⁶¹ This is a randomized trial involving the experimental treatment and the conventional treatment, with the goal of safety and efficacy.⁶² The ultimate issue here is whether the median disease free survival time in the experimental group is superior to the control group.⁶³ These trials mark the last stage⁶⁴ of the clinical testing of a new treatment required before the Food and Drug Administration will license any drug for distribution.⁶⁵ Unfortunately, many clinical trials disregard this last phase if it is determined that phase two was a success.⁶⁶ This is unfortunate because it is possible that the results in phase two could statistically

cancer. Each new phase of a clinical trial depends on and builds on information from an earlier phase. If treatment has shown activity against cancer in Phase II, it moves to Phase III. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 16.

54. Comment, *supra* note 48, at 2041.

55. Interview, *supra* note 51. For example, in cancer trials, this phase determines if the drug has an effect on the cancerous tumor.

56. See, e.g., *Researchers Call for Renewed Efforts in the War on Cancer*, MED. & HEALTH, Nov. 7, 1994. A key weapon in the war against cancer is support for "translational" research into cancer therapies. This research is the stage at which basic science discoveries are first tested in humans to determine their safety and efficacy (generally pre-clinical Phase I and/or II trials). *Id.* at 44.

57. Comment, *supra* note 48, at 2042.

58. Interview, *supra* note 51.

59. In Phase III, the new treatment is directly compared with the standard treatment to see which is more effective. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 16, 17.

60. Interview, *supra* note 51.

61. *Id.*

62. *Id.*

63. *Id.*

64. In cancer trials, the study continues to Phase IV where the new research treatment becomes part of standard treatment in patient care. For example, a new drug that has been found effective in a clinical trial may then be used together with other effective drugs, or with surgery and/or radiation therapy. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 17.

65. *Perspective AIDS Vaccines: A Flickering Light at the Tunnel's End*, MED. & HEALTH, May 23, 1994, at 21.

66. Interview, *supra* note 51.

be insignificant, and thus inaccurate, if put to the randomized trial involved in phase three.⁶⁷ This concept is often misconstrued, especially by juries.⁶⁸

Currently, there are two basic routes through which randomized clinical cancer trials can be effectuated.⁶⁹ One is performed by the National Cancer Institute ("NCI"),⁷⁰ and the other is by a privately sponsored trial.⁷¹

The NCI trials involve multi-center, randomized clinical trials that occur all over the country.⁷² To participate, the person leading the prospective trial must submit a protocol to the NCI.⁷³ The protocol is reviewed anonymously by experts who determine whether the NCI should sponsor the trial.⁷⁴ When such a trial becomes NCI sponsored, the information gained from the trial becomes a public good in that anyone and everyone can benefit from the findings.⁷⁵ These trials are considered first rate; the experts who grant them are well recognized in their field.⁷⁶

Other trials are often considered "home grown," and frequently are not as cogent.⁷⁷ These trials essentially are as good as the internal review board ("IRB") that comments on the trial.⁷⁸ The IRB's duty is to formally comment on, and reach conclusions regarding, the ethics and legality of the trial. It also is tasked with determining the trial's scientific merit, although it is not obligated to.⁷⁹ Whether the privately sponsored

67. *Id.*

68. *Id.*

69. Again, this really pertains only to cancer trials.

70. A nationwide effort to conquer cancer intensified with the National Cancer Act of 1971. This created the National Cancer Program which brings together a network of researchers at many public and private institutions around the country. These include the National Cancer Institute, cancer centers, universities, community hospitals and private industry. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 19.

71. Interview, *supra* note 51.

72. *Id.*

73. *Id.* The doctors who conduct a clinical trial follow a carefully designed treatment plan called a "protocol." This spells out what will be done and why. Studies are planned to safeguard the medical and psychological health of patients as well as to answer research questions. OFFICE OF CANCER COMMUNICATIONS, *supra* note 47, at 17.

74. Interview, *supra* note 51.

75. *Id.*

76. *Id.*

77. *Id.* But see Christine Gorman, *Are Surgeons too Creative: New Operations Don't Face the Same Scrutiny as New Drugs*, TIME, Sept. 4, 1995, at 56. All hospitals have an institutional review board that examines a doctor's proposal for a new procedure and makes sure he or she publishes the results. *Id.*

78. *Id.*

79. *Id.*

trial is accurate and reliable is a difficult conclusion for insurers to make, especially when the NCI does not make any recommendations.

According to the 1971 Cancer Act, the NCI shall monitor the safety and efficacy of experiments.⁸⁰ The NCI, however, does not desire to be a regulator; this would entail it engaging in biomedical politics.⁸¹ Because the NCI's support primarily comes from oncologists (its largest contributors), it naturally does not want to alienate that support.⁸²

How then, are the research and the many trials to be sponsored? Funding the trials through employer-sponsored insurance policies is an option, but that is comparable to a hidden form of taxation as the research is funded via covering patient care costs, and higher premiums.⁸³ Some argue that trials should be funded through general funds regulated by the government.⁸⁴ The "home grown" promoters prefer the funding to come from employer-sponsored insurance because the trials then are subject to less vigorous peer review.⁸⁵ Also, such a method is a simple and more consistent source of funding. Trials that conclude that a treatment is 100% effective, however, are very expensive to cover, more so than the trials that do not reach that level of success. Therefore, it is logical to suspect that "home grown" trials often do not reach an optimum determination of safety and efficacy.⁸⁶

III. INCONSISTENCY AMONG THE COURTS

The executive and legislative branches have been very active in issues of health care coverage. The judiciary has not sat idly in observation either. Recognizing that insurance coverage is provided for by a contract—the insurance policy—the courts very often are used, and perhaps abused, to interpret these contracts.

The case law involving experimental exclusions is "remarkably inconsistent,"⁸⁷ with splits abounding among the circuit courts of appeal. In fact, contradictions exist even within circuits. The health care industry

80. *Id.*

81. *Id.*

82. See, e.g., Jonathan Gaw, *A Question of Control, Company Struggles to Get Health Insurers to Pay For Trials of Device that Helps Quadriplegics Use Their Hands Again*, THE PLAIN DEALER, Apr. 2, 1995, at 1H.

83. Dave Lenckus, *Fight*, BUS. INS., Aug. 14, 1995, at 40.

84. Interview, *supra* note 51.

85. *Id.*

86. *Id.*

87. Richard Saver, Note, *Reimbursing New Technologies: Why are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095 (1992).

has criticized the judiciary for ordering payment too often for experimental treatment.⁸⁸ One can question whether the courts should even be involved in such a sensitive area, or whether there is no option but to have the courts be major participants.

Experimental exclusion cases most often arise under contract or tort disputes. The litigation usually focuses on ambiguous terms in insurance policies that are capable of two or more reasonable interpretations.⁸⁹ Courts have developed several benchmarks to define experimental status,⁹⁰ and are struggling to apply consistent standards in assessing controversial technology.⁹¹ Still, different approaches are used by the judiciary when it decides whether benefits should be denied or provided. It is useful to examine these approaches to determine what steps the insurance industry can take to avoid these disputes.

When an insured/patient is seeking reimbursement from the insurer for an allegedly experimental treatment, there are basically three scenarios that can be encountered.⁹² The first is that the patient's insurance policy does not contain an exclusionary provision that expressly precludes coverage of "experimental" medical treatments. Second, the health insurance policy may contain both an exclusionary provision and a definition of what qualifies as an "experimental" medical treatment under that provision. The last scenario is one in which the insurance policy contains an exclusionary provision, but lacks a dispositive definition of the term "experimental."

When reviewing an experimental exclusion issue, courts first must look to the organization that is providing the coverage. Courts then determine the appropriate standard of review; this varies based upon whether the insurance coverage is offered by a self-insured, public, or private payer.⁹³ For example, the United States Supreme Court has held that a denial of benefits challenged under ERISA is to be reviewed under a *de novo* stan-

88. See, e.g., Franklin M. Zweig & Seymour Perry, *Health Care Goes to Court: Judges Need Access to Impartial Medical Expertise*, WASH. POST, July 17, 1990, (Health Magazine), at 26.

89. See, e.g., *Frederis v. Blue Cross Blue Shield of Mich.*, 873 F. Supp. 1153, 1156 (N.D. Ill. 1995).

90. Note, *supra* note 87, at 1106.

91. *Id.* at 1116.

92. Barbara A. Fisfis, Comment, *Who Should Rightfully Decide Whether a Medical Treatment Necessarily Incurred Should be Excluded From Coverage Under a Health Insurance Policy Provision which Excludes From Coverage "Experimental" Medical Treatments?*, 31 DUQ. L. REV. 777, 779 (1993).

93. See, e.g., *Wheeler v. Dynamic Engineering, Inc.*, 850 F. Supp. 459 (E.D. Va. Apr. 4, 1994).

dard, unless the benefit plan expressly grants the plan administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan.⁹⁴ The arbitrary and capricious standard of review is appropriate only where an ERISA administrator is given such discretionary authority.⁹⁵ Thus, the standard of review encompasses the standard that the appellate court utilizes when reviewing the lower court's decision,⁹⁶ as well as the standard that trial courts use regarding the appropriate measure with which to review the benefits under a specific plan.⁹⁷

The court then considers the language of the contract in conjunction with the questioned treatment.⁹⁸ Here, a determination is made with regard to who bears the burden of proving the insured's entitlement to the insurance coverage.⁹⁹ If the disputed provision of the insurance contract resides in the benefits section, as opposed to the exclusions section, then the insured bears the burden of establishing entitlement to the insurance benefits.¹⁰⁰

Courts also look to the language of the contract to determine whether the insurance contract between the parties requires coverage for a particular procedure.¹⁰¹ This involves determining whether the exclusionary

94. *Id.* at 464.

95. *Id.*

96. When the district court bases its determination of whether a medical procedure meets a contract's definition on facts presented and the opinions of experts, the question is one of fact and appellate courts will not reverse the findings unless they are found to be clearly erroneous. *Hendricks v. Central Reserve Life Ins. Co.*, 39 F.3d 507, 512 (4th Cir. 1994).

97. *See, e.g., Bailey v. Blue Cross & Blue Shield of Va.*, No. 94-2531, 1995 WL 596172 (4th Cir. Oct. 11, 1995). The Court of Appeals reviewed de novo the district court's grant of summary judgment, and reviewed Blue Cross's denial of benefits under the ERISA plan it administers. *Id.* at *1, 2.

98. *See, e.g., Heasley v. Belden & Blake Corp.*, 2 F.3d 1249 (3d Cir. 1993).

Different standards of review govern our consideration of the district court's ruling. The court's choice of the de novo standard and its definition of the term "experimental procedure" were mixed questions of law and fact, involving the application of legal precepts, . . . and the interpretation of contractual language to determine the parties' intent.

Id. at 1254 (citations omitted).

99. It is a basic rule of insurance law that the insured carries the burden of showing a covered loss has occurred and the insurer must prove facts that bring a loss within an exclusionary clause of the policy. *McGee v. Equicor-Equitable HCA Corp.*, 953 F.2d 1192, 1204 (10th Cir. 1992).

100. *Fuja v. Benefit Trust Life Ins. Co.*, 18 F.3d 1405, 1408 (7th Cir. 1994).

101. Under policies governed by ERISA, a summary plan description must be provided to participants and beneficiaries of the plan and must be written in a manner calculated to be understood by the average plan participant, and shall be sufficiently accurate and com-

clause is clear or ambiguous; if the clause is ambiguous, the insured prevails,¹⁰² if it is clear, the court then ascertains if it can be construed to exclude the experimental treatment.¹⁰³ At this point, the court has the difficult task of determining the correct definition of "experimental."¹⁰⁴ In any event, the case law can be examined by separating the two outcomes, policyholder prevailing or insurer prevailing. Of course, there are variables under both outcomes that entail what jurisdiction the case is filed, the type of policy that is being questioned, and who the provider is that is being sued.

Federal circuit court decisions regarding exclusionary language clauses virtually cover the spectrum of possibilities. Timely examples of conflicting approaches are *Smith v. Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)*,¹⁰⁵ and *Wilson v. Office of Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS)*.¹⁰⁶ These cases present very similar fact situations, involve the same health insurer with the same director, regulations, and policy manual, but achieve completely different results.

A. Insurer Prevails

In *Smith v. Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)*, the plaintiff, Smith, brought suit against CHAMPUS and William Perry, in his capacity as Secretary of the Defense, challenging their refusal to pay for certain procedures recommended by Smith's doctors.¹⁰⁷ These procedures were to treat Smith's breast cancer and involved high-dose chemotherapy ("HDC"),¹⁰⁸ cou-

prehensive to reasonably apprise such participants and beneficiaries of their rights and obligations under the plan. *Hendricks*, 39 F.3d at 511.

102. See, e.g., *Wolf v. Prudential Ins. Co. of America*, 50 F.3d 793, 799-80 (10th Cir. 1995).

103. See, e.g., *McGee*, 953 F.2d at 1202.

104. See, e.g., *Hendricks*, 39 F.3d at 511.

105. 97 F.3d 950 (7th Cir. 1996), *cert dismissed*, 117 S. Ct. 1027 (1997). In a footnote to the most recent release of the circuit court's opinion, it indicates that the original opinion was vacated and plaintiff's petition for a rehearing was granted. The court noted the conflict with *Wilson v. Office of Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS)*, 65 F.3d 361 (4th Cir. 1995). However, upon circulation of the court's original opinion to the full court, a majority of the judges voted not to rehear the case en banc. *Id.* at 950 n.1.

106. 65 F.3d 361 (4th Cir. 1995).

107. *Smith*, 97 F.3d at 951.

108. This procedure is carried out in several stages. In most cases conventional chemotherapy is used to see if the tumor is vulnerable to the cell-killing drugs. Next, stem cells are extracted and stored from the patient's bone marrow or circulating blood or both.

pled with peripheral stem cell rescue (“PSCR”).¹⁰⁹ The doctors informed Smith that her cancer had spread to her lymph nodes and that HDC with PSCR would provide her with the best chances of survival. Neither Smith’s doctors nor the hospital, however, would commence treatment until they received assurances that Smith had the means to pay for the costs.¹¹⁰

The oncology department at the hospital filed a claim with CHAMPUS,¹¹¹ on Smith’s behalf, that outlined the particulars of her case and made a request for pre-treatment determination as to whether the prescribed treatment would be covered.¹¹² The medical director of CHAMPUS, Dr. David Bogner, issued an initial determination that the HDC/PSCR would not be covered as per the terms of the policy, which does not provide coverage for treatments or procedures that are considered experimental or investigational.¹¹³ The director invited Smith’s doctors to support their position, that the treatment did meet the generally accepted standards, with documentation—such as well-designed, outcome-based studies that have been published in refereed medical journals.¹¹⁴

Smith’s attorney submitted a request for reconsideration along with affidavits of two of Smith’s oncologists along with a third who was familiar with Smith’s case.¹¹⁵ Each doctor maintained that HDC/PSCR was generally accepted in the medical community and was not considered experi-

Then, high doses of chemotherapy drugs are given over four or five days. Afterwards, the patient’s stem cells are reinfused so that blood cells can once again be manufactured. Peta Gillyatt, *Breast Cancer: Bone-Marrow Transplants*, HARVARD HEALTH LETTER, July 1, 1995.

109. *Smith*, 97 F.3d at 951.

110. *Id.*

111. This was different than how CHAMPUS usually covers its insureds. Traditionally, CHAMPUS beneficiaries generally receive medical care first and then submit a claim. CHAMPUS then makes an after-the-fact determination as to whether the medical care received was a covered service. Hence, the beneficiary is “at risk” in that the medical services may not qualify for payment under CHAMPUS. *Id.* at 952.

112. *Id.*

113. *Id.* The director explained that whether a treatment is experimental is determined by whether it meets the “generally accepted standards of usual professional medical practice in the general medical community.” This is determined by the evaluation of outcomes of clinical trials which have been published in the medical literature. Because of the absence of such clinical trials in the medical literature, the director concluded that HDC/PSCR did not yet meet the generally accepted standards in the general medical community for the treatment of breast cancer. *Id.* at 952-53.

114. *Id.* at 953.

115. *Id.*

mental for the treatment of breast cancer.¹¹⁶ However, Smith's attorney did not provide any clinical studies published in medical journals indicating general acceptance in the medical community.¹¹⁷ Accordingly, the director denied Smith's request for reconsideration, noting the failure to provide the requested medical literature upon which CHAMPUS could base a decision to provide coverage for the treatment.¹¹⁸ Smith subsequently filed suit.

The Court of Appeals for the Seventh Circuit, in reviewing CHAMPUS' appeal from the district court that found the denial of coverage was arbitrary and capricious, was presented with two issues in the case.¹¹⁹ The first issue was whether CHAMPUS properly interpreted its regulations, contained in 32 C.F.R. § 199.4(g)(15), as requiring publicized results of Phase III clinical trials in order to determine whether HDC/PSCR met accepted professional medical standards, and thus was no longer experimental.¹²⁰ Second, if the regulations were interpreted properly, the court examined whether CHAMPUS' decision to deny benefits to Smith was arbitrary and capricious.¹²¹ The court saw no basis in the record for concluding that CHAMPUS' decision was arbitrary and capricious,¹²² and found no rational basis for the district court to cast aside the Director's findings.¹²³ Accordingly, even though it was such a "sympathetic case," the Court of Appeals reversed the district court, ordering the denial of Smith's coverage.¹²⁴

B. Policyholder Prevails

Wilson v. Office of Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS) involves a similar fact pattern as *Smith*, but an opposite result. Gail Wilson was diagnosed with breast cancer, and her doctor recommended a series of treatments of HDC/PSCR to treat her condition.¹²⁵ Wilson was a beneficiary of CHAMPUS, which specifically provides coverage for chemotherapeutic agents and their adminis-

116. *Id.*

117. *Id.*

118. *Id.* at 953-54.

119. *Id.* at 954-957.

120. *Id.*

121. *Id.*

122. *Id.* at 961.

123. *Id.* at 957-961.

124. *Id.* at 161.

125. *Wilson v. Office of Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS)*, 65 F.3d 361 (4th Cir. 1995).

tration.¹²⁶ However, the CHAMPUS policy manual stated that autologous bone marrow transplants were covered for certain diseases under specific circumstances, although breast cancer was not listed as one such disease.¹²⁷

Dr. Bogner, the director of CHAMPUS, received and denied Wilson's request for coverage. Again, he stated that "in the absence of published randomized, prospective trials, CHAMPUS must continue to consider this therapy as investigational for the treatment of breast carcinoma."¹²⁸ Wilson's physician and the treatment's provider would not begin HDC/PSCR without an advance commitment from CHAMPUS to cover its cost. Wilson filed suit.

The United States District Court for the Eastern District of Virginia entered a judgment permanently enjoining CHAMPUS from denying Wilson coverage for the desired treatment.¹²⁹ The Court of Appeals for the Fourth Circuit reviewed the criteria CHAMPUS utilized in making such decisions involving coverage, specifically the clinical trials. The court recognized that such tests are important in determining the validity of medical treatments, and may be an important factor in determining whether a particular therapy meets the generally accepted standards of usual professional medical practice in the general medical community. It noted, however, that nothing in the Code of Federal Regulations or the CHAMPUS policy manual indicates that published, Phase III clinical trial results are required before a benefit can be provided.¹³⁰ Consequently, the court affirmed the decision that CHAMPUS's refusal to pay for Wilson's HDC/PSCR was arbitrary and capricious and not in accordance with the law. The permanent injunction prohibiting denial of coverage was enforced.

IV. RECONCILING THE "EXPERIMENTAL" ISSUE

It is clear that litigating the issue of nonreimbursement can result in inconsistent outcomes because the case law on experimental exclusions remains unsettled. Such inconsistency is caused by differences in contract language, varying postures of those involved in the litigation, and the spe-

126. *Id.* at 363.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.* at 365. The court also noted that in addition to overemphasizing the necessity of Phase III clinical trials, CHAMPUS ignored abundant evidence that HDC/PSCR is gaining widespread acceptance within the medical community. *Id.*

cific facts of each case.¹³¹ However, as seen in *Smith and Wilson*, courts do have standards with which to approach these cases. Because of the prevalence of exclusionary provisions that specifically exclude experimental medical treatments from their coverage terms, the courts have applied basic contract and insurance law principles. But when these definitions appear in the policy, the insured-patient still has a chance to obtain reimbursement if the court determines the insurer's definition is ambiguous.¹³²

Courts evaluate every case on an individual basis. But when a court cannot find at least the existence of confusing language in the insurance policy, the treatment will not be covered. This can play very hard on the minds of judges, and it is for this reason, among others, that a more suitable approach should be considered in not only resolving these cases, but avoiding them altogether.

A. Dynamics to Consider Before Making Recommendations

In a perfect world, insured-patients would be entitled to all known medical treatments to control whatever disease or sickness from which they suffer.¹³³ But in a perfect world, there also would be no disease or sickness that needs treating. Because many Americans suffer from a myriad of sicknesses and diseases¹³⁴—AIDS,¹³⁵ Parkinson's disease,¹³⁶ emphysema,¹³⁷ numerous forms of cancer (including, *inter alia*, leukemia,¹³⁸ brain cancer,¹³⁹ skin cancer,¹⁴⁰ lung cancer,¹⁴¹ and breast cancer),¹⁴² ath-

131. Note, *supra* note 87, at 1106.

132. See, e.g., *Nationwide Mutual Ins. Co. v. United States Fidelity and Guaranty Co.*, 529 F. Supp. 194 (E.D. Pa. 1981). A provision of an insurance contract is ambiguous if reasonably intelligent individuals, on considering it in the context of the entire policy, would honestly differ as to its meaning, and if alternative or more precise language would have put the meaning of the language beyond a reasonable question. *Id.* at 197.

133. *Harris*, 1992 WL 421489 *1.

134. At the risk of sounding morbid, the following provides an indication of how broad the issue of experimental treatment has reached.

135. *Florence Nightingale Nursing Serv., Inc. v. Blue Cross/Blue Shield of Ala.*, 41 F.3d 1476 (11th Cir. 1995).

136. *Gorman*, *supra* note 77, at 56.

137. *Id.*

138. *Dexter v. Kirschner*, 972 F.2d 1113 (9th Cir. 1992).

139. Michael A. Hiltzik, *When Care is Denied*, L. A. TIMES, Aug. 27, 1995, (Home Edition), at A16.

140. *Farley v. Benefit Trust Life Ins. Co.*, 979 F.2d 653 (8th Cir. 1992).

141. *Hendricks*, 39 F.3d 507.

142. *Wolf*, 50 F.3d 793.

erosclerosis,¹⁴³ obesity,¹⁴⁴ short-bowel syndrome¹⁴⁵—there are a variety of treatments being discovered and tested every day.

Along with the discovery of new treatments comes heated controversy as insurers attempt to distinguish between experimental and standard medical treatments,¹⁴⁶ consumers pressure for the acceptance of new treatments as standard procedures,¹⁴⁷ and physicians just try to treat their patients. Because the realization of new technology can no longer be supported through health-care coverage,¹⁴⁸ much of the controversy gets settled through litigation. The logical inquiry that follows from these realities involves what can be done to avoid such litigation. The answer should be easy: make the language of coverage exclusions for experimental treatments clear,¹⁴⁹ and establish guidelines and procedures by which proposed treatments can become accepted. In this way, insureds will know how and when they will be covered, doctors will know exactly when their procedure has become conventional, and insurers can keep the costs of insurance reasonable. This is, however, much easier said than done.

An awareness of how courts settle these disputes can shed light on how to avoid such problems. Courts apply general insurance law and contract principles in experimental exclusion cases.¹⁵⁰ A court observes the coverage language, and considers only whether the disputed medical treatment falls within the scope of the insurer's definition of precluded experimental procedures.¹⁵¹ Keeping in mind the general rule that when a health insurance policy expressly precludes coverage of experimental medical treatments and defines what types of treatments qualify as experimental,¹⁵² a court will not inject into its analysis of the case its own opinion of what is experimental.¹⁵³ One of two results should occur. If the treatment qualifies as experimental, then the court will find for the insurer and

143. *Friedrich v. Secretary of Health and Human Serv.*, 894 F.2d 829 (6th Cir. 1989).

144. *Exbom v. Central States*, 900 F.2d 1138 (7th Cir. 1990).

145. *Miller v. Whitburn*, 10 F.3d 1315 (7th Cir. 1993).

146. Matthew P. Schwartz, *Experimental Debate is Intensifying*, NAT'L UNDERWRITER LIFE & HEALTH, Apr. 24, 1995.

147. *Id.*

148. Gina Kolata, *When Doctors Say Yes and Insurers No*, 69 MED. ECON. 87 (1992).

149. Charles J. Steele, *Plans: Make Language of Coverage Exclusions for Experimental Treatments Clear*, 4 MANAGED CARE OUTLOOK 12 (1992).

150. Jennifer Belk, Comment, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Reform*, 66 WASH. L. REV. 809, 812 (1991).

151. Comment, *supra* note 92, at 780.

152. See *Zuckerberg v. Blue Cross and Blue Shield of Greater N.Y.*, 108 A.2d 56 (S.D. N.Y. 1985).

153. Comment, *supra* note 92, at 780.

deny the insured/patient's claim for damages.¹⁵⁴ Conversely, if the treatment does not qualify under the policy's definition as being experimental, then the insured-patient's claim will prevail and the insurer will have to pay for or reimburse the insured/patient for the medical expenses.¹⁵⁵

Most often, the disputed language in an experimental exclusion is unclear. When contract ambiguities exist, courts construe the equivocal language against the insurer.¹⁵⁶ "The court generally has to err on the side of coverage because it's the insurance company that writes the policy, chooses the words, and markets the coverage."¹⁵⁷ This approach exists because insurers have more control over contract provisions and greater bargaining power than insureds.¹⁵⁸ Also, this approach attempts to force insurers to disclose all relevant information so that insureds can fully understand the contract terms.¹⁵⁹ Only fully informed insureds can make rational purchases with regard to the extent of their coverage. Along these lines, coverage clauses are interpreted broadly while exclusion clauses are construed narrowly.¹⁶⁰

Experimental exclusions are drafted inadequately by insurers even with the threat of a contract being construed against them. Many believe that insurers are using the experimental label more often as an excuse to avoid paying for accepted treatments.¹⁶¹ This argument may be valid when insurers use undefined exclusions—then opportunities for insurer manipulation can arise.¹⁶² Undefined exclusions create uncertainty about coverage because no agreement on what constitutes experimental treatment exists. This uncertainty about an insurer's willingness to pay medical bills may influence the patient's or physician's decision about whether to seek treatment.¹⁶³ The threat of litigation often acts as an effective deterrent to enforce a possible legitimate use of health care resources.

Given the expense of some experimental treatments, there is a financial interest that complements insurer's decisions to categorize treatments

154. *Id.*

155. *Id.*

156. Comment, *supra* note 150, at 815.

157. Holoweiko, *supra* note 20, at 41.

158. R. Keeton, INSURANCE LAW BASIC TEXT § 6.3(a) (1971).

159. Comment, *supra* note 150, at 815.

160. *McLaughlin v. Connecticut Gen. Life Ins. Co.*, 565 F. Supp. 434, 440 (N.D. Cal. 1983). "Exclusion clauses had better exclude everything because, by definition, anything that's not excluded is included." Holoweiko, *supra* note 20, at 41.

161. Findlay, *supra* note 10, at 80.

162. Comment, *supra* note 150, at 821.

163. Grumet, *Health Care Rationing Through Inconvenience*, 321 NEW ENG. J. MED. 607 (1989).

as experimental.¹⁶⁴ There is no doubt that many of the questioned treatments are very expensive;¹⁶⁵ health insurers are having difficulty keeping up with the coverage requests. There are fewer and fewer health care dollars to spend each year and more and more to spend them on; insurers can no longer afford to support the diffusion of new technology through health care.¹⁶⁶

Even with the legitimate claim that treatment costs are rising, technology assessment is an area that can be manipulated quite easily. What is experimental to one person, is standard treatment to another.¹⁶⁷ Inconsistencies that exist from one insurer to the next regarding what is covered creates added uncertainty,¹⁶⁸ as does inharmonious coverage for treatment of one disease and not a different disease calling for the same treatment.¹⁶⁹ Adding to the inconsistencies is the fact that many procedures are not studied rigorously.¹⁷⁰ In fact, within the three phase clinical trial procedure, the third phase might be skipped when positive results are realized on the second phase.¹⁷¹ It can be reasoned that change would be good for this area of the law.

Because much of the uncertainty in insurance reimbursement litigation is due to the fact that the judiciary is being forced to make decisions in an area in which it is, arguably, unqualified,¹⁷² the question of what can be done to end the chaos that faces the insurer and the insured/patient remains.¹⁷³ What exists certainly is chaotic, "you can't imagine what it's like to go through one of these coverage battles."¹⁷⁴

164. Comment, *supra* note 150, at 821.

165. See, e.g., *Dexter*, 972 F.2d at 1114. The average cost of an allogenic bone marrow transplant at the University Medical Center in Tucson, Arizona is \$170,000. *Id.*

166. Kolata, *supra* note 148, at 88.

167. Holoweiko, *supra* note 20, at 41.

168. Findlay, *supra* note 10, at 81.

169. Most Blues plans cover large dose chemotherapy treatment when it is used against advanced leukemia or lymph-system cancer, but not for breast cancer. Findlay, *supra* note 10, at 81.

170. See Faltermayer, *Medical Care's Next Revolution*, FORTUNE, Oct. 10, 1988, at 126.

171. See *supra* note 58.

172. The judiciary has little medical background but is making medical decisions which unquestionably have life and death consequences. Comment, *supra* note 92, at 782

173. Reconciling the apparent conflict between payers and providers is becoming increasingly difficult. Charles Culhane, *Fight Intensifying Over Paying for New Technology*, AM. MED. NEWS, Dec. 2, 1991, at 8.

174. Richard A. Knox, *Expensive New Treatments Cause Dispute With Insurers*, THE BOSTON GLOBE, Feb. 22, 1994, at 13.

B. Relieve Tensions Between Insurers and Insureds

Insurance companies do not want to pay for experimental treatments or therapies that are not proven to be safe and effective.¹⁷⁵ Heartless greed most often is not the motivating factor for the denial of coverage. Some insurance companies even fault doctors and hospitals by claiming they are too eager to profit in various ways by prematurely pushing new technologies. Clearly, the ultimate goal for all involved is to produce treatment that will cure. After achieving this goal, hopefully the doctors' and insurers' goals of profiting financially while providing quality treatment can be realized as well. The first step is to understand the commonality of purpose that exists among all those involved in an attempt to work together to solve the problem.

C. Improve Funding

The process by which experiments become conventional must be revised. The current state of NCI sponsorship, private sponsorship, and trial and error through insurance company funding is not adequate. This method of research is the root of the whole problem, as this is where the largest amounts of money are needed. It also is where the most important decisions are made, especially with regard to what protocols are chosen to be funded to go through the trial process.

One proposal has emerged that would empower a national board to decide not only what gets covered, but what treatment receives funding in an attempt to realize its effectiveness. This board would inject consistency, fairness, and coherence into the funding process. The goal here would be to achieve reliability on a greater scale than currently exists.

Because of the many different trial processes a protocol can be placed into, it is not uncommon for there to be varying standards as to what is considered safe and effective. The current standard primarily involves publication and peer review. While this provides an adequate forum for criticism and suggestion, there is no real enforcement behind it. The fact that an experimental treatment is examined by others in the medical field does not necessarily prevent the initiator from proceeding with its administration despite harsh criticism from his "peers." While this lack of enforcement would be resolved in the courts eventually, it should never have to get that far.

With the organization and empowerment of a national board to mea-

175. David S. Hilzenrath, *Insurers "Arbitrary" on Breast Treatments*, WASH. POST, Feb. 17, 1994, at A1.

sure objectively the safety and efficacy of a treatment, and further decide on the funding of its research without bias, a greater, more reliable level of care could be provided. Also, a more efficient process could be developed to decrease the lag time that currently is inevitable as technology gains acceptance in the medical community. By decreasing the procedural hurdles a new treatment must jump over to get funding, a quicker determination can be made of what experimental procedure is valid and what treatment is not worthy of further research. This in turn would conserve the limited research funds for only those treatments that have a genuine likelihood of success when put to the test.

D. Remove Judicial Subjectivity From the Process

Currently, judicial review occupies the primary role of resolving reimbursement litigation. It is inevitable, even with the most consistent and equitable procedures, that cases will arise regarding reimbursement and the unfairness of a particular exclusionary clause. While it would be most ideal to relieve the burdens of these decisions from the judicial system completely, it is unrealistic that this would ever happen. Therefore, objective criteria should be developed, standard in all jurisdictions, by which to measure an exclusionary clause.

First, if there is no exclusionary clause, then the insurer automatically should lose. It is troubling to think that an insurance company could impose its own subjective interpretation of the insurance contract, where there exists legitimate confusion or absence of a clause, on an insured with, most likely, limited resources with which to enforce the contract. Hence, without any definition as to what is experimental, or without any such clause, the contract should be read in favor of the insured-patient.

Where there does exist a definition of the term "experimental," the use of independent medical experts by the court would enable the most objective decisions regarding the questioned clause to prevail. While this method imposes a burden on the adversary process by infringing on counsel's ability to present and argue the case as he sees fit, it is an acceptable casualty. This objectivity would allow some of the burden to be relieved from judges and placed into the hands of those who are better suited to evaluate issues like this.

V. CONCLUSION

General insurance law and contract principles require insurers to define fully their coverage exclusions, especially those for experimental

treatment. The process of defining and interpreting these exclusions, however, is a long and arduous one. It begins with an idea that progresses into a clinical trial with continuous research. This trial is then used to treat patients who desperately need the treatment. Finally, when the trial is discovered by a patient or doctor, an attempt to apply it to an insurance policy occurs; then the policy's coverage is litigated. While this is what numerous exclusionary clauses go through, it should not be the case.

Litigation involving who should pay for experimental treatment usually turns on judicial interpretation of policy language. However, the judiciary, while an institution designed to resolve disputes, has not been entirely able to harmonize its decisions regarding experimental treatment. This can and does create uncertainty about what treatments will eventually be covered, if at all. This uncertainty can foster adversarial relationships between insurers and physicians, hospitals and insureds. Thus, it is evident that a mechanism by which treatments can be definitively considered experimental, or medically accepted, should be established to provide assurance to health care providers and insureds. This would be the goal of a national board comprised of neutral examiners.

It is important to emphasize that an attempt should be made to avoid litigation. A national board, while not removing decisions from the judiciary when lawsuits do occur, should strive to decrease litigation, and when necessary, provide a framework for judges to decide what is experimental and what is conventional. Along these lines, objective criteria would need to be established by which insurers, health care providers, insureds, and judges could ascertain the "acceptance level" of certain treatments. The aspiration of neutral examiners would be to improve efficiency and accuracy by encouraging the use of clear, specific, identifiable language. Thus, striving for safety and efficacy should be an exclusionary clause's goal, not litigation.

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