

DOES MY HEALTH INSURANCE COVER IT? USING EVIDENCE-BASED MEDICINE AND BINDING ARBITRATION TECHNIQUES TO DETERMINE WHAT THERAPIES FALL UNDER EXPERIMENTAL EXCLUSION CLAUSES IN HEALTH INSURANCE CONTRACTS

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I. INTRODUCTION

The advent of new medical procedures that benefit society by increasing the length and quality of life also generates an escalation in the cost of health care. The soaring costs that accompany these high-technology procedures are forcing society to decide whether and how to pay for all of these new medical procedures.¹

Under our country’s current health system, in which most insurance comes from either employer-sponsored health plans² or the government in the form of Medicare and Medicaid,³ a significant portion of the burden to

1. See Michael J. Malinowski, *Capitation, Advances in Medical Technology, and the Advent of a New Era in Medical Ethics*, 22 AM. J.L. & MED. 331, 341–47 (1996) (discussing how advances in medical technology and their uses partially account for the rising costs of medicine).

2. Sherry A. Glied & Phyllis C. Borzi, *The Current State of Employment-Based Health Coverage*, 32 J.L. MED. & ETHICS 404, 405 (2004) (stating that 64.2% of Americans had employer-based health coverage in 2002). Moreover, over 80% of privately-insured persons acquire health insurance through their employers. *Id.*; see also Julie Rovner, *The Health Care System Evolves*, 348 LANCET 1001, 1001 (1996) (noting that “a majority of Americans—though the percentage is shrinking all the time—receive health insurance coverage through their employers”).

3. In 2002, Medicare covered an estimated 40.6 million Americans while Medicaid covered 39.9 million Americans. U.S. DEP’T OF HEALTH & HUMAN SERVS., 2003 CMS STATISTICS 1 (2003), <http://new.cms.hhs.gov/MedicareMedicaidStatSupp/downloads/03CMSstats.pdf>. Medicare is the single largest health insurance program.

make these decisions falls on private insurance companies. Insurance companies, faced with the financial burden associated with these high-technology procedures, are “in the unenviable position of deciding which medical procedures they will cover and which procedures will fall outside the coverage of their policies.”⁴

The problem of substantial increases in the cost of health care caused by new medical procedures and technologies has been exacerbated by the rise in expectations regarding patient outcomes, which is also created by advances in medicine.⁵ Patients and their loved ones, particularly those affected by life-threatening conditions, expect everything possible to be done to save their lives. Aware of the plethora of cutting-edge therapies that are constantly being discovered, patients and their families want to try any treatment, even if it may still be experimental.⁶

Almost all health insurance policies attempt to control costs in the face of rising patient expectations and ever-changing technology by explicitly excluding coverage of “experimental therapy.”⁷ Although the presence of exclusion clauses may be standard, the policies fail to clearly define what therapies are considered experimental and, thus, not covered.⁸

Medicare.gov, Medicare Eligibility Tool, <http://www.medicare.gov/MedicareEligibility/home.asp> (last visited Feb. 14, 2006).

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

5. See Steven I. Friedland, *The Health Care Proxy and the Narrative of Death*, 10 J.L. & HEALTH 95, 98 (1995–1996) (noting that although medical advances have increased life expectancies, these advances have fueled unrealistic patient expectations).

6. See *id.* at 108–11 (discussing how Americans use the advancements in modern medicine to prolong life at all costs).

7. See Jennifer Belk, Comment, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 WASH. L. REV. 809, 812 (1991) (explaining that experimental therapies are excluded in most health insurance policies); William T. McGivney, Letter to the Editor, *Making Hard Decisions*, N.Y. TIMES, Apr. 5, 1994, at A20. McGivney writes about one insurance company’s efforts to balance costs and patient demands through the use of such clauses:

Aetna Health Plans, for example, has established a prototype process that maintains the balance between the needs of dying patients and assuring the efficiency of the health care system. The foundation of the process is an independent panel of 130 expert physicians who are asked to review questionable requests for coverage

Id.

8. Belk, *supra* note 7, at 813–14; see also *infra* Part II.C (describing different

This ambiguity has produced substantial conflict between health insurers and policyholders.⁹ Almost everyone knows, or knows of, someone who has sought treatment, been denied, and fought to obtain coverage.¹⁰ Further, this conflict has led to extensive litigation between health insurers and policyholders.¹¹ Litigation, however, has not proved to be a particularly effective means of resolving these conflicts in a manner beneficial to either insurers or policyholders, as courts are ill-equipped to resolve these issues.¹²

This Article proposes a new, more effective way to resolve this conflict through the use of evidence-based medicine techniques and binding arbitration. It describes a novel method to remove the ambiguity surrounding health insurance coverage by determining what is not included because of experimental therapy exclusion clauses without significantly altering the entire health care system.

In Part II, this Article documents the rise of health care costs attributable to new medical procedures. It then discusses the purpose of the experimental exclusion clauses and how these clauses have been

methods of attempting to define which treatments fall under experimental exclusion clauses and, therefore, are not covered by the health insurance policy).

9. See Belk, *supra* note 7, at 810 (indicating that the lack of definitions in insurance policies allows providers to “apply experimental treatment exclusions to inappropriately deny coverage” to insureds that are expecting coverage for their treatments).

10. See, e.g., Robert V. Russo, Letter to the Editor, *I’ll Have to Sell the House to Pay for Treatment*, N.Y. TIMES, Apr. 5, 1994, at A20. In his letter, Russo writes of his emotional fight:

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

Unless the case is settled soon in our favor, I will be forced to sell my house, borrow from friends and relatives, and mortgage my children’s future. Blue Cross’s position has created a huge financial, emotional and physical burden for my wife, my family and me. I have no sympathy for insurance companies that play these life-threatening games with policyholders.

Id.

11. See cases cited *infra* note 60 (listing examples of various lawsuits and the range of different outcomes reached by courts).

12. See, e.g., Harris v. Mut. of Omaha Cos., 992 F.2d 706, 713 n.4 (7th Cir. 1993) (noting the courts that have wrestled with interpreting exclusion clauses regarding bone marrow transplants for breast cancer patients have reached different outcomes).

interpreted by courts. Part III examines the problems for patients, insurers, and the courts in interpreting contracts under the current system. In particular, it looks at the effect of the *Aetna Health Inc. v. Davila*¹³ decision on experimental exclusion litigation and the problems it creates for policyholders seeking recourse for unfavorable policy coverage decisions. Part IV explores the use of evidence-based medicine techniques to interpret what is and is not covered by health insurance policies. It offers a recommendation for a uniform, industry-wide definition of “experimental” and explores the advantages and limitations of that definition. Part IV concludes with the development of a binding arbitration process for appealing treatment coverage decisions that will remove industry conflicts of interest, reduce future litigation, and address the problems created in light of the *Davila* decision.

II. WHAT ARE EXPERIMENTAL EXCLUSIONS?

A. *The Growth of Health Care Technology and the Corresponding Rise in Health Care Costs*

At the dawn of the twenty-first century, humans possess an unprecedented ability to increase the length and quality of their lives. It is now possible to prevent, cure, or, at the very least, treat many illnesses that were previously terminal; this capacity to treat the seriously ill is a consequence of the explosion in society’s knowledge of the health sciences that occurred in the late twentieth century.¹⁴ Scientists discovered a vaccine for polio, gained a better understanding of how to prevent and treat heart disease and many cancers, and developed organ transplantation techniques.¹⁵

As alluded to previously, these advances did not come without costs. Often today the question is not, “Is it possible?” Instead, people are asking, “Can I afford it?” or, “Does my insurance cover it?”¹⁶ Spending on

13. *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004).

14. *See* *Am. Dental Ass’n v. Martin*, 984 F.2d 823, 833 (7th Cir. 1993) (Coffey, J., concurring in part and dissenting in part) (noting that there have been dramatic, unforeseeable “advancements in the field of medical technology, such as heart catheterization and angioplasty procedures, heart bypass surgery, organ transplants, microscopic surgery, and the developments in nuclear medicine among others”).

15. *See id.*; *see also* Elizabeth M. Anderson, *Foreword: Bioethics at the Beginning, Middle, and End of Life*, 17 NOTRE DAME J.L. ETHICS & PUB. POL’Y 1, 1 (2003) (providing a general comment on the advancements in medical technology).

16. The question as to whether insurance covers various types of treatment is often highly controversial and leads to extensive litigation. *See supra* notes 7–12 and

health care now accounts for 14.1% of the total economy, or \$1.4 trillion.¹⁷ If medical costs continue to rise at a rate of 18% a year, health care costs might consume all of the gross national product by 2050.¹⁸

This dichotomy is particularly apparent in the area of organ transplantation. The first bone marrow transplant with long-term survival occurred in 1960, the first heart transplant was performed in 1966, and in July 2001, doctors made yet another advance in the field of organ transplantation when a team of surgeons in Kentucky implanted the first

accompanying text. Further, these questions are excruciatingly difficult for the judicial system. As Judge Barry stated in *Rollo v. Blue Cross/Blue Shield*:

I was called upon to decide whether eight year old Tishna Rollo could live or whether she must die, a humbling and sobering decision. Tishna, I was told, had virtually no chance of surviving the relapsed Wilms' tumor [of the kidney] from which she is suffering and Blue Cross/Blue Shield had denied coverage for autologous bone marrow transplant ("ABMT") with accompanying high dose chemotherapy, a treatment which could well prolong and quite possibly save her life and which, concededly, provided her only realistic hope of either. The University of Nebraska Medical Center . . . would not admit her without coverage, her parents could not afford to pay the projected \$130,000–\$140,000 costs of the treatment, and there was simply no time to wait, for Tishna's "window of opportunity" would soon close. The coverage issue had to be litigated, and litigated quickly.

Rollo v. Blue Cross/Blue Shield, No. 90-597, 1990 WL 312647, at *1 (D.N.J. Mar. 22, 1990). Accordingly, the importance of finding a process for evaluating whether the insurance covers the treatment that is consistent, informed, and eases the burden on the already congested courts cannot be understated.

Another extremely significant question that should be asked along with, "Is it possible?" is, "Should we do it?" Asking this type of bioethics question is critical and its importance cannot be underestimated if we are "to ensure that medical advancements are not made in an unethical or immoral manner." Anderson, *supra* note 15, at 3. However, discussion of the ethics surrounding various medical advancements lies beyond the scope of this Article. For a thorough discussion of this topic, see *Symposium on Bioethics*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 1 (2003).

17. Robert Pear, *Spending on Health Care Increased Sharply in 2001*, N.Y. TIMES, Jan. 8, 2003, at A12. Total spending on health care equates to an average cost of \$5,035 per person in the United States. *Id.*

18. Stuart A. Brock, *Redefining the "Experimental or Investigational" Exclusion: A Guide for ERISA Health Plans*, 24 N.C. CENT. L.J. 24, 24 (2001) (footnote omitted). In fact, the government recently announced that total health spending will double in the next decade to \$3.6 trillion in 2014, up from \$1.8 trillion in 2004. Robert Pear, *Health Costs Will Keep Rising, U.S. Says, Along With Government Share of Paying Them*, N.Y. TIMES, Feb. 24, 2005, at A20. That amount will constitute 18.7% of the total United States economy. *Id.*

permanent replacement artificial heart.¹⁹ Today, physicians are now able to perform bone marrow transplants that do not require a separate donor; rather, patients are re-infused with their own marrow after receiving therapy.²⁰

At the same time, however, the costs of transplantation are significant. In 2003, half of the ten most expensive hospital procedures were organ transplants.²¹ The most expensive medical procedure in the United States that year was a heart transplant, which had an average cost of \$341,753.²² The aggregate cost of all heart transplants totaled \$702,780,614.²³ As indicated in Table 1, the cost of all organ transplants²⁴ in

19. See Will Morton, *For the Sake of a Cure*, June 1997, <http://www.washington.edu/alumni/columns/june97/cure1.html> (observing the first bone marrow transplant which took place at the University of Washington); NAT'L HEART, LUNG, AND BLOOD INST., NAT'L INST. OF HEALTH, 50 YEARS OF PROGRESS IN HEART, LUNG, AND BLOOD RESEARCH: NHLBI CELEBRATES ITS GOLDEN ANNIVERSARY, HEARTMEMO 1, 13 (Fall 1997), http://www.nhlbi.nih.gov/health/prof/heart/other/hm_fa97.pdf (noting the first successful heart transplant); Guy Gugliotta, *In Ky., a First for Artificial Hearts*, WASH. POST, July 4, 2001, at A1 (discussing the operation giving a patient the first artificial replacement heart).

20. See Papantonis, *supra* note 4, at 219–20 (describing the use of this procedure during chemotherapy treatment).

21. HCUPNET, 2003 National Statistics: Rank Order of Diagnosis Related Group by Charges, \$ (mean), <http://hcup.ahrq.gov/HcupNet.asp> (follow “National and Regional Statistics from the NIS” hyperlink; then follow “Lay person, data novice” hyperlink; then follow “Rank order specific diagnosis/conditions and surgeries/procedures” hyperlink; then follow “2003” hyperlink; then follow “Diagnosis Related Groups (DRGs)?” hyperlink; then follow “All” hyperlink; then follow “By hospital charges (dollars), mean” hyperlink; then follow “All patients in all hospitals” hyperlink) [hereinafter *Order of Diagnosis Related Group by Charges*].

22. *Id.*

23. HCUPNET, 2003 National Statistics: Rank Order of Diagnosis Related Group by Aggregate Charges, \$ (the “National Bill”), <http://hcup.ahrq.gov/HcupNet.asp> (follow “National and Regional Statistics from the NIS” hyperlink; then follow “Lay person, data novice” hyperlink; then follow “Rank order specific diagnosis/conditions and surgeries/procedures” hyperlink; then follow “2003” hyperlink; then follow “Diagnosis Related Groups (DRGs)?” hyperlink; then follow “All” hyperlink; then follow “By ‘national bill’ (aggregate charges)” hyperlink; then follow “All patients in all hospitals” hyperlink) [hereinafter *Order of Diagnosis Related Group by Aggregate Charges*]. These statistics are based upon ranking medical procedures according to their diagnostic-related group (DRG) and their average cost nationwide. For the average cost of transplants other than heart transplants, see Table 1.

24. “All organ transplants” refers to all transplants listed by HCUPnet. The transplant procedures listed are bone marrow, heart, kidney, liver, lung, simultaneous kidney/pancreas, pancreas, and corneal. *Order of Diagnosis related Group by*

the United States was a staggering \$6,123,951,015.²⁵

TABLE 1
Costs of Organ Transplantation

Type of Transplant	Mean Charge per Patient in Dollars ²⁶	Aggregate National Bill in Dollars ²⁷
Heart transplant	341,753	702,780,614
Liver transplant	271,121	1,365,106,281
Lung transplant	256,288	323,247,199
Bone marrow transplant	205,529	2,184,899,663
Simultaneous pancreas/kidney transplant	191,557	153,407,822
Pancreas transplant	105,270	28,668,728
Kidney transplant	104,808	1,356,249,571
Corneal transplant ²⁸	20,871	9,591,137
Total	—	6,124,237,763

Aggregate Charges, *supra* note 23; HCUPNET, 2003 *National Statistics: Principal Procedure Outcomes for Corneal Transplant*, <http://hcup.ahrq.gov/HcupNet.asp> (follow “National and Regional Statistics from the NIS” hyperlink; then follow “Lay person, data novice” hyperlink; then follow “Information on specific diagnosis/conditions and surgeries/procedures” hyperlink; then follow “2003” hyperlink; then follow “Procedures/surgeries” hyperlink; then select “Corneal transplant (transplanting the clear coating over pupil)” and click “Next”; then check both “Hospital charges (dollars) mean” and “The ‘national bill’ (aggregate charges)” and click “Next”; then check “All patients in all hospitals” and click “Next”) [hereinafter *Principal Procedure Outcomes for Corneal Transplant*]. This list, however, may not be exhaustive. For example, it does not include ovary transplants, which are still being developed.

25. See *Order of Diagnosis Related Group by Aggregate Charges*, *supra* note 23.

26. All of the information in this column, with the exception of corneal transplants, is taken from *Order of Diagnosis Related Group by Charges*, *supra* note 21.

27. All of the information in this column, with the exception of corneal transplants, is taken from *Order of Diagnosis Related Group by Aggregate Charges*, *supra* note 23.

28. The corneal transplant information was obtained from *Principal Procedure Outcomes for Corneal Transplant*, *supra* note 24.

B. Definition and Purpose of Experimental Exclusions

Experimental exclusions are contractual clauses in private health insurance policies that remove from plan coverage any therapies that are considered experimental or “investigational.”²⁹ The purpose of this type of clause is to attempt to resolve the conflict between the increasing expectations of patient outcomes and the limited resources of private insurers.³⁰

The cost of quenching the insatiable demand for new procedures and technology is reflected in the amount charged in premiums.³¹ Insurers argue that experimental exclusion clauses are necessary “to avoid paying for unproven, fraudulent, or useless treatments” that needlessly drive up premiums.³² They also assert that the clauses are necessary to protect patients from paying for unsafe or wasteful treatments when a more standard treatment exists.³³ This position often places them in direct conflict with health care providers and patients regarding certain procedures and treatment modalities, such as bone marrow transplant. One commentator explains, “As consumers battle for access to treatments of choice, physicians [and insurers] struggle with balancing research findings from innovative treatments against more generally accepted standards of care and payers attempt to avoid the increased costs for unproven therapies.”³⁴

Experimental exclusions attempt to resolve this conflict by examining the safety and efficacy of a treatment and excluding from policy coverage those therapies that have not yet been shown to be standard, proper care

29. Patricia C. Kuszler, *Financing Clinical Research and Experimental Therapies: Payment Due, but from Whom?*, 3 DEPAUL J. HEALTH CARE L. 441, 466–67 (2000).

30. See *supra* Part I.

31. See Papantonis, *supra* note 4, at 217 (discussing how insurance companies often choose not to cover experimental procedures in order to maintain reasonable premium costs).

32. *Id.* It is important to note that not all such therapies prove to be effective. See, e.g., E. Haavi Morreim, *From the Clinics to the Courts: The Role Evidence Should Play in Litigation Medical Care*, 26 J. HEALTH POL. POL'Y & L. 409, 411–13 (2001) (discussing litigation regarding a treatment plan involving high-dose chemotherapy followed by bone marrow transplant that later proved to be ineffective).

33. Denise S. Wolf, Comment, *Who Should Pay for “Experimental” Treatments? Breast Cancer Patients v. Their Insurers*, 44 AM. U. L. REV. 2029, 2046–47 (1995).

34. Brock, *supra* note 18, at 24.

for a specific diagnosis.³⁵ Thus, insurers assess the status of the procedure or technology to determine whether the treatment is effective, and they will only provide coverage if it is a proven therapy regimen.³⁶ If the evidence regarding a new therapy is inconclusive or if the particular procedure or technology is still being developed, it is deemed to fall under the experimental or investigational exclusion and is excluded from coverage by that insurer's policy.³⁷

Insurance companies, however, have struggled to define the terms "experimental" and "investigational" in their contracts.³⁸ Furthermore, the conflict that experimental exclusions attempt to resolve is: (1) critical to insurers and affected policyholders; and (2) lacks a simple, obvious solution. The absence of an unambiguous, consistent definition coupled with the complex nature of the problem the clauses are attempting to address has led to the development of different types of experimental exclusion clauses.³⁹

C. Types of Experimental Exclusions

Experimental exclusion clauses come in different forms. However, the majority of them can be grouped into two major types. The first type of exclusion clause specifically lists particular treatments that are not included

35. Mary Ader, *Access to Investigational Treatments*, 6 HEALTH MATRIX 187, 189–90 (1996). Health insurance companies also control costs through the use of a variety of other exclusions. Wolf, *supra* note 33, at 2047–48. The most prominent and common exclusion, besides the experimental exclusion, is a clause stating that the insurer will only cover procedures and treatments that are "medically necessary." Ader, *supra*, at 189–90. The question of what is medically necessary "address[es] the issue of the appropriateness of care for a given diagnosis, including the appropriate level of care." *Id.* at 190. The issue of medical necessity, therefore, overlaps with the question of what should be excluded by experimental therapy clauses. This Article will focus on how to determine if a treatment is experimental, not whether it is medically necessary.

In questions of both what is medically necessary and what treatments fall under experimental exclusion clauses, another important issue that is outside the scope of this Article is what standard of review should be used, particularly with ERISA plans. For a discussion of this topic, see generally Julia Field Costich, Note, *Denial of Coverage for "Experimental" Medical Procedures: The Problem of De Novo Review Under ERISA*, 79 KY. L.J. 801 (1990–1991).

36. Ader, *supra* note 35, at 190.

37. See *id.* at 190–92 (discussing the effect of the assessment process).

38. See *id.* at 192–95 (discussing the various approaches that health plans take in attempting to define such terms).

39. See *infra* Part II.C.

in the insurance coverage.⁴⁰ This type of exclusion makes it easier for the insurer to articulate what treatments are considered experimental under the policy.⁴¹ Furthermore, it is more difficult for policyholders to argue that they were not on notice as to what was covered by a policy with regard to the particular treatments listed, as it is expressly stated in the policy for the purchaser of the coverage to consider when evaluating the insurance policy.⁴² Consequently, some argue that these exclusions are easier to defend in court.⁴³

Any notion that specific exclusions are unambiguous or do not pose any problems is false. The largest problem is that given the rate at which new discoveries are being made in medicine, it is extremely difficult, if not impossible, for a policy to list every possible treatment and use that is covered.⁴⁴ It requires continuous evaluation of the latest medical innovations and continuous policy revisions by insurers, as what is experimental versus what is standard therapy is in constant flux.⁴⁵ Another problem is that a significant number of policyholders do not freely choose their health insurance policy in the same manner that, for example, a

40. See Kuszler, *supra* note 29, at 467–68 (citing examples of health plans that exclude coverage for specifically listed treatments and plans that utilize specific criteria to determine whether a treatment is experimental); Wolf, *supra* note 33, at 2048 & n.124 (citing a health plan setting forth “specific exclusions for acupuncture, sex hormones related to sex transformation surgery, hypnosis, and martial counseling services”). Other items not covered by various insurance plans include dental services, custodial care, cosmetic surgery except to repair disfigurement resulting from accidental injury or birth defect, and rehabilitation services. Wolf, *supra* note 33, at 2048 n.124. Many insurers also explicitly exclude bone marrow transplants and accompanying services for particular cancers, such as breast cancer. *Id.* at 2107.

For another example of this type of exclusion, see *Glauser-Nagy v. Medical Mutual of Ohio*, 987 F. Supp. 1002, 1005–06 (N.D. Ohio 1997). In that case, the insurance company’s initial definition of “experimental” was, “[A]ny treatment, procedure, facility, equipment, drug, device or supply which we do not recognize as accepted medical practice or which did not have required governmental approval when you received it. Determination will be made by the Plan in its sole discretion and will be conclusive.” *Id.* at 1005 (alteration in original) (quotation omitted). The company eventually changed its definition to more scientific, process-based criteria. *Id.* at 1005–06.

41. Wolf, *supra* note 33, at 2048. In particular, specific exclusions make it easier for insurers to articulate the following exclusions: (1) the terms of the actual policy; (2) the insurance company’s interactions with patients and their families; (3) the insurance company’s interactions with physicians and hospitals; and (4) litigation.

42. *Id.*

43. *E.g., id.*

44. *Id.* at 2049.

45. *Id.*

consumer seeking to buy a car does. On the contrary, many policyholders receive their insurance policies through their employers, and often their only choice is to sign onto that plan or no plan at all because their financial condition makes it impossible for them to afford health insurance without an employer contribution or discount.⁴⁶

The second prevalent type of exclusion broadly removes from coverage any therapies that the insurer deems experimental.⁴⁷ Before an insurer can state that any treatments that are experimental or investigational will be excluded, its policies must attempt to define “experimental” based on a set of “criteria that will be used to evaluate a given procedure.”⁴⁸

The criteria insurers use vary, but generally follow one of three methods.⁴⁹ One approach is to use professional criteria: to accept the

46. See Rovner, *supra* note 2, at 1001 (noting that while a majority of people are insured through their employers, many of those that are not, such as retirees, are forced to rely on government programs such as Medicare).

47. See *supra* note 7 and accompanying text; *infra* note 48 and accompanying text.

48. Kuszler, *supra* note 29, at 468 (discussing United HealthCare’s plan, which “opted for articulated, published criteria for evaluating whether a treatment would be considered ‘experimental’”); see also BLUE CROSS BLUE SHIELD ASS’N, TECH. EVALUATION CTR., <http://www.bcbs.com/tec/ahrqepc.html> (last visited Feb. 14, 2006). The site lists the criteria Blue Cross Blue Shield uses to make its evaluations and explains that:

In 1997, TEC was designated as one of 12 Evidence-based Practice Centers (EPC) to receive a five-year contract from the Agency for Healthcare Research and Quality (AHRQ; then the Agency for Health Care Policy and Research, AHCPR). . . . The findings of the EPCs serve as the foundation for organizations to develop clinical practice guidelines as well as tools and strategies for improving the quality of healthcare services they provide.

Id.

Interestingly, “Blue Cross has been criticized by the courts for failure to incorporate its Technology Evaluation Criteria into its contracts.” Brock, *supra* note 18, at 40 & n.143 (citing *Pirozzi v. Blue Cross-Blue Shield of Va.*, 741 F. Supp. 586, 591 (E.D. Va. 1990)); see also *Bucci v. Blue Cross-Blue Shield of Conn., Inc.* 764 F. Supp. 728, 733 (D. Conn. 1991) (showing two instances where courts found Blue Cross and Blue Shield’s “reliance on its Technology Evaluation Criteria unpersuasive” because the plan was not based on the criteria and the criteria were not defined in the plan).

49. Wolf, *supra* note 33, at 2049–50. For a comparison of the various definitions and methods used by insurance companies, see Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 798–800 (1994) (examining the use of criteria ranging from asking “‘friends who are doctors’” to explicit lists of what therapies are and are not covered).

current “professional consensus.”⁵⁰ A second method is to “adopt the positions of other entities, such as the federal Office of Technology Assessment, the National Institutes of Health, or the AMA.”⁵¹ A final option, used by the BlueCross BlueShield Association, is to develop an internal technology assessment process and use objective, scientific factors as much as possible.⁵² Failure to meet the insurer’s stated criteria under one of these approaches, a conclusion normally reached by a team of consultants, advisors, or scientists employed by the insurance company, typically results in the treatment being deemed experimental.⁵³

Assessing whether a treatment is effective is a delicate balancing act. At one extreme, a refusal to pay for a treatment that later proves to be significantly beneficial may delay the availability of that therapy,⁵⁴ and therein costs lives. At the other extreme, the assessment process may save the health care system from wasting substantial amounts of money on technologies, the benefit of which prove to be minimal, by not paying for them before the evidence was conclusive.⁵⁵ The end result of the conflict between patients’ search for any possible treatment and the insurance companies’ desire to keep costs under control has been litigation.⁵⁶

D. Interpretation of Experimental Exclusion Clauses by the Courts

Litigation has proven experimental exclusions to be “an effective and appropriate barrier to payment for unorthodox treatments, such as coffee enemas and tomato therapies.”⁵⁷ Another positive consequence of the litigation has been that insurers “have tightened their exclusionary language” and improved their review processes.⁵⁸ The litigation has not resolved, however, how to determine whether a particular treatment falls under experimental exclusion clauses or if experimental exclusions should exist at all.⁵⁹ On the contrary, the result of these often emotional decisions

50. Ader, *supra* note 35, at 193.

51. *Id.*

52. *Id.* at 193–94; *see also supra* note 48 and accompanying text (discussing the Blue Cross Blue Shield Association’s technology assessment factors).

53. *See* Ader, *supra* note 35, at 192–93 (arguing that certain minimum elements must be met in order to exclude a treatment as experimental).

54. *Id.* at 191.

55. *Id.*

56. *Id.* at 191–92.

57. *Id.* at 195–96.

58. *Id.* at 192.

59. *Id.* at 195.

has been contradictory and has resulted in inconsistent conclusions by courts that provide little or no precedential value to use in resolving future controversies.⁶⁰

1. *The Legal Status of Experimental Exclusion Clauses*

Health insurance policies are “contracts for the purposes of judicial interpretation.”⁶¹ Insurance companies, as offerors of the policy, draft all of the terms in the contract.⁶² As the drafters, they have the right to cover or exclude some therapies and not others.⁶³ The choices insurance companies make regarding what procedures to cover must be stated in the policy so that the consumer is able to make an informed choice.⁶⁴

60. For examples of the vast array of different conclusions reached by various courts, see Melody L. Harness, Note, *What Is “Experimental” Medical Treatment?: A Legislative Definition Is Needed*, 44 CLEV. ST. L. REV. 67, 75 n.59 (1996). Many of the initial cases in this area concerned breast cancer patients seeking bone marrow transplants. See, e.g., *Bechtold v. Physicians Health Plan of N. Ind., Inc.*, 19 F.3d 322, 323–24 (7th Cir. 1994); *Reed v. Wal-Mart Stores, Inc.*, 197 F. Supp. 2d 883, 885 (E.D. Mich. 2002); *Glauser-Nagy v. Med. Mut. of Ohio*, 987 F. Supp. 1002, 1006 (N.D. Ohio 1997); *Sluiter v. Blue Cross & Blue Shield of Mich.*, 979 F. Supp. 1131, 1133 (E.D. Mich. 1997); *Healthcare Am. Plans, Inc. v. Bossemeyer*, 953 F. Supp. 1176, 1179 (D. Kan. 1996); *Taylor v. Blue Cross/Blue Shield of Mich.*, 517 N.W.2d 864, 866 (Mich. Ct. App. 1994). Recently, a significant portion of the litigation surrounding experimental treatment exclusions has focused on bone marrow transplants for multiple myeloma and other cancers that involve stem cell transplants. See, e.g., *Pitman v. Blue Cross & Blue Shield of Okla.*, 217 F.3d 1291, 1293–94 (10th Cir. 2000) (multiple myeloma); *Parks v. Blue Cross & Blue Shield of Or.*, No. 96-35181, 1997 WL 303308, at *3 n.1 (9th Cir. June 2, 1997) (multiple myeloma); *Hendricks v. Cent. Reserve Life Ins. Co.* 39 F.3d 507, 509 (4th Cir. 1994) (small cell lung cancer); *Hooper v. Demco, Inc.*, 37 F.3d 287, 288 (7th Cir. 1994) (multiple myeloma); *Kopicki v. Fitzgerald Auto. Family Employee Benefits Plan*, 121 F. Supp. 2d 467, 469 (D. Md. 2000) (multiple myeloma); *Glutzer v. Prudential Ins. Co. of Am.*, 183 F.R.D. 632, 633 (N.D. Ill. 1999) (ovarian cancer); *Elsroth v. Consol. Edison Co. of N.Y.*, 10 F. Supp. 2d 427, 429–30 (S.D.N.Y. 1998) (epithelial ovarian cancer). All of these cases are also notable for the fact that they document that a very short amount of time can lead to radically different results due to the rate at which biomedical research transforms experimental therapies into standard therapies.

61. Jessica L. Basso, “*Experimental*” *Chemotherapy Treatment for Advance Stage Breast Cancer: Judicial Interpretation of Insurance Policy Coverage*, 1 DEPAUL J. HEALTH CARE L. 105, 108 (1996).

62. *Id.*

63. *Id.*

64. *Id.* The concept of the patient as an informed consumer raises a multitude of concerns. Primarily, serious questions arise as to whether it is possible for people to truly be informed regarding their choices and, secondarily, whether they even have a choice, given that most employees obtain their coverage through the policy

Additionally, both for-profit and not-for-profit insurance companies seek to maximize their profit.⁶⁵ Accordingly, it is in the interest of any health insurance company to refuse as many claims as possible while still maintaining its reputation as a reasonable arbiter of claims.⁶⁶ The insurance company's status as drafter and its pecuniary interest in refusing claims demands that courts scrutinize insurance companies' refusals carefully when an ambiguity exists regarding terms in the policy.⁶⁷ If conflicting yet plausible interpretations exist, a court analyzing a case under a de novo standard of review must construe the ambiguity against the insurance company and, in most instances, resolve the question of coverage in favor of the insured.⁶⁸

2. *Judicial Interpretation of Experimental Exclusion Clauses*

Unfortunately, however, different courts have reached different conclusions when they attempt to interpret these clauses. Most recently, a substantial amount of litigation has been brought by multiple myeloma patients seeking injunctions to compel insurance companies to pay for high-dose chemotherapy combined with stem cell transplants.⁶⁹ The results in these cases have varied significantly.⁷⁰ Despite the fact that the

their employer offers. See Rovner, *supra* note 2, at 1001. These issues, however, extend far beyond the scope of this Article.

65. Holder, *supra* note 49, at 801.

66. *Id.*

67. *Id.*; see, e.g., *Hightshue v. AIG Life Ins. Co.*, 135 F.3d 1144, 1149 (7th Cir. 1998) (noting that under de novo review in ERISA cases, ambiguous language is construed against the drafter).

68. *Hightshue*, 135 F.3d at 1149; accord *Gallagher v. Reliance Standard Life Ins. Co.*, 305 F.3d 264, 269 (4th Cir. 2002) (stating that under de novo review ambiguous language is construed against the drafter); *Perreca v. Gluck*, 295 F.3d 215, 223 (2d Cir. 2002) (same); *Wilson v. Group Hospitalization & Med. Servs., Inc.*, 791 F. Supp. 309, 313 n.6 (D.D.C. 1992) (same). But see, e.g., *Finley v. Special Agents Mut. Benefit Ass'n*, 957 F.2d 617, 619 (8th Cir. 1992) (stating that the rule of construction that construes contract language against a drafter has no place in de novo review of an ERISA plan).

69. See, e.g., *Parks v. Blue Cross & Blue Shield of Or.*, No. 96-35181, 1997 WL 303308, at *3 n.1 (9th Cir. June 2, 1997); *Kopicki v. Fitzgerald Auto. Family Employee Benefits Plan*, 121 F. Supp. 2d 467, 469 (D. Md. 2000).

70. Compare *Kopicki*, 121 F. Supp. 2d at 480-82 (finding that the policy covered chemotherapy and tandem transplant but not thalidomide treatment), with *Pitman v. Blue Cross & Blue Shield of Okla.*, 217 F.3d 1291, 1298 (10th Cir. 2000) (holding that the plan expressly excluded a transplant but that chemotherapy was improperly denied), and *Parks*, 1997 WL 303308, at *4 (holding that denial of treatment was appropriate). It is possible that courts may also use the arbitrary and

circumstances of each case were different because each patient's condition was different, as was each insurance policy's exclusion clause, comparing these cases is still informative. Such a comparison shows how each court examined the issue of coverage differently in each case and utilized distinct rationales to come to each conclusion. Accordingly, none of these cases provide much precedent for resolving future coverage issues involving multiple myeloma or other conditions. In fact, it may not be possible, due to the fact-intensive nature of these cases, for any clear method of analysis to be developed. This predicament is one of many problems created by the current methods of defining "experimental" and the use of litigation as patients' means of recourse.

III. PROBLEMS WITH THE CURRENT SYSTEM FOR DETERMINING WHAT THERAPIES ARE EXPERIMENTAL

A. *Lack of Consistency*

The courts' lack of consistency prevents insurers from being able to predict how their contracts will be construed, and people attempting to become informed consumers cannot rely on how various terms in the plan will be interpreted.⁷¹ This uncertainty, and the resulting litigation, forces insurers to constantly rewrite their exclusion clauses and draft ones that withstand judicial scrutiny and achieve their purpose.⁷² Accordingly, operating costs and premiums that already make insurance prohibitively expensive for many people continue to increase.⁷³

B. *Lack of Predictability*

The problem of the lack of predictability is exacerbated by the fact that most judges "are no more qualified to reach medical conclusions regarding the investigational nature of cancer treatments [or any other treatments than] insurance policy drafters," leaving judges dependent upon physicians and other expert witnesses.⁷⁴ For example, in the early 1990s, when many women were bringing lawsuits to obtain coverage for breast

capricious standard to evaluate multiple myeloma cases, as they did with breast cancer cases. *See, e.g.,* Bucci v. Blue Cross-Blue Shield of Conn., Inc., 764 F. Supp. 728, 733 (D. Conn. 1991) (finding that Blue Cross's decision was arbitrary and capricious and that the treatment should be covered).

71. *See infra* Part III.B.

72. *See infra* note 117 and accompanying text.

73. *See infra* Part III.E.

74. Basso, *supra* note 61, at 114.

cancer therapies involving bone marrow transplants, some judges “look[ed] beyond the insurance plan” and heard testimony regarding whether the treatment was experimental.⁷⁵ Not surprisingly, courts have reached different conclusions, even in cases involving a similar diagnosis, insurance policy, and proposed treatment.⁷⁶ Even if a plan’s exclusion clause is unambiguous, judges’ ability to turn to other evidence regarding what is experimental—evidence that is constantly changing as physicians learn more—may make it virtually impossible for insurers and consumers to predict what treatments are excluded.⁷⁷

Results reached by courts are also highly unpredictable because they often rely heavily on parties’ experts.⁷⁸ What the court hears depends upon

75. *Id.*

76. Compare *Pirozzi v. Blue Cross-Blue Shield of Va.*, 741 F. Supp. 586, 594 (E.D. Va. 1990) (holding that high-dose chemotherapy with autologous bone marrow transplant (HDCT-ABMT) is not experimental for multiple myeloma), with *Schnitker v. Blue Cross/Blue Shield of Neb.*, 787 F. Supp. 903, 906 (D. Neb. 1991) (holding that HDCT-ABMT is investigative for multiple myeloma). It is interesting to note when comparing these two cases that *Pirozzi*, which found the treatment to not be experimental, was decided before *Schnitker*. As such, it cannot be said that scientific progress over time was the difference between the two cases.

The most well known example of courts reaching different conclusions in similar cases is a series of lawsuits that occurred in the late 1980s and early 1990s involving women seeking insurance coverage for HDCT-ABMT therapy for metastatic breast cancer. Compare *Holder v. Prudential Ins. Co. of Am.*, 951 F.2d 89, 91 (5th Cir. 1992) (holding HDCT-ABMT experimental for metastatic breast cancer), and *Sweeney v. Gerber Prods. Co. Med. Benefits Plan*, 728 F. Supp. 594, 596–97 (D. Neb. 1989) (same), and *Thomas v. Gulf Health Plan, Inc.*, 688 F. Supp. 590, 595 (S.D. Ala. 1988) (same), with *Kulakowski v. Rochester Hosp. Serv. Corp.*, 779 F. Supp. 710, 716–17 (W.D.N.Y. 1991) (holding HDCT-ABMT not experimental for metastatic breast cancer), and *White v. Caterpillar, Inc.*, 765 F. Supp. 1418, 1423 (W.D. Mo. 1991) (same), and *Bucci v. Blue Cross-Blue Shield of Conn., Inc.*, 764 F. Supp. 728, 733 (D. Conn. 1991) (same), and *Adams v. Blue Cross/Blue Shield of Md., Inc.*, 757 F. Supp. 661, 677 (D. Md. 1991) (same), and *Pirozzi*, 741 F. Supp. at 594 (same). It is critical to observe that among these cases, no procedure was found to be experimental after 1989. This fact points out how quickly and abruptly scientific opinion can change regarding what constitutes experimental therapy for a given diagnosis and treatment option.

77. See, e.g., *Bailey v. Blue Cross & Blue Shield of Va.*, 67 F.3d 53, 55, 57–58 (4th Cir. 1995) (ruling in favor of the plaintiff by finding that a policy stating that certain specific bone marrow transplants or other forms of “stem cell rescue (in which the patient is the donor) with high dose chemotherapy or radiation” are not covered was ambiguous (internal quotation omitted)).

78. David M. Eddy, Commentary, *The Use of Evidence and Cost Effectiveness by the Courts: How Can It Help Improve Health Care?*, 26 J. HEALTH POL. POL’Y & L. 387, 392–93 (2001); see, e.g., *Wolf v. Prudential Ins. Co. of Am.*, 50 F.3d 793, 800 (10th Cir. 1995) (referencing expert testimony regarding the non-experimental status of

what the lawyers choose to present.⁷⁹ If all of the experts agree, resolution comes easily.⁸⁰ However, experts almost never agree in our adversarial system, leaving the court, which normally possesses little or no scientific or medical knowledge, to evaluate the credibility of the experts and decide which view is correct.⁸¹ Typically, courts will turn to the expert's credentials, supporting evidence, or both.⁸² What the court hears might vary from primary to secondary evidence,⁸³ and it may hear testimony from the world's foremost expert or someone who has a lesser capacity to evaluate the situation.⁸⁴ Courts are ill-prepared to analyze this evidence and testimony, and their reliance on information that they fail to fully understand decreases the predictability of the decisions they will reach.

C. Duration of Litigation

A third serious problem, caused by the current method of determining what is experimental, is that courts may not reach a coverage decision until long after the patients need to begin the treatment if they are to have any chance of survival.⁸⁵ Most patients cannot wait six months or a year for a trial court, and possibly an appeals court, to decide whether their insurance covers a procedure without endangering their prognosis.⁸⁶ Moreover, most people cannot afford to pay cash for a treatment, such as a bone marrow transplant plus the after care, in hopes that their insurance

HDCT-ABMT); *Holder*, 951 F.2d 91 (deferring to the trial court's decision, which relied on expert testimony).

79. Eddy, *supra* note 78, at 393.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.* at 394.

84. *See id.* at 393 (noting the criteria that courts rely on in order to assess the credibility of expert witnesses).

85. In fact, many patients' prognoses are such that they may die without quick resolution of their claims. *See, e.g.,* Cicio v. Does, 321 F.3d 83, 88 (2d Cir. 2003) (observing that the patient died prior to the filing of the claim, while coverage was being disputed), *vacated sub nom.* Vytra Healthcare v. Cicio, 542 U.S. 933 (2004) (mem.); *Turner v. Fallon Cmty. Health Plan, Inc.*, 127 F.3d 196, 197 (1st Cir. 1997) (same).

86. *See Turner*, 127 F.3d at 197 (recognizing that, without unconventional treatments, patient had twelve to eighteen months to live); Wendy K. Mariner, *The Supreme Court's Limitation of Managed-Care Liability*, 351 NEW ENG. J. MED. 1347, 1349-50 (2004) (noting that sick patients may not have the emotional or physical energy to pursue a court battle).

company will later reimburse them if a court finds the therapy is covered.⁸⁷ This disconnect between the window of opportunity available to patients to receive successful treatment and the speed at which courts move poses a significant problem.

D. *Conflicts of Interest*

The conflict of interest that arises when insurance companies decide what is covered under their own plan creates yet another predicament. In *Pitman v. Blue Cross & Blue Shield of Oklahoma*,⁸⁸ the Tenth Circuit found Blue Cross had “a financial interest in denying claims in order to remain economically viable as well as competitive within the insurance industry.”⁸⁹ *Pitman* further recognized that “corporate officers have incentives to maintain an economically healthy and successful company.”⁹⁰ Based on the Tenth Circuit’s reasoning, for-profit corporations have similar, if not more substantial, conflicts of interest in being both the insurer and administrator overseeing coverage decisions. Accordingly, under the current system in which insurers are immunized from any liability for their decisions,⁹¹ nonprofit and for-profit entities with significant financial conflicts of interest are effectively making the final determination regarding coverage decisions for policyholders.

E. *The Effect of the Davila Decision*

The recent decision by the United States Supreme Court in *Aetna Health Inc. v. Davila*⁹² creates the most significant problem for resolving

87. See *supra* notes 21–25 and accompanying text (detailing the high cost of innovative medical procedures, such as organ transplantation). The real median household money income in the United States in 2003 was \$43,318, making these new high-cost medical procedures far from affordable for the average American family. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2003, 2 (2004), <http://www.census.gov/prod/2004pubs/p60-226.pdf>.

88. *Pitman v. Blue Cross & Blue Shield of Okla.*, 217 F.3d 1291 (10th Cir. 2000).

89. See *id.* at 1296 (citing *Lee v. Blue Cross/Blue Shield of Ala.*, 10 F.3d 1547, 1552 (11th Cir. 1994)).

90. *Id.*

91. See *Aetna Health Inc. v. Davila*, 542 U.S. 200, 221 (2004) (holding that plaintiffs’ claims against insurers for breach of a duty to exercise ordinary care in making coverage decisions was preempted by ERISA, which allows only for recovery of the benefits denied); see also *infra* Part III.E (providing a more detailed analysis of the *Davila* decision).

92. *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004).

conflicts between insurers and policyholders regarding what therapies are experimental. *Davila* “effectively immunize[s] managed-care organizations (MCOs) from liability for negligent decisions about the care of patients in private employer-sponsored health plans.”⁹³ This immunization hinders resolution of insurer and policyholder conflicts over exclusion clauses because it provides private health insurers with little or no incentive to clarify ambiguities in their experimental exclusion clauses or resolve conflicts outside of litigation. “[T]he only penalty for wrongful conduct is no more than what they should have paid in the first place”;⁹⁴ that is, what the policy states it covers. It also exacerbates the problems previously discussed.⁹⁵

Davila involved two policyholders suing their health maintenance organizations (HMOs) under Texas state law for negligence for failure to exercise ordinary care when making decisions regarding whether a particular treatment is medically necessary.⁹⁶ The HMOs argued that the Employee Retirement Income Security Act (ERISA),⁹⁷ which governs private employer-sponsored health plans, preempted Texas state law.⁹⁸ As such, they argued that the cases properly belonged in federal court.⁹⁹ The HMOs argued that policyholders *Davila* and *Calad* “were really suing for denial of insurance benefits, not negligence in making medical decisions, and that because they were enrolled in ERISA plans, their only remedy lay in a lawsuit under ERISA to recover insurance payments due.”¹⁰⁰

Section 502(a)(1)(B) of ERISA permits a plan participant “to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.”¹⁰¹ This cause of action amounts to a claim of breach of

93. Mariner, *supra* note 86, at 1347.

94. *Id.* at 1349.

95. See *supra* Part III.A–D.

96. *Davila*, 542 U.S. at 204 (citing Texas Health Care Liability Act, TEX. CIV. PRAC. & REM. CODE ANN. §§ 88.001–88.003(a) (Vernon Supp. 2004)).

97. Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C.A. §§ 1001–1461 (1999 & Supp. 2005).

98. *Davila*, 542 U.S. at 205.

99. *Id.*

100. Mariner, *supra* note 86, at 1347. However, the United States Supreme Court has suggested that § 502(a)(1)(B) of ERISA limits recovery to nothing “more than the value of the benefits denied.” *Id.* (citing *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985)).

101. ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B). In *Davila*’s case it would be the value of a Vioxx prescription; in *Calad*’s case, it would be the cost of an

contract for failure to provide plan benefits.¹⁰² The Supreme Court has interpreted ERISA as preempting claims of denial of benefits under state law.¹⁰³ Furthermore, ERISA § 502 “prevents [policyholders] from recovering more than the value of the benefits denied.”¹⁰⁴

Wendy Mariner correctly points out that this limitation on recovery, however, did not work well in the context of managed care.¹⁰⁵ In response, courts began to distinguish between various decisions made by managed care organizations (MCOs).¹⁰⁶ Courts divided decisions into medical judgments that were subject to state malpractice laws¹⁰⁷ and coverage

additional day or two in the hospital. Mariner, *supra* note 86, at 1347–48. In many experimental exclusion clause cases, however, it would be the final clause dealing with interpretation of future benefits that would be significant.

102. Mariner, *supra* note 86, at 1347 (“When an ERISA plan wrongfully denies benefits to a participant, Section 502 allows, in essence, a claim of breach of contract to be brought under the federal law, instead of ordinary state contract law.”).

103. *See e.g.*, Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 54–55 (1987).

104. Mariner, *supra* note 86, at 1347; *see also id.* at 1348 (stating that “ERISA was enacted to protect employees from losing their pensions as a result of inadequate funding or mismanagement of pension plans” (citing S. REP. NO. 93-1090 (1974); H.R. REP. NO. 93-1280 (1974))). The appellants, therefore, sued under Texas law in an attempt to obtain compensation for personal injury that was not available under ERISA. *Id.*

105. *See id.*

106. *Id.*; *see discussion infra* notes 107–08 and accompanying text.

107. Mariner, *supra* note 86, at 1348; *see, e.g.*, DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 452–53 (3d Cir. 2003) (holding that plaintiff’s claim was a medical judgment decision and, thus, not preempted by ERISA); Land v. CIGNA Healthcare of Fla., 339 F.3d 1286, 1293–94 (11th Cir. 2003) (holding that plaintiff’s claim alleging that improper diagnosis of a condition led to the loss of his finger was a tort claim not preempted by ERISA), *vacated*, 542 U.S. 933 (2004) (mem.); Cicio v. Does, 321 F.3d 83, 101–02 (2d Cir. 2003) (holding that the claim was both a malpractice and coverage issue), *vacated sub nom.* Vytra Healthcare v. Cicio, 542 U.S. 933 (2004) (mem.); Lazorko v. Pa. Hosp., 237 F.3d 242, 248–49 (3d Cir. 2000) (holding that plaintiff’s claim, which challenged the soundness of provider’s medical decision, was not completely preempted by ERISA); *In re* U.S. Health Care, Inc., 193 F.3d 151, 162–64 (3d Cir. 1999) (holding that plaintiff’s claims against defendant HMO for negligence in adopting policies that encouraged the discharge of newborn infants and discouraged readmittance of such infants was not completely preempted by ERISA); Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 351–52 (3d Cir. 1995) (holding that the removal of plaintiff’s “claims from state court was improper” given that they were “not claims ‘to recover [plan] benefits due . . . under the terms of [the] plan, to enforce . . . rights under the terms of the plan, or to clarify . . . rights to future benefits under the terms of the plan’ as those phrases are used in § 502(a)(1)(B) of ERISA” (internal quotation omitted)).

decisions that were subject to challenge only under ERISA.¹⁰⁸ In *Pegram v. Herdrich*,¹⁰⁹ the Supreme Court classified decisions into: (1) eligibility decisions; (2) treatment decisions; and (3) mixed decisions.¹¹⁰ The decision led to speculation about “whether the Supreme Court expected that claims of negligent treatment and mixed decisions should be heard in state courts under state malpractice law, rather than in federal court under ERISA.”¹¹¹

Davila resolved this dispute. The Court concluded that “if an individual, at some point in time, could have brought his claim under ERISA § 502(a)(1)(B), and where there is no other independent legal duty that is implicated by a defendant’s actions, then the individual’s cause of action is completely pre-empted by ERISA § 502(a)(1)(B).”¹¹² In its opinion, “[t]he Court emphasized that ERISA gave Davila and Calad a remedy for wrongful decisions.”¹¹³ Moreover, the appellants could have challenged the coverage decisions when they were initially “made or paid for the care they wanted and then sued for reimbursement.”¹¹⁴ Finally, “[t]he Court left open the possibility that patients could sue MCOs for breach of fiduciary duty.”¹¹⁵

This decision hinders resolution of insurer and policyholder conflicts over exclusion clauses because it provides insurers with little incentive to change their policies.¹¹⁶ In an effort to keep premiums under control, “*Davila* may encourage MCOs to adopt more restrictive agreements . . . to

108. Mariner, *supra* note 86, at 1348; see, e.g., *Klassy v. Physicians Plus Ins. Co.*, 371 F.3d 952, 955 (7th Cir. 2004) (finding claim, though framed as a medical malpractice claim, to be a coverage decision governed by ERISA); *Pryzbowski v. U.S. Healthcare, Inc.*, 245 F.3d 266, 273 (3d Cir. 2001) (holding claims were coverage decisions under ERISA); *Turner v. Fallon Cmty. Health Plan, Inc.*, 127 F.3d 196, 198–200 (1st Cir. 1997) (same); *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482, 1485 (7th Cir. 1996) (holding that plaintiff’s negligence and vicarious liability claims were within the scope of ERISA “and therefore completely preempted”).

109. *Pegram v. Herdrich*, 530 U.S. 211 (2000).

110. *Id.* at 228–29.

111. Mariner, *supra* note 86, at 1348.

112. *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 210 (2004).

113. Mariner, *supra* note 86, at 1349.

114. *Id.*

115. *Id.* “Under ERISA Section 502(a)(3), patients can sue for a breach of other fiduciary duties or a violation of the plan or the statute.” *Id.*; see also *Varity Corp. v. Howe*, 516 U.S. 489, 507 (1996) (indicating that Congress provided “remedies for individual beneficiaries harmed by breaches of fiduciary duty”). It is not possible, however, to obtain money damages for these violations. Mariner, *supra* note 86, at 1349.

116. Mariner, *supra* note 86, at 1349.

discourage [physicians] from recommending too much costly care.”¹¹⁷ Experimental therapies are the prime example of this type of care. Mariner argues that if MCOs do not adopt more restrictive agreements, the alternative is to transfer the decision to policyholders and their physicians through the use of consumer choice plans.¹¹⁸ These plans “allow patients to buy care up to a certain dollar amount directly from physicians without approval from the MCO.”¹¹⁹ This provides the patient with greater choice and insulates the insurer from responsibility for injury to the patients.¹²⁰ However, this situation does little to eliminate the initial problem because after the designated amount is spent, patients and their insurers still “confront the same benefit decisions” that led to *Davila* and cases like it.¹²¹

Davila also exacerbates current systemic problems discussed in the earlier sections.¹²² The decision does not take into consideration the fact that few policyholders challenging exclusion clauses can afford expensive treatments “in the hope of future reimbursement.”¹²³ Besides financial costs, the opinion wrongly assumes that patients have the capacity—physically, mentally, and emotionally—to challenge a major insurance corporation while battling an illness that may or may not be curable through an experimental therapy.¹²⁴ It also fails to consider that many policyholders challenging decisions may die before the court system resolves their claim.¹²⁵

These problems were at issue in the case of *Cicio v. Does*,¹²⁶ which was vacated and remanded by the Supreme Court in light of *Davila*. In *Cicio*, the plaintiff sought high-dose chemotherapy and a double stem cell transplant for multiple myeloma.¹²⁷ The claim was brought after a denial of coverage, a multitude of appeals by Cicio’s doctor, and an approval of a

117. *Id.* at 1350.

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. See *supra* Part III.A–D (discussing problems with the current system for determining which therapies are experimental).

123. Mariner, *supra* note 86, at 1349; see *supra* notes 22–28 and accompanying text (discussing the increased cost of health care).

124. Mariner, *supra* note 86, at 1349–50.

125. See *supra* note 85 and accompanying text.

126. *Cicio v. Does*, 321 F.3d 83 (2d Cir. 2003), *vacated sub nom.* Vytra Healthcare v. Cicio, 542 U.S. 933 (2004).

127. *Id.* at 87.

single, rather than double, transplant.¹²⁸ By this time, however, Cicio was no longer a viable candidate for transplant and died less than two months after approval—thirteen months after his diagnosis.¹²⁹ *Cicio* demonstrates why the current method of interpreting experimental exclusion clauses, and especially the judicial system in light of *Davila*, is ill-suited to handle these types of cases because the rate at which the judicial system moves is too slow for most patients.¹³⁰ Even though the cause of action in *Cicio* was brought by the patient's wife after his death, the case took two years to reach and be decided by the Second Circuit—significantly longer than the time between Cicio's diagnosis and death.¹³¹ It is likely he would not have survived long enough to have the courts resolve a coverage question had he chosen to fight rather than settle for a single transplant, which he did not receive because the settlement took too long to be reached. Thus, *Cicio* shows that litigation under ERISA, the exclusive remedy after *Davila*, is not the proper vehicle for resolving experimental exclusion disputes because the court system simply cannot move fast enough to keep up with either the rate of change in biomedical research or reach a conclusion within the limited time frame patients have to be treated for conditions like multiple myeloma.

Each of the problems¹³² with the current system of resolving conflicts arises when litigation is the principal means by which patients and insurance companies determine which treatments are experimental. To better resolve these problems, a new model using evidence-based medicine and binding arbitration needs to be developed.

IV. A POSSIBLE SOLUTION: EVIDENCE-BASED MEDICINE AND BINDING ARBITRATION AS A MEANS OF DETERMINING WHETHER A TREATMENT IS EXPERIMENTAL OR STANDARD

It is unreasonable to expect judges to have the knowledge necessary to evaluate which therapies are experimental and which are standard. It is simply irrational to expect judges to stay current on both the law and medicine, to “learn experimental methods, read scores of reports of clinical trials, weigh benefits against harms,”¹³³ and get enough sleep to make a

128. *Id.* at 87–88.

129. *Id.* at 88. His wife filed a claim on behalf of herself and her husband's estate. *Id.*

130. *See id.* at 94–97 (discussing the timeliness of claims).

131. *Id.* at 87–88.

132. *See supra* Part III.A–E.

133. Eddy, *supra* note 78, at 394.

rational decision. Additionally, as David Eddy points out in his article on the need to use empirical evidence, the current methods of determining care standards are based on certain assumptions regarding expert testimony that are unreasonable.¹³⁴ Eddy articulates how this confusion over the role of evidence and its persuasiveness “can wreak havoc on court cases,” such as cases involving high-dose chemotherapy and stem cell transplant.¹³⁵ A system that is based on evidence-based medicine would enable more consistent rulings to be made and allow findings that would not be based on the subjective opinions of experts.

*A. Definition and Application of Evidence-Based Medicine to
Experimental Exclusion Clauses*

For many years the practice of medicine was based on physicians’ opinions, depending largely on each physician’s particular “medical training, individual experience, and local custom.”¹³⁶ In this paternalistic system, patients and payers had little information and few ways to control costs, as they were both heavily dependent on physicians.¹³⁷ As part of the efforts to control costs, and as patients sought greater participation in their own care, the evidence-based medicine (EBM) movement developed as a new means of evaluating medical practices.¹³⁸ Simultaneously, in contrast to patients’ and insurers’ lack of information, the information available to physicians has skyrocketed—it is so voluminous that no practicing doctor could be current on all of it.¹³⁹ As Professor Lars Noah explains: “Today, there are more than 25,000 biomedical journals worldwide, which publish more than two million articles annually. MEDLINE, an electronic database covering less than 4,000 of these journals, contains over nine million citations and adds more than 30,000 new references each month.”¹⁴⁰

134. *Id.* at 394–99 (discussing how each of the assumptions made regarding community care standards is unreasonable).

135. *Id.* at 398–99.

136. Marc A. Rodwin, Commentary, *The Politics of Evidence-Based Medicine*, 26 J. HEALTH POL. POL’Y & L. 439, 440 (2001).

137. *Id.*

138. *Id.* EBM is “the movement to evaluate the safety, effectiveness, and cost of medical practices using tools from science and social science and to base clinical practice on such knowledge.” *Id.* at 439.

139. *Id.* (stating that while doctors had knowledge about their colleagues’ work through observation or reputation, “there was little in the way of external assessment or control over medical practice outside of informal professional self-regulation”).

140. Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 402–03 (2002) (footnotes omitted). This dissemination of information will only encourage the

EBM is a way to help physicians make decisions, aid insurers in making less ambiguous coverage policies, and help patients understand what is and is not covered by various policies so that they will be informed consumers.¹⁴¹

EBM is a means of evaluating “the safety, effectiveness, and cost of medical practices using tools from science and social science and to base clinical practice on such knowledge.”¹⁴² EBM suggests that when a clinical problem arises, physicians “should, in descending order of preference, look for guidance in systematic reviews of randomized controlled trials, the results of individual controlled clinical trials, observational (uncontrolled) studies, and anecdotal reports of clinical observations.”¹⁴³ This protocol is applicable to creating a better definition of “experimental” for health insurance contracts.

A uniform definition of “experimental” based on EBM could be used throughout the insurance industry. The definition would be based on the pre-existing “phase system” used throughout medical research.¹⁴⁴ Under the phase system, clinical trials are divided into four phases.¹⁴⁵ In Phase I, a new treatment is given to a small number of patients.¹⁴⁶ Phase I studies are

evidence-based medicine revolution.

141. See Rodwin, *supra* note 136, at 442 (noting that “the hope [is] that medical information will lead . . . to better clinical decision making, better medical care, and better health policy”).

142. *Id.* at 439. It is important to note, however, that EBM shows if a treatment is safe and effective and what it costs. It does *not* show if the treatment is cost effective nor does it analyze the cost effectiveness of a treatment as compared to other standard or experimental therapies. This would demand further and different analysis.

143. Noah, *supra* note 140, at 381 (citing Gordon H. Guyatt et al., *Users’ Guides to the Medical Literature: XXV. Evidence-Based Medicine: Principles for Applying the Users’ Guides to Patient Care*, 284 JAMA 1290, 1292–93 (2000) (“The hierarchy implies a clear course of action for physicians addressing patient problems—they should look for the highest available evidence from the hierarchy.”)).

144. See NAT’L CANCER INST., CLINICAL TRIALS: QUESTIONS AND ANSWERS 5–6 (2004), http://www.cancer.gov/PDF/FactSheet/fs2_11.pdf [hereinafter NCI CLINICAL TRIALS] (providing a summary of the phase system used in clinical trials).

145. *Id.* A patient can only be entered on one study for a given condition at one time and can only be at one phase of a trial at a given time. Thus, it is not possible for a person to be in two different phases of research for the same study at two different institutions. However, it might be possible to be entered into more than one study if the studies are investigating two different conditions or illnesses. Therefore, an individual could be in one phase of research regarding one condition at one institution and in another phase on another study at a different institution.

146. *Id.* at 5.

conducted, after extensive lab and animal studies, to find the best and safest way to administer the new treatment.¹⁴⁷ Phase II trials study the effect of a treatment, both in terms of effectiveness and safety, on a particular disease.¹⁴⁸ It typically involves fewer than 100 patients.¹⁴⁹ Phase III studies are randomized trials that “compare a new agent or intervention (or new use of a standard one) with the current standard therapy.”¹⁵⁰ Participants are randomly assigned to either the new therapy or standard therapy group.¹⁵¹ Phase III trials only occur after Phases I and II have been completed and typically involve large numbers of patients, sometimes hundreds of patients at multiple institutions.¹⁵²

When multiple Phase III studies of the same experimental therapy exist, it is possible to sum up the data from all studies in a meta-analysis.¹⁵³ The larger sample size in the meta-analysis allows greater certainty of the magnitude of benefit and toxicity than from any one individual trial.¹⁵⁴ Such meta-analyses are frequently accepted as stronger evidence of efficacy.¹⁵⁵

Phase IV trials are different in their purpose. Phase IV trials are used to “further evaluate the long-term safety and effectiveness of a treatment,” typically after it “has been approved for standard use.”¹⁵⁶ Often thousands of people participate in Phase IV trials.¹⁵⁷

Using this system, any treatment that falls into Phases I–III would be deemed experimental therapy.¹⁵⁸ Clinical trials in Phase IV would be

147. See *id.* (noting that Phase I is “the first step in testing a new approach in humans”).

148. *Id.*

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

153. John H. Noble, Jr., *Meta-analysis: Methods, Strengths, Weaknesses, and Political Uses*, 147 J. LABORATORY & CLINICAL MED. 7, 7 (2006).

154. *Id.* at 11–14.

155. *Id.*

156. NCI CLINICAL TRIALS, *supra* note 144, at 5.

157. *Id.*

158. A Phase III trial will compare a standard treatment plus an experimental agent against the standard treatment. *Id.* Many insurance carriers will pay for an established practice if enough data has been gathered. Often plans will not cover clinical trials if the insurance agency considers the new approach “investigational.” In this way, the insurance companies pay only for standard care as contracted but indirectly subsidize the research process. This system would not be altered by this

considered standard therapy.¹⁵⁹ If a legitimate medical reason existed such that a randomized controlled study is not possible regarding that treatment, reliable evidence¹⁶⁰ showing a consensus among experts that further

definition. *Id.*

159. This prong of the definition based on “phase status” is supported by Denise S. Wolf’s recommendations in her Comment on who should pay for experimental breast cancer therapy. See Wolf, *supra* note 33, at 2104. In her Comment, Wolf argues the following:

Courts should compel an insurer to define Experimental Exclusions clearly in its policy through objective, unambiguous criteria. Insurers have many options in attempting to satisfy this requirement:

- Require formal endorsements from national medical organizations (e.g., the National Institutes of Health, American Medical Association, or American Society of Clinical Oncology) or governmental bodies (e.g., the Food and Drug Administration or Medicare);
- Expressly exclude or include treatments involved in Phase I, II, III, or IV clinical trials;
- Insist that research protocols be consistent with procedures endorsed by a nationally recognized medical organization;
- Insist that board certified physicians and nurses perform the medical treatment in appropriate facilities;
- Require that the proposed medical treatment be reviewed and approved by a qualified institutional review board;
- Require that the proposed medical treatment be received favorably by the most qualified institutional review board;
- Require that the medical treatment be received favorably by the most recent medical conferences and peer-reviewed literature;
- Insist that there exists no therapy that is clearly superior to the proposed treatment; and/or
- Require that the primary purpose of the treatment is therapeutic, with research merely a collateral goal.

Id. at 2104–05.

160. Harness, *supra* note 60, at 96 (recommending an excellent definition of what should constitute reliable evidence). Harness writes the following:

research is necessary to determine its dosage, toxicity, safety, or efficacy compared to standard treatment would render a therapy experimental.¹⁶¹ The second prong of the definition would use evidence in descending order of persuasiveness within the EBM system,¹⁶² not in a random order or based on who is testifying. Any therapy that falls under either of these two definitions would not have to be covered by health insurance,¹⁶³ nor would any of the accompanying costs of clinical care associated with the therapy. A uniform definition by itself, however, is insufficient. This definition of “experimental,” based on EBM’s structured examination of medical information, offers many advantages, but also presents shortcomings that must be considered.

1. *Advantages of a Definition Founded in Evidence-Based Medicine*

EBM provides a solution to three of the five problems discussed above.¹⁶⁴ The binding arbitration scheme is discussed later as an attempt to resolve the other two problems.¹⁶⁵ The principal advantage of using EBM to resolve the problem of determining which treatments fall under experimental exclusion clauses is that the objectiveness of EBM removes the subjective, emotional elements by making decisions not about a particular patient with a sympathetic case, but about the treatment’s proven record of success in a broader sample of patients.¹⁶⁶ EBM decisions

Reliable Evidence means published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device or medical treatment; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

Id.

Instead of creating an industry-wide, uniform definition through private action, Harness proposes creating a uniform standard through federal legislation. *Id.*

161. *Id.*

162. *See supra* note 143 and accompanying text (discussing the process of using a hierarchy of evidence to resolve treatment issues).

163. Insurers could contract to cover more than standard therapy. It is likely that any plan that covered more than standard therapy would have significantly higher premiums.

164. *See supra* Part III.

165. *See infra* Part IV.B.

166. *See* Noah, *supra* note 140, at 391 (“[B]iomedical researchers contend that placebo-controlled trials provide the best method for judging efficacy, especially for highly variable and subjective conditions such as depression or pain.” (footnotes omitted)).

are rooted in random clinical control trials, multiple regression analyses, meta-analyses, and cost-effectiveness analyses, as opposed to anecdotal evidence.¹⁶⁷ In the case of experimental exclusions, decisions would be more objective because they are based on what phase the research had progressed to when a decision needed to be made.

Greater objectiveness in the decision would increase the predictability of the result. Insurance companies (and their medical utilization directors who oversee the decision of which treatments are experimental and which are standard), physicians, and patients would have a more definite means of knowing what treatments will be covered. Insurance companies' costs would decrease because they would know which treatments their premiums must cover.

Besides increasing consistency, this definition and its basis in EBM would make what is considered experimental less political. One of the problems with many of the recently proposed solutions¹⁶⁸ is that they politicize the definition of experimental. For example, Denise Wolf proposes looking to endorsements from medical associations or government agencies and to whether the therapy has been presented at conferences.¹⁶⁹ The effect of this type of plan would be to politicize which treatments attained standard status, to increase the burden on government agencies including the Department of Health and Human Services and the Food and Drug Administration, or both. Moreover, she suggests that institutional review boards, already overwhelmed with overseeing human subjects research, should be responsible for making decisions as to what qualifies as experimental.¹⁷⁰ In comparison, EBM would at least reduce the political aspects of the decision and would not burden a government or institutional agency with more responsibilities.

Wolf does, however, suggest some aspects that are similar to EBM. She suggests that treatments in any phase of study can be excluded or included as provided in the insurance policy.¹⁷¹ In contrast, this Article suggests excluding all but Phase IV, because therapies in Phase IV have often already been approved. Wolf's criteria for defining the term

167. See *id.* at 391 (discussing how EMB urges physicians to reduce their reliance on anecdotal evidence).

168. See, e.g., Harness, *supra* note 60, at 95–96 (proposing a means of solving the problem of ambiguity and inconsistency in current definitions of “experimental”); Wolf, *supra* note 33, at 2105 (same).

169. Wolf, *supra* note 33, at 2104.

170. *Id.*

171. *Id.*

“experimental” in insurance policies¹⁷² are helpful because they increase the objectivity of the process compared to how it currently exists. EBM, however, would make the process even more objective by being more dependent on objective factors such as what phase of study the treatment is in and by prioritizing the factors Wolf suggests and other factors. Thus, while Wolf and others have the right idea by trying to make the decision process more objective, a definition and decision based on EBM would be better because it would further reduce the political nature of the decision and would not burden government agencies.

An EBM-based definition would also deal with the problem of judges’ lack of qualifications and reliance on expert testimony¹⁷³ because it would give them a more definite, objective definition. If litigation did arise under the new definition, a judge would first examine what phase of development was taking place with the therapy. With such an unambiguous definition, there would be less need for courts to turn to other evidence regarding what is experimental. If the uniform definition did not resolve the issue, then a judge could turn to other evidence in the order EBM prescribes.¹⁷⁴ A judge would not have to rely as much on experts, and a judge’s qualifications (or lack thereof) would not play as significant of a role because the judge would only be dependent on experts in the rare instance when absolutely no objective data exists. Any decision reached would depend less on who was giving the information and more on what type of information they were sharing.

A final advantage of this definition and the EBM method is that they could reduce insurers’ liability exposure. If Wendy Mariner is correct in her prediction that the *Davila* decision “creates an incentive for patients to challenge every MCO decision they disagree with,”¹⁷⁵ insurance companies would benefit substantially from being able to use uniform, objective criteria to illustrate the justifications for their decisions. The capacity to demonstrate that decisions regarding treatment fell under Phases I–III—or in the absence of a randomized trial, evidence that such an individual trial was ongoing—would provide this type of stronger, more persuasive evidence that would aid insurance companies at trial.

172. See *supra* note 159 and accompanying text.

173. See *supra* Part III.B.

174. See Noah, *supra* note 140, at 381 (discussing the process of using a hierarchy of evidence to resolve treatment issues).

175. Mariner, *supra* note 86, at 1349.

2. *Limitations of a Definition Founded in Evidence-Based Medicine*

EBM is not without its limitations. The most significant critique placed on using a set definition and EBM is that they could “alter the locus of decisionmaking power in the health care community, threatening the traditional hegemony of physicians while empowering statisticians and managers.”¹⁷⁶ There is a distinct risk in making decisions not based on the particular facts of an individual patient’s needs, but rather on the probability of success based on objective data. Many people may have serious concerns about treating only those patients who statistically have the best odds of success.

Second, this definition and EBM do not address the problem that patients are not informed consumers without the ability or the opportunity to make an informed selection regarding health insurance.¹⁷⁷ Lack of choice is inherent in a system in which insurance is at least partially subsidized by employers.¹⁷⁸ Moreover, insurance policies are lengthy and complicated contracts. An improved definition of what is excluded by the experimental clause may make policyholders more informed, but it has no effect on the choices they have.

The third concern not addressed by this solution is that for most patients who turn to experimental therapy, it represents their only hope for survival. These patients present sympathetic, but often rejected, requests for experimental therapy. Given our finite resources, making choices that involve denying a patient coverage can be heart wrenching but necessary. A new definition and the use of EBM will make it clearer what therapies are covered, but it does nothing to combat the disconnect between our capacity to discover new cures and our limited resources.

A final possible limitation of this definition, as well as EBM, is that they do not remove the conflict of interest concerns that arise when insurance companies decide what is covered under their policies.¹⁷⁹ The problem of a conflict of interest, a lack of judicial knowledge, and a need for a faster appeal process can be combatted if this new definition is combined with a system of binding arbitration to remove these controversies from the courts.

176. Noah, *supra* note 140, at 386.

177. *Id.* at 403–04 & n.131.

178. See Glied & Borzi, *supra* note 2, at 406 (noting that in employer-provided insurance plans, the employee is limited to one plan option).

179. See *supra* Part III.D.

*B. Using Binding Arbitration Instead of Litigation to Resolve
“Experimental” Exclusion Clause Disputes*

Litigation is a costly option for both insurance companies and those seeking coverage of a particular therapy. For example, litigation added 10% to the cost of premiums in 2001.¹⁸⁰ For a person faced with a serious illness, bringing a lawsuit against a large corporation only exacerbates a difficult situation and may not even be financially, physically, or emotionally feasible.¹⁸¹

Binding arbitration offers an alternative solution that addresses many of the problems posed by the current system.¹⁸² As John W. Cooley suggests, “[Alternative dispute resolution] is particularly appropriate in disputes over ‘experimental treatments.’”¹⁸³ As a means of reducing the amount of slow and costly litigation, health insurance policies should include a process to address disputes over coverage between the policyholder and the corporation whereby the dispute would go before a predetermined arbitrator who is knowledgeable in that particular field of medicine. The expert will serve as arbiter and will have the authority, per the insurance policy, to reach a decision that is binding on both parties. Although binding on the parties, the decision would be subject to appeal in the courts under ERISA § 502(a)(1)(B). The policyholder would not lose

180. U.S. DEP’T OF HEALTH & HUMAN SERVS., ADDRESSING THE NOW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF CARE 17 (2003), <http://aspe.hhs.gov/datcp/reports/medliab.pdf>.

181. See Mariner, *supra* note 86, at 1349–50.

182. See *supra* Part III.A–E (discussing the problems created by the lack of consistency, lack of predictability, effects of a long litigation process, conflicts of interest, and recent Supreme Court cases in the current system).

183. John W. Cooley, *A Dose of ADR for the Health Care Industry*, DISP. RESOL. J., Feb.–Apr. 2002, at 16, 17. Cooley suggests that arbitration, mediation, or a neutral expert can all be effective alternatives to litigation. *Id.* at 17; see also Lucille M. Ponte, *Putting Mandatory Summary Jury Trial Back on the Docket: Recommendations on the Exercise of Judicial Authority*, 63 FORDHAM L. REV. 1069, 1069–70 (1995). Professor Ponte states the following:

With the spiraling costs, excessive delays, and exploding caseloads of the civil courts, many disputants view traditional litigation as unable to meet their conflict resolution needs. More and more parties are turning away from the judicial system and are resorting to private dispute resolution firms. Recognizing this growing trend towards alternative dispute resolution (“ADR”), an increasing number of state and federal courts are offering a wide range of ADR mechanisms to litigants.

Id. (footnotes omitted).

his or her right to sue to recover benefits under ERISA.¹⁸⁴ This system would merely attempt to provide an expedited, better informed process that would handle many cases and reduce the number that had to go through the costly process of litigation.

1. *Advantages of Binding Arbitration*

The use of an expert in the field to serve as an arbitrator eliminates the problem of a lack of expertise that exists with a judge. It would also encourage the use of evidence-based medicine techniques and spread the use of a uniform definition of “experimental.”¹⁸⁵ Decisions by arbitrators would increase consistency and predictability because the experts read similar journals and other materials in their field. Furthermore, use of arbitration would create a substantial number of decisions that, as nonbinding precedents, would make the resolution of appeals more predictable and consistent for insurers.¹⁸⁶ This consistency would decrease costs for health insurance companies, which could lower premiums for policyholders.

By making the intermediary’s decision binding and by placing the decision in the hands of someone who does not have a judge’s docket, the appeal would be heard much faster. The faster resolution would save both insurers and policyholders money. If the policyholder prevails, it would make post-decision treatment a more viable option than it currently is with litigation.

To remove the problem of insurance company conflict of interest, the cost of hiring an expert to serve as an arbitrator would have to be shared equally between the insurer and the policyholder. Although this fee will be costly for many people, it is less expensive than litigation, making appeal of coverage decisions a viable option for more people than it currently is today.

A final advantage of this system is that it would combat the problems posed by *Davila* by offering an incentive to insurers to clarify ambiguities

184. See ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B) (stating a person may bring a civil suit “to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan”).

185. See discussion *supra* Part IV.A.

186. This advantage is similar to the benefits of decisions by administrative agencies, such as those of the National Labor Relations Board, which provide insight for courts evaluating labor issues.

in their experimental exclusion clauses.¹⁸⁷ Binding arbitration offers an incentive to rewrite contracts based on the knowledge gained from experts' decisions, particularly if they incorporate a standard definition based on evidence-based medicine. This proposal does not attempt to alter the immunization *Davila* offers insurers.¹⁸⁸ Instead, it proposes a pragmatic alternative solution to the problems policyholders and insurers face in a post-*Davila* health world defined more and more by contracts and not medical judgments.¹⁸⁹ As Mariner points out in her article on *Davila*, medical judgments cannot be separated from contract decisions in the real world.¹⁹⁰ This proposal addresses this problem by recognizing that the real world is "messier,"¹⁹¹ and therefore uses informed medical experts who understand the issues present in each coverage decision to make those decisions within the framework outlined by *Davila*.

2. *Obstacles to the Use of Binding Arbitration*

This system faces two significant obstacles, but neither is insurmountable. The first obstacle will be finding knowledgeable experts to serve as arbiters. Yet, given the number of experts willing to serve as expert witnesses at trials today, it is likely that some proportion of those health care professionals will be willing to serve as arbiters. Absent this problem, arbitration overseen by a medical expert removes the conflict of interest, lack of expertise, and speed of decision problems that currently plague disputes over experimental exclusion clauses.

The second challenge facing this system is that policyholders possess a right to sue insurance companies under ERISA.¹⁹² Consequently, not all controversies will be resolved through this type of arbitration.¹⁹³ Policyholders would still have a cause of action under ERISA if they were not satisfied with the outcome of the arbitration, and insurers would still be able to litigate if they were not satisfied. Although this may appear to be a weakness in this solution, if only some fraction of the cases currently before

187. See discussion *supra* Part III.E.

188. See discussion *supra* Part III.E.

189. See Mariner, *supra* note 86, at 1351.

190. *Id.*

191. *Id.*

192. ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B) (allowing a plan participant "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan").

193. See *supra* note 183 and accompanying text (discussing how arbitration would work and that policyholders would still have a cause of action under ERISA).

courts can be resolved by medical experts serving as arbiters, it will ease the burden on courts' caseloads and increase the expertise of the person deciding these types of matters. It also may create a more thorough and reliable evidentiary record for courts to draw from by providing an expert's opinion on the issue.

This proposal does not suggest that ERISA should be amended such that policyholders would lose the option to litigate their case and have their grievances heard. On the contrary, it is an attempt to ensure that both policyholders and insurers get a fair hearing of the issue by an informed factfinder by amending insurance contracts within the current ERISA framework. There may be merit, however, to the idea of amending ERISA to create a system that mandates the use of binding arbitration while still offering policyholders a means of appealing coverage decisions, as ERISA currently does. It is unclear at this point which method would be more effective. The notion of amending ERISA to mandate this proposal is an idea that may or may not be beneficial to participants in the health care system, but it should be considered by future scholars and policymakers. Regardless of whether it is enacted by amending ERISA or by adding an arbitration clause to insurance contracts, the use of medical experts, evidence-based medicine, and arbitration to help insurance companies and policyholders resolve conflicts over ambiguous experimental therapy clauses offers a more effective and efficient solution without taking away policyholders' rights under ERISA.

V. CONCLUSION

The rate at which new treatments are being discovered and the limits on what health care costs the insurance industry can cover continue to grow rapidly. The costs of litigation only exacerbate the insurance company expenses and policyholder premiums, thereby further limiting what society can afford to pay for high-technology therapies. Although what is possible may never be the same as what is affordable, the potential exists to cover more, reduce costs, and increase insurer and consumer understanding by formulating a better definition of experimental therapy and creating an efficient, effective process using binding arbitration to resolve health care coverage controversies.