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NOTES

Denial of Coverage for “Experimental” Medical Procedures: The Problem of *De Novo* Review Under ERISA

INTRODUCTION

The recent proliferation and diversity of medical interventions have led health care consumers, providers, and third party payors to disagree regarding the effectiveness of specific procedures in the management of injury and disease.¹ While consumers seek access to their treatments of choice, physicians attempt to balance research findings concerning innovative approaches with more generally accepted standards of care, and payors try to avoid increased expense for unproven therapies.²

In principle, the decision to attempt a novel course of treatment should be the subject of discussion and informed consent between the physician and the patient.³ New medical technology, however,

¹ Apart from the widely discussed problems of health care cost containment, the effort to assess the value of various treatments is related to the interest among governmental and private payors in ways to measure and compare the outcomes of medical treatments in order to make both efficient and effective use of finite resources. See Ellwood, *Shattuck Lecture—Outcomes Management: A Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549 (1988) (an overview of the topic of outcome assessment); Morreim, *Cost Containment and the Standard of Medical Care*, 75 CALIF. L. REV. 1719 (1987) (analysis of the interaction between cost constraints and medicolegal concerns); Morreim, *Stratified Scarcity: Redefining the Standard of Care*, 17 LAW MED. & HEALTH CARE 356 (1989) (recommendations for judicial evaluation of the standard of medical care).

² See Eddy, *Comparing Benefits and Harms: The Balance Sheet*, 263 J. A.M.A. 2493 (1990) (review of quantitative and qualitative assessment methodologies); Roper, Winkenwerder, Hackbarth & Krakauer, *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197 (1988) (discussion of the federal government's agenda for outcome assessment).

³ See, e.g., Abrams, *Patient Advocate or Secret Agent?*, 256 J. A.M.A. 1784 (1986) (potential adverse effects of payor constraints on role of physician as patient's advocate); Agich, *Rationing and Professional Autonomy*, 18 LAW MED. & HEALTH CARE 77 (1990) (complex interaction between physician decision making and third party requirements); Gaylin, Sadler & Sadler, *Autonomy-Paternalism-Community—A 15th Anniversary Sympo-*

is rarely unambiguous in its demonstrated efficacy and tends to be more expensive than established methods.⁴

Contracts for payment of health care expenses normally limit the type or amount of coverage available.⁵ Such limitations are influenced by both market pressures and state and federal statutes that require health insurance carriers to adhere to minimum standards of equitable dealing with insured parties.⁶ These statutes generally govern administrative procedures,⁷ deferring to the expertise of payors' medical panels and treating physicians in the choice of intervention. Since 1987, however, suits regarding denial of benefits under employer-sponsored health insurance plans have frequently come under federal jurisdiction,⁸ because of the Supreme Court's interpretation of provisions of the Employee Retirement Income Security Act of 1974 (ERISA).⁹

Insurance coverage for some medical interventions may be denied because their efficacy is not proven.¹⁰ The 1989 establishment of a *de novo* standard of review for denial of health plan benefits under ERISA¹¹ has placed federal district court judges in the position of ruling on the validity of such treatments. This raises difficult questions regarding the appropriateness of the adversarial process as a forum for clinical decision making.¹²

sum, 14 HASTINGS CENTER REP 5 (1984) (comprehensive survey of changes in the role of the physician); Siegler, *The Progression of Medicine: From Physician Paternalism to Patient Autonomy to Bureaucratic Parsimony*, 145 ARCH. INTERN. MED. 713 (1985) (influence of payors on physician-patient relationships).

⁴ Ginzberg, *High-Tech Medicine and Rising Health Care Costs*, 263 J. A.M.A. 1820, 1820 (1990) (contribution of new technology to cost increases).

⁵ See generally Annotation, *Coverage and Exclusions Under Hospital or Medical Services (Blue Cross-Blue Shield) Contracts*, 81 A.L.R. 2d 927, 931-33 (1962).

⁶ The complex relationship between state regulatory statutes and preemption by the federal Employee Retirement Income Security Act of 1974 [hereinafter ERISA], is discussed by the Supreme Court in three cases that place increasing emphasis on preemption: Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985); Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983); Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504 (1981); see also Engel, *ERISA: To Preempt or Not to Preempt, That is a Question!*, 22 TORT & INS. L. J. 431 (1987) (pre-*Pilot Life* discussion of preemption clause interpretation); Nelson, *Pilot Life Insurance Co. v. Dedeaux: The Supreme Court's Federalization of Employee Benefit Law*, 23 TORT & INS. L.J. 507 (1988) (case analysis and implications).

⁷ See, e.g., *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47-50 (1987) (discussing Mississippi statutes governing administrative procedures).

⁸ *Id.* at 41.

⁹ 29 U.S.C. §§ 1001-1461 (1988).

¹⁰ See *infra* notes 53-55 and accompanying text.

¹¹ See *Firestone Tire and Rubber Co. v. Bruch*, 489 U.S. 101 (1989) [hereinafter *Firestone II*] (establishing *de novo* standard). For applications of this standard, see *McGee v. Equicor-Equitable HCA Corp.*, No. 87-1721-K (D. Kan., Mar. 27, 1990) (LEXIS, Genfed

The following analysis presents the framework for ERISA preemption of claims appealing a denial of insurance benefits¹³ and the recent trend away from deferential treatment of administrative decisions regarding experimental procedures.¹⁴ While courts have generally reached the same conclusions under *de novo* review as under the previous standard,¹⁵ the troubling implications of this trend suggest the need for a structure that allows more objective data collection and judicial determination.¹⁶

I. ERISA REGULATION OF EMPLOYER-SPONSORED GROUP HEALTH PLANS

The origins of ERISA¹⁷ may be traced to Congressional dissatisfaction with the ability of its statutory predecessors, most notably the Welfare and Pension Plans Disclosure Act of 1958,¹⁸ to curb abuses by plan fiduciaries.¹⁹ The definition of an ERISA fiduciary hinges on the discretion vested in an individual or entity to control plan management, administration, or investments.²⁰ The fiduciary is thus distinguished from one with merely ministerial duties, who lacks discretion regarding benefit denial. Although the duties and standards of care for these fiduciaries derive from the common law of trusts,²¹ exculpatory clauses and other shields commonly found in the language of trusts are not available to them.²² Con-

library, Dist. file); *Rollo v. Blue Cross-Blue Shield*, No. 90-597 (D.N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist. file); *Pirozzi v. Blue Cross-Blue Shield*, 741 F Supp. 586 (E.D. Vir. 1990); *Dozsa v. Crum & Forster Ins. Co.*, 716 F Supp. 131 (D.N.J. 1989); *Stringfield v. Prudential Life Ins. Co. of America*, 732 F Supp. 69 (E.D. Tenn. 1989).

¹² *Zweig and Perry, Health Care Goes to Court, Judges Need Access to Impartial Medical Expertise*, Wash. Post, July 17, 1990, § Health, at 5; see also *infra* notes 156-65 and accompanying text.

¹³ See *infra* notes 17-62 and accompanying text.

¹⁴ See *infra* notes 63-91 and accompanying text.

¹⁵ See *infra* notes 92-155 and accompanying text.

¹⁶ See *infra* notes 156-65 and accompanying text.

¹⁷ 29 U.S.C. §§ 1001-1461 (1988).

¹⁸ 29 U.S.C. §§ 301 et seq. (1958), repealed by ERISA § 111, 29 U.S.C. § 1031 (1988).

¹⁹ See H.R. REP. No. 533, 93d Cong., 1st Sess. 3, reprinted in 1974 U.S. CODE CONG. & ADMIN. NEWS 4639, 4642.

²⁰ The relevant portions of the statute, ERISA § 3(21)(A), for employee welfare plans reads as follows:

[a] person is a fiduciary with respect to a plan to the extent (i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets or (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan.

29 U.S.C. § 1002(21)(A) (1988).

²¹ ERISA § 404 (a)(1) provides for a "prudent man" standard of care and requires a

gress explicitly directed that ERISA reform and preempt weaker state and federal statutes, which had led to "abuses and unsound practices which jeopardize[d] the security of assets and threaten[ed] the availability of funds for employees."²³

Like much of ERISA, this language is more applicable to employee retirement plans than to welfare plans such as those providing health benefits. The administration of retirement plans is largely a question of prudent investment, while for welfare plans, such elements as disclosure of the terms of the plan, adherence to these terms, and fiduciary conflict of interest are often in controversy. The elaboration of guidelines for administration of ERISA employee welfare plans has been left to the evolutionary process of case law

A. *The Evolution of Preemption*

Because ninety percent of all full-time employees in medium and large companies participate in employer-sponsored health insurance,²⁴ any change in health plan regulation has widespread effects. ERISA includes three provisions that have led to its preemptive regulation of group health plans:

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.²⁵

Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any state which regulates insurance, banking or securities.²⁶ Neither an employee benefit plan described in § 1003(a) of this title, which is not exempt under § 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer or to be engaged in the business of insurance for purposes of any law of any State purporting to regulate insurance companies,

fiduciary to act "for the exclusive purpose of providing benefits to participants and their beneficiaries; and defraying reasonable expenses of administering the plan[.]" 29 U.S.C. § 1104 (1988).

²² ERISA § 410, 29 U.S.C. § 1110 (1988) explicitly overrides such provisions.

²³ LEGISLATIVE HISTORY OF THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974, 1 SUBCOMM. ON LABOR OF THE SENATE COMM. ON LABOR AND PUBLIC WELFARE, 94th Cong., 2d Sess., at 204 (remarks of Sen. Javits).

²⁴ Levit, Freeland & Waldo, *National Health Care Spending Trends: 1988*, HEALTH AFFAIRS, Summer 1990 at 177.

²⁵ ERISA § 514(a), 29 U.S.C. § 1144(a) (1988) (preemption clause).

²⁶ ERISA § 514(b)(2)(A), 29 U.S.C. § 1144 (b)(2)(A) (1988) (saving clause).

insurance contracts, banks, trust companies, or investment companies.²⁷

Thus, health insurance acquired as a benefit of employment, as distinguished from insurance purchased directly from a carrier, is generally subject to federal, rather than state, regulation.²⁸ After several years of divergent rulings among the circuits, broad federal preemption was upheld by the Supreme Court in *Pilot Life Insurance Co. v Dedeaux*.²⁹ *Pilot Life* disallowed state law tort claims, such as those for bad faith denial of insurance coverage, when insurance was provided through a self-funded, employer-sponsored plan.³⁰ The scope of preemption remains less than comprehensive,³¹ but exceptions are rapidly diminishing. For example, federally preempted plans are shielded from the indirect regulation by which states govern independent providers of technical services.³²

²⁷ ERISA § 514(b)(2)(B), 29 U.S.C. § 1144(b)(2)(B) (1988) (deemer clause). The difficulty in interpreting this and the preceding "saving" clause arises because statutes are variously construed as to their regulation of insurance. Generally, the three-factor test established in the McCarran-Ferguson Act, 15 U.S.C. §§ 1011-1015 (1988), has been applied, following *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 743-44 (1985) ("[F]irst, whether the practice has the effect of transferring or spreading a policyholder's risk; second, whether the practice is an integral part of the policy relationship between the insurer and the insured; and third, whether the practice is limited to entities within the insurance industry.").

²⁸ At this time, only Montana and West Virginia recognize private actions under unfair insurance practice statutes. See *Moradi-Shalal v. Fireman's Fund Ins. Co.*, 758 P.2d 58, 63 (finding federal jurisdiction and discussing exceptions); *contra McDonough v. Blue Cross*, 131 F.R.D. 467, 468 (April 25, 1990 W.D. Pa.) (Where "ERISA's exclusive enforcement provisions do not vindicate the same interests that the plaintiff's state law claims seek to vindicate," specifically in the area of compensatory relief, state court jurisdiction may be found.).

²⁹ 481 U.S. 41 (1987). For a detailed discussion of *Pilot Life*, see Nelson, *supra* note 6.

³⁰ *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 57 (1987).

³¹ See *Self-Insurance Inst. v. Gallagher*, 909 F.2d 1491 (N.D. Fla. 1989) (unpublished) (preserving distinction between self-funded and fully insured plans). "Self-funded" plans customarily involve two layers of administration: the quotidian decisions of the employer-sponsor, and administrative guidance in more arcane areas, such as provider credentialing, utilization review, case management, and quality assurance, from a large and diverse insurance provider. The majority of courts previously had refused to consider limitations on employer risk as jeopardizing self-funded status. However, *Firestone II* has had the effect of abolishing what was often a very slight distinction between fully insured and self-funded plans for regulatory purposes. For a decision subjecting assertions of self-funding to closer examination when stop-loss provisions allowed limitation of employer risk, see *Hall v. Pennwalt Group Comprehensive Medical Expense Benefits Plan*, No. 88-7672 (March 29, 1989 E.D. Pa.) (LEXIS, Genfed library, Dist. file). Other plans not covered by ERISA are those made available to government employees, including school districts, plans required by statute, such as those for workers' compensation, unemployment, and disability coverage, and certain church plans. See 29 U.S.C. § 1003(b) (1988).

³² Advantages thus gained by ERISA regulation include avoidance of expensive and

Group health plans subject to ERISA regulation may limit coverage of medical interventions on a variety of grounds,³³ but challenges to the interpretation of specific exclusions are authorized under ERISA.³⁴ Conversely, the validity of exclusionary language itself may come under state court jurisdiction when state mandates fall within the traditional purview of state authority, affect relations among the major ERISA participants, or have a relatively minor impact on the plan as a whole.³⁵ Concerns have been raised regarding the apparent restraints placed by ERISA preemption on consumer protection available to health insurance purchasers in the state courts.³⁶ The plaintiff under ERISA not only must bring suit in federal court, but loses the right to a jury trial,³⁷ punitive damages,³⁸ and compensation for mental distress.³⁹ Monetary com-

burdensome state regulations, greater control over cash outlays, and exemption from state taxation of insurance premiums, including those used to fund high-risk pools.

³³ See *supra* note 5; for examples of exclusions, see *infra* note 53.

³⁴ Under the civil enforcement provisions, ERISA § 502(A), 29 U.S.C. § 1132(a) (1988), a plan participant or beneficiary may sue to recover benefits due under the plan, to enforce the participant's rights under the plan, or to clarify rights to future benefits. Relief may take the form of accrued benefits due, a declaratory judgment on entitlement to benefits, or an injunction against a plan administrator's improper refusal to pay benefits. Such relief also may be sought against a plan fiduciary under 29 U.S.C. § 1109(a) (1988).

³⁵ The courts continue to diverge regarding the relationship between ERISA and state-mandated provider laws. Compare *Blue Cross Hosp. Serv., Inc. v. Frappier*, 698 S.W.2d 326 (Mo. 1985) (state law not preempted) with *Metropolitan Life Ins. Co. v. Insurance Comm.*, 441 A.2d 1098 (Md. Ct. Spec. App. 1982), *rev'd*, 463 A.2d 793 (Md. 1983) (ERISA preempts). These laws, as opposed to common-law principles, are frequently given force on the grounds that they "regulate insurance," a determinative criterion under the McCarran-Ferguson Act principles. See *supra* note 27; see also *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1 (1987); *Firestone Tire & Rubber Co. v. Neusser*, 810 F.2d 550 (6th Cir. 1987).

³⁶ 29 U.S.C. § 1132(a)(1)(B) (1988) places general restrictions on consequential damages. See DiPaola, *Wrongful Denial of Health Insurance Benefits: Litigating the ERISA Preemption Defense*, FLA. BAR J. April 1990, at 64; Strand & Mickelsen, *Will ERISA Continue to Screen Self-Funded Plans from Regulators' Glare?*, *Healthweek*, July 20, 1990, at 35. At least one court has found these restrictions inconsistent with the "central policy goal of ERISA [which] is to protect the interests of employees and their beneficiaries in employee benefit plans." *McKinnon v. Blue Cross-Blue Shield*, 691 F. Supp. 1314, 1315-16 (N.D. Ala. 1988), *citing* *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983). Another recent decision used a procedural loophole to prevent removal, finding that ERISA preemption as a defense "does not appear on the face of a well-pleaded complaint and therefore, does not authorize removal to a federal court." *McDonough*, 131 F.R.D. 467, 468 (W.D. Pa. April 25, 1990), *citing* *Metropolitan Life v. Taylor*, 481 U.S. 58, 63 (1987). This case is distinguished because benefits were not sought for plaintiff's decedent; compensatory and wrongful death damages represented interests that would not be vindicated by an ERISA action in federal district court.

³⁷ See, e.g., *Blau v. Del Monte Corp.*, 748 F.2d 1348 (9th Cir. 1984).

³⁸ *Massachusetts Mutual Life Ins. Co. v. Russell*, 473 U.S. 134, 147 (1985), *quoting* *Northwest Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 97 (1981); see also *Harris v.*

pensation is limited generally to recovery of plan benefits, although equitable relief may be granted at the court's discretion.⁴⁰ In specific circumstances, for example, courts have allowed attorney fees and costs for victorious ERISA plaintiffs.⁴¹

B. Exclusion of Benefits

Health insurance policies commonly exclude benefits for medical procedures found to be "experimental" or "investigational" in nature.⁴² In medical usage, a procedure is thus designated when "there is no consensus on the (a) safety or (b) effectiveness of this technology to date, there is insufficient evidence to determine its appropriateness, or it warrants further study; use of this technology for the given indication in the specified patient population should be confined largely to research protocols."⁴³

Blue Cross & Blue Shield, 729 F. Supp. 49 (N.D. Tex. 1990) (denial of punitive damages in health benefit context).

³⁹ See, e.g., *Russell*, 473 U.S. 134; *Johnson v. Dist. 2 Marine Eng. Beneficial Ass'n.*, 857 F.2d 514, 517-18 (9th Cir. 1988); *Sokol v. Bernstein*, 803 F.2d 532, 534-38 (9th Cir. 1986); *Powell v. Chesapeake & Potomac Tel. Co.*, 780 F.2d 419 (4th Cir. 1985), *cert. denied*, 476 U.S. 1170 (1986); *Rollo v. Maxicare of Louisiana*, 698 F. Supp. 111 (E.D. La. 1988).

⁴⁰ See 29 U.S.C. § 1132(a)(3) (1988).

⁴¹ See, e.g., *McGee v. Equicor-Equitable HCA Corp.*, No. 87-1721-K (D. Kan. Mar. 27, 1990) (LEXIS, Genfed library, Dist. File); *Rollo v. Blue Cross & Blue Shield*, No. 90-597 (D.N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist. file).

⁴² See, e.g., *Jones v. Laborers Health and Welfare Trust Fund*, 906 F.2d 480 (9th Cir. 1990); *Exbom v. Central States, Southeast and Southwest Areas Health & Welfare Fund*, 900 F.2d 1138 (7th Cir. 1990) (gastroplasty); *Johnson*, 857 F.2d 514 (liver transplant); *Reilly v. Blue Cross & Blue Shield United*, 846 F.2d 416 (7th Cir. 1988) (*in vitro* fertilization); *McGee*, No. 87-1721-K (LEXIS) ("coma arousal" therapy); *Washington v. Winn-Dixie of La.*, 736 F. Supp. 1418 (E.D. La. 1990) (hyperbaric oxygen for quadriplegia); *Rollo*, No. 90-597 (LEXIS) (HDCT-ABMT); *Pirozza v. Blue Cross & Blue Shield*, 741 F. Supp. 586 (E.D. Va. 1990) (HDCT-ABMT); *Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131 (D.N.J. 1989) (ABMT); *Stringfield v. Prudential Ins. Co. of America*, 732 F. Supp. 69 (E.D. Tenn. 1989) (radial keratotomy); *Thomas v. Gulf Health Plan, Inc.*, 688 F. Supp. 590 (S.D. Ala. 1988) (bone marrow transplantation); *McLaughlin v. Connecticut Gen. Life Ins. Co.*, 565 F. Supp. 434 (N.D. Cal. 1983) (immune-augmentative therapy). See generally Annotation, Coverage and Exclusions Under Hospital or Medical Services (Blue Cross-Blue Shield) Contracts, 81 A.L.R.2d 927, 931-33 (1962).

⁴³ This is the definition used by the American Medical Association's Diagnostic and Therapeutic Technology Assessment [hereinafter DATTA] program, where "investigational" appears at the middle of a five-point rating scale, between the "interim" ratings of "promising" and "doubtful." The DATTA panel decision regarding safety and efficacy is ultimately based on collapsing the five categories into three, with ratings of "promising" weighing in favor of acceptance and ratings of "doubtful" in favor of rejection. "Investigational" ratings, while supporting neither position, have the effect of diminishing the likelihood of acceptance upon statistical analysis. See, e.g., *Alpha-Interferon and Chronic Myelogenous Leukemia*, 264 J. A.M.A. 2137 (H. Cole, ed. 1990).

These exclusions reflect the complex interactions among the provider, the patient, and the third party payor. First, treatments that are undertaken as part of an experimental protocol are often funded by the scientific or governmental entities sponsoring the research and take place at no cost to the provider or patient.⁴⁴ Second, exclusions of unproven treatments help to curb physician deviation from accepted standards of care.⁴⁵

The third rationale involves the interaction of patient care reimbursement with the cost of health plan premiums.⁴⁶ While there is no intrinsic reason for new treatments to be more expensive than established ones, contemporary medical research in areas traditionally resistant to effective intervention often leads to increased costs. These increased costs usually occur during the early stages of a new treatment's use in the clinical setting.⁴⁷ When incurred by the insurer, these costs are passed on to the employer-sponsor in the form of higher premiums. Increases in the cost of health insurance are a subject of significant concern, especially in light of their disproportionate contribution to costs in the manufacturing sector.⁴⁸ Thus, public policy as well as patient-specific justifications

⁴⁴ In such cases, requiring insurance reimbursement would have the effect of compensating providers twice for the same procedure.

⁴⁵ Unproven treatments may thus be excluded on the basis that there is no "medical necessity" for their provision, as in *Washington*, 736 F Supp. 1418 (hyperbaric oxygen for quadriplegia); *Shumake v. Travelers Ins. Co.*, 383 N.W.2d 259 (Mich. Ct. App. 1985) (Laetrile); *Zuckerberg v. Blue Cross & Blue Shield*, 487 N.Y.S.2d 595 (N.Y. App. Div. 1985) ("Gerson therapy").

⁴⁶ This is especially true in complex cases where high benefit costs are incurred. Savings in general are more difficult to demonstrate, as decreased benefit outlays are balanced against increased administrative costs, higher costs for covered procedures, and added benefits in specific areas such as home health care, outpatient services, and rehabilitation. See INSTITUTE OF MEDICINE, CONTROLLING COSTS & CHANGING PATIENT CARE? THE ROLE OF UTILIZATION MANAGEMENT: CONCLUSIONS AND RECOMMENDATIONS 143-62 (B. Gray & M. Field, eds. 1989).

⁴⁷ See *supra* note 4 and accompanying text.

⁴⁸ In 1987, spending for health care by business equaled about 6% of total labor compensation, compared with about 2% in 1965. Levit & Freeland, *Health Spending and Ability to Pay*, 10 HEALTH CARE FIN. REV. 1, 1-12 (Spring 1989). Surveys of employer health insurance premiums have noted increases of 8 to 25 percent for the single year 1987-88. Gabel, DiCarlo, Fink & de Lissovoy, *Employer Sponsored Health Insurance in America*, in Research Bulletin of the Health Ins. Association of America, (Jan. 1989); Higgins, HEALTH CARE BENEFITS SURVEY OF NEW YORK (1989); Levit, Freeland & Waldo, *supra* note 24. Meanwhile, insurance underwriters have sustained losses so great as to lead several to withdraw from the group health insurance market, including Kemper, Provident Mutual, Allstate, and Transamerica Occidental. Meyer & Page, *New Era in Utilization Review*, Am. Med. News, 1, 45 (December 9, 1988).

may explain exclusions on the basis that procedures are unproven or investigational.

The difficulties encountered by practicing physicians and third party payors in evaluating new treatments are complicated by the contingencies surrounding potential benefits from these treatments.⁴⁹ The clinical setting, the patient's age, social circumstances, and the values placed on short- and long-range outcomes interact to make such decisions highly individualized and difficult to generalize.⁵⁰ A test or treatment that is shown to be cost effective only in a specific patient group is often given to persons outside that group.⁵¹ On the other hand, studies demonstrating substantial benefits for a small group of patients but minimal benefits for others may lead payors to deny payment for all patients on the grounds that utilization monitoring would be excessively complex.⁵²

Several levels of evaluation can be triggered by a request for coverage of a new procedure. Explicit policy language may exclude coverage for specific procedures, leaving the decision whether to choose such an exclusionary policy within the discretion of the insurance purchaser.⁵³ A general exclusion of procedures not "in accordance with generally accepted standards of medical practice," lacking "scientifically proven value," or "experimental or investigational" is commonly found either alone or in conjunction with specific language excluding certain procedures. Recent insurance benefits litigation both within and beyond the ERISA context has led insurers "to search for increasingly precise and understandable descriptions for contract exclusions . . . and for defensible criteria for their application to specific cases."⁵⁴

⁴⁹ INSTITUTE OF MEDICINE, *ASSESSING MEDICAL TECHNOLOGIES* (1985); Fuchs & Garber, *The New Technology Assessment*, 323 *NEW ENG. J. MED.* 673, 676 (1990).

⁵⁰ For example, in the case of a common condition, benign prostatic hypertrophy, the patient's attitude toward different states of health may determine whether surgery is appropriate. Barry, Mulley, Fowler & Wennberg, *Watchful Waiting vs. Immediate Transurethral Resection for Symptomatic Prostatism: The Importance of Patients' Preferences*. 259 *J. A.M.A.* 3010-17 (1988).

⁵¹ An example is the dubious value of computerized tomography scanning in low back pain. See Wiesel, Tsourmas, Feffer, Citrin & Patronas, *The Incidence of Positive CT Scans in an Asymptomatic Group of Patients*, 9 *SPINE* 549 (1984).

⁵² This appears to be the rationale governing the payor's decision to refuse funding for coma arousal programs in *McGee*, No. 87-1721-K (LEXIS).

⁵³ Common exclusions include reasons for service (e.g., diagnostic testing as opposed to therapeutic treatments); types of service (cosmetic surgery, routine physicals); specific providers (psychologists, chiropractors, optometrists); lengths or incidents of service (e.g., limit of 30 physical therapy sessions per year); and medical appliances or equipment (glasses, hearing aids).

⁵⁴ INSTITUTE OF MEDICINE, *supra* note 49, at 225. The exclusion language given in

Beyond the level of policy language, decisions regarding exclusion of certain procedures may be referred on a case-by-case basis to the medical director of the sponsoring plan, who then consults with an advisory board and computerized technical data bases.⁵⁵ These individuals and resources also engage in a continual process of evaluation and reformation. New procedures are approved for coverage, while previously authorized treatment may be eliminated from future coverage.⁵⁶ Such decisions are subject to judicial review with the obvious public policy goals of monitoring uniform treatment of plan subscribers and ensuring that effective treatments are not excluded from coverage merely to enhance the plan's profitability.⁵⁷

An innovative method of coping with the lack of insurance coverage for new medical procedures is the extension of reimbursement for treatments within the context of approved clinical trials.⁵⁸

Reilly, 846 F.2d 416, 419, reads,

Services and procedures which are experimental/investigative in nature. Experimental/investigative means the use of any treatment, procedure, facility, equipment, drugs, devices or supplies not yet recognized as accepted medical practice by Blue Cross & Blue Shield United and any of such items requiring federal or other governmental agency approval and for which approval has not been granted at the time services were rendered.

In this case, the *in vitro* fertilization procedure at issue was specifically excluded.

⁵⁵ Technical criteria are listed in *Pirozzi*, 741 F. Supp. at 590-91, as consisting of the following five questions:

(1) Is the drug or device approved by the Food and Drug Administration ("FDA") to market for the particular indication or application in question?

(2) Is there sufficient information in the peer-reviewed medical and scientific literature to enable Blue Cross to make conclusions about the drug's, device's, or procedure's safety and efficacy?

(3) Does the available scientific evidence demonstrate a net beneficial effect on health outcomes?

(4) Is the drug, device or procedure as safe and efficacious as existing diagnostic or therapeutic alternatives?

(5) Can the drug, device or procedure reasonably be expected to satisfy criteria 3 and 4 when applied outside the research setting?

For proposed federal criteria, see Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302 (1989), which includes lack of FDA approval, explicit research purposes, and inadequate evidence regarding safety and effectiveness as indices of "experimental and investigational" status. See also *supra* note 53 and accompanying text.

⁵⁶ Thus, in *Pirozzi*, 741 F. Supp. at 593, the fact that Blue Cross's evaluation of HDCT-ABMT had not been updated since 1988 was found to vitiate the defendant plan administrator's case. *Id.*

⁵⁷ See *infra* notes 63-75 and accompanying text.

⁵⁸ Newcomer, *Defining Experimental Therapy—A Third-Party Payer's Dilemma*, 323 NEW ENG. J. MED. 1702 (1990); *Experimental Therapy—Who Shall Pay*, 324 NEW ENG. J. MED. 1291 (1991) (letters to the editor presenting investigators' points of view on the subject of payment for unproven treatment). See also *infra* note 132 and accompanying text.

A specific treatment protocol at a designated institution becomes not merely a "preferred provider," but the uniquely favored patient care setting.⁵⁹ This option has much to recommend it: patients who might otherwise be unwilling to do so are encouraged to enroll in randomized trials, thereby facilitating determination of treatment efficacy; insurance dollars are added to the resources available for such trials; and patients have greater freedom of choice than in systems that simply deny coverage for unproven therapy.⁶⁰ It is important to note, however, that the nature of such trials dictates that a significant number of patients are randomly assigned to groups not receiving the treatment in question.⁶¹ Furthermore, the insurance company choosing this route would exercise discretion regarding the choice of trials to be funded. Finally, the insurance company must possess expertise in study design and be able to prioritize funding.⁶² Recent innovations in the use of clinical trials will be followed with interest by the growing number of parties to the debate over coverage of "investigational" treatments.

II. STANDARD OF REVIEW

Until February 1989, judicial review of ERISA fiduciary behavior in benefit denials was limited to an "arbitrary and capricious" standard.⁶³ In *Firestone Tire & Rubber Co. v. Bruch*,⁶⁴ the Supreme Court rejected this standard in favor of *de novo* review in the context of pension plan benefit denials.⁶⁵ When the *de novo* standard is applied to health plan benefits, a court abandons deference to the fiduciary's decision and examines evidence regard-

⁵⁹ An example is the Blue Cross and Blue Shield sponsorship of ABMT clinical trials at the National Cancer Institute. See Winslow, *Blue Cross to Help Pay for Clinical Test of Controversial Breast Cancer Therapy*, Wall St. J., October 30, 1990 at B4; Southwick, *Blues Pay for Clinical Trials of Cancer Therapy*, Healthweek, Nov. 5, 1990 at 1.

⁶⁰ Newcomer, *supra* note 58, at 1703.

⁶¹ *Id.*

⁶² Payors are placed in a position similar to that of the reviewer of an academic funding application and understandably would be reluctant to fund less than optimally designed studies. *Id.*

⁶³ See *Reilly v. Blue Cross & Blue Shield United*, 846 F.2d 416, 423 (7th Cir. 1988), citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁶⁴ 489 U.S. 101 (1989), *aff'g* *Bruch v. Firestone Tire & Rubber Co.*, 828 F.2d 134 (3d Cir. 1987) [hereinafter *Firestone I*].

⁶⁵ *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 102 (1989) [hereinafter *Firestone II*].

ing the extent of a procedure's acceptance by the medical community in order to determine the validity of that decision.⁶⁶

A. The "Arbitrary and Capricious" Standard

The "arbitrary and capricious" standard of review⁶⁷ is primarily an assessment of compliance with the benefit determination procedure stated in the policy, and is thus readily amenable to judicial scrutiny. The court's deference to the fiduciary's decision is based on the rationale that the plan trustees have superior expertise in the application and interpretation of their plans, as well as the ability to balance the interests of the plan beneficiaries.⁶⁸ Even when the court might interpret a plan's language differently, the actions of plan sponsors, insurers, or administrators are not contested if they are based on plausible readings.⁶⁹

The "arbitrary and capricious" standard is effectively identical to the abuse of discretion standard,⁷⁰ which was applied to ERISA

⁶⁶ See *infra* notes 108-39 and accompanying text.

⁶⁷ See *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (defining the arbitrary and capricious standard for a decision by a federal agency); see also *Pokratz v. Jones Dairy Farm*, 771 F.2d 206, 209 (7th Cir. 1985) (adopting the *Motor Vehicle* standard for an administrator of an ERISA plan); *Dennard v. Richards Group Inc.*, 681 F.2d 306, 314 (5th Cir. 1982) (arbitrary and capricious standard under ERISA analyzed according to (1) uniformity of construction; (2) fair reading and reasonableness of that reading; and (3) unanticipated costs); Note, *Judicial Review of Fiduciary Claim Denials Under ERISA: An Alternative to the Arbitrary and Capricious Test*, 71 CORNELL L. R. 986 (1986); Comment, *The Arbitrary and Capricious Standard Under ERISA: Its Origins and Application*, 23 DUQUESNE L. R. 1033 (1985). But see *Firestone II*, 489 U.S. at 115 (summary and rejection of the arbitrary and capricious standard).

⁶⁸ *Firestone I*, 828 F.2d at 144 (rejecting the rationale claiming greater expertise on the part of the trustee as the reason for the deference given to the trustee's determination and accepting the rationale that the trustee is better able to balance the interests of the plan beneficiaries); see Comment, *supra* note 67, at 1049-50 ("The courts have no experience in administering employee benefit plans, and are therefore content to defer to the decision of the trustees when that decision is supported by the evidence or by rational explanation.").

⁶⁹ Matthews, *Common ERISA Issues Affecting Group Health Care Plans*, HEALTH LAW HANDBOOK 139, 143 (A. Gosfield ed. 1990).

⁷⁰ *Id.* at 144. The abuse of discretion standard has been retained in cases where plan fiduciaries were explicitly given total discretion over benefit determinations. *Anderson v. Blue Cross/Blue Shield*, 907 F.2d 1072 (11th Cir. 1990) (reversing district court *de novo* decision in beneficiary's favor because discretion found to have been conferred); *Sweeney v. Gerber Products Co.*, 728 F. Supp. 594 (D. Neb. 1989) (discretion retained, fiduciary action upheld); compare *Lowry v. Bankers Life and Cas. Ret. Plan*, 871 F.2d 522 (5th Cir. 1989) (discretion retained; fiduciary action upheld) with *Brown v. Apes-Pittsburg Corp.*, 11 E.B.C. 1034 (6th Cir. 1989) (no discretion, fiduciary reversed). See also *Egert v. Connecticut General Life Ins. Co.*, 900 F.2d 1032, 1036 (7th Cir. 1990) (discussion of qualifications placed on fiduciary discretion and interaction among "abuse of discretion" and "arbitrary and capricious" standards).

claims by analogy to claims arising under Section 302(c)(5) of the Labor Management Relations Act (LMRA).⁷¹ LMRA standards reflect principles of the common law of trusts,⁷² which defer to the discretion of the trustee in allocation decisions unless the decisions are found to constitute an abuse of discretion. Decisions may be found to be abusive when “the trustee has an interest conflicting with that of the beneficiary,”⁷³ or when “the trustee’s interpretation of a plan is in direct conflict with express language in a plan.”⁷⁴ Before the *Firestone II* decision, the concept that “a court is not to substitute its judgment”⁷⁵ for that of an ERISA fiduciary was widely accepted.

B. *The De Novo Standard*

The *de novo* standard differs from the “arbitrary and capricious” standard in two important ways. First, the court does not defer to fiduciary judgment in a *de novo* review, seeking instead to determine the interpretation of the policy language that most accurately represents the intentions of all parties to the agreement.⁷⁶ Second, in making this determination, the court is not limited to the evidence available to the defendant fiduciary and its representatives, or even to the information that a good faith decision would have taken into consideration.⁷⁷ The court has the option to examine “all the circumstances and such other evidence as is not inadmissible.”⁷⁸ This second distinction has implications that have not yet been fully realized regarding the introduction of scientific evidence into the judicial context.⁷⁹

⁷¹ 29 U.S.C. § 186(c)(5) (1988). The “arbitrary and capricious” standard was also necessary to assert federal jurisdiction over LMRA suits, unlike ERISA, which explicitly authorized such suits in 29 U.S.C. § 1132(a)(f). See *Firestone II*, 489 U.S. at 109-10.

⁷² ERISA, as a statute regulating pension as well as welfare plans for employees, is founded upon the law of trusts. See *Firestone I*, 828 F.2d at 141. However, courts reviewing fiduciary investment behavior have applied higher standards. See Note, *supra* note 67, at 989.

⁷³ *Firestone I*, 828 F.2d at 141 (citing RESTATEMENT (SECOND) OF TRUSTS § 187 comment g (1959)).

⁷⁴ *Dennard*, 681 F.2d at 314 (5th Cir. 1982); see also Comment, *supra* note 67, at 1047-55. This line of reasoning is applied most logically when the beneficiary’s interest in a trust is a matter of equity, rather than contract, and more specifically, when the beneficiary has not contributed to the creation or funding of the trust.

⁷⁵ *Motor Vehicle*, 463 U.S. at 43; accord *Reilly*, 846 F.2d at 420 (“We may not undertake a *de novo* review as to whether we agree with Blue Cross’ decision.”).

⁷⁶ *Firestone II*, 489 U.S. at 112-13.

⁷⁷ *Id.*, citing 3 W FRATCHER, SCOTT ON TRUSTS § 201, at 221.

⁷⁸ *Id.*, citing RESTATEMENT (SECOND) OF TRUSTS, § 4 comment d (1959).

⁷⁹ See *infra* notes 156-65 and accompanying text.

Firestone II's novel contribution to the standard of review was its holding that the *de novo* standard should be used "to evaluate the propriety of the involved [benefit] system's actual operation and its content and design, as well as the selection of its administrative service providers and the review of its operations."⁸⁰ The Supreme Court held that this standard should be utilized whenever there is an absence of explicit plan language giving the administrator complete discretion over the construction of uncertain terms or eligibility determinations.⁸¹ Such discretion is not inherent to the plan⁸² and must yield to judicial interpretation of the plan's terms in light of applicable rules of the law of trusts.⁸³

The two rationales behind the "arbitrary and capricious" standard—trustee expertise in the management of pension plans and the ability to allocate the resources equitably among the beneficiaries⁸⁴—were examined and rejected in *Firestone I*. The argument for superior expertise was invalidated by inquiry into the type of expertise required, which was found to be legal rather than administrative.⁸⁵ Further, "there is a significant danger that the plan administrator will not be impartial,"⁸⁶ and that his expertise will be used to the detriment of the plaintiff beneficiaries. The second rationale also encounters potential conflicts of interest: determinations in favor of individual beneficiaries will place financial burdens on the insurer and employer, rather than on other potential beneficiaries in whose favor the trust is intended to operate.⁸⁷

Congress rejected the *de novo* standard of review under ERISA in 1982,⁸⁸ but the reasons for this rejection are obscure and failed

⁸⁰ Matthews, *supra* note 69, at 163.

⁸¹ *Firestone II*, 489 U.S. at 115.

⁸² *Id.* at 112; see *supra* note 70 and accompanying text.

⁸³ The specific provision of the law of trusts upon which the Court relies states that "the extent of the duties and powers of a trustee is determined by the terms of the trust as the court may interpret them, and not as they may be interpreted by the trustee himself or by his attorney." *Firestone II*, 489 U.S. at 112, citing 3 W. FRATCHER, *supra* note 77 (emphasis added by the Court).

⁸⁴ See *supra* notes 67-69 and accompanying text.

⁸⁵ *Firestone I*, 828 F.2d at 144. This argument is addressed *infra* notes 92-155 and accompanying text.

⁸⁶ *Id.*

⁸⁷ *Id.* at 144-45. While this argument may be valid in the short term for individual cases, the cumulative effect of increased benefits has had adverse effects upon other employee beneficiaries.

⁸⁸ See H.R. 6226, 97th Cong., 2d Sess. (1982), reprinted in *Pension Legislation: Hearings on H.R. 1614 et al. Before the Subcommittee on Labor-Management Relations of the House Committee on Education and Labor*, 97th Cong., 2d Sess., 60 (1983).

to convince the Supreme Court of the validity of the “arbitrary and capricious” standard.⁸⁹ The new standard was announced in *Firestone II* as applicable “regardless of whether the plan at issue is funded or unfunded and regardless of whether the administrator or fiduciary is operating under a possible or actual conflict of interest.”⁹⁰ The only exception to this rule would be a benefit plan giving explicit discretion over the matter at issue to administrators or fiduciaries. In most cases brought subsequently under this standard, such language has not been found, and *de novo* review has been applied.⁹¹

III. APPLICATIONS OF THE *DE NOVO* STANDARD

The standard of review established by *Firestone II* has, as the appellant corporation and its *amici* feared, given rise to “more litigation by employees, participants, and beneficiaries who wish to assert their right to benefits.”⁹² The additional weight granted

⁸⁹ *Firestone II*, 489 U.S. at 114, citing *Bowsher v. Merck & Co.*, 460 U.S. 824, 837 n.12 (1983) (“failure to act on the proposed bill is not conclusive of Congress’ views on the appropriate standard of review”).

⁹⁰ Further, the attention to questions of impartiality characterizing the *Firestone I* decision is explicitly eliminated in the Supreme Court’s ruling. See *Firestone II*, 489 U.S. at 115.

⁹¹ The 11th Circuit has recently reversed two lower court decisions which applied *de novo* review where fiduciary discretion in plan language dictated the narrower standard. See *Anderson*, 907 F.2d 1072; *Jett*, 890 F.2d 1137. When such discretion is found by the court, an “abuse of discretion” standard is applied according to which review is limited to the evidence presented to the plan fiduciary, and abuse is found only when factual findings are “clearly erroneous.” See, e.g., *Jones v. Laborers Health & Welfare Trust Fund*, 906 F.2d 480, 481 (9th Cir. 1990); *Dewitt v. A State Farm Ins. Co. Retirement Plan*, 905 F.2d 798, 800-01 (4th Cir. 1990). But see *QuesTech Inc. v. Hartford Acc. & Indem. Co.*, 713 F Supp. 956, 963 (E.D. Va. 1989); see also *Jett*, 890 F.2d at 1140-41 (Johnson, J., dissenting) (standard of judicial review where lower court applied *de novo* standard inappropriately). In *Dewitt*, the following language was found to grant such broad discretionary powers as to make the abuse of discretion standard applicable:

The plan administrator shall have the power to make all determinations that the plan requires for its administration, and to construe and interpret the plan whenever necessary to carry out its intent and purpose and to facilitate its administration. All such rules, regulations, determinations, constructions, and interpretations made by the plan administrator shall be binding.

Dewitt, 905 F.2d at 801. In *Jones*, the effect of similar language was buttressed by the fact that the reviewing entity included union representatives. *Jones*, 906 F.2d at 481. It is obvious that discretionary language is likely to be written into an increasing proportion of plans and that delegation of fiduciary duties will be closely monitored to ensure compliance with the allocation of the discretion.

⁹² Brief for the American Council of Life Insurance *et al. as Amici Curiae*, at 10-11, *Firestone Tire and Rubber Co. v. Bruch*, 489 U.S. 101 (1989) [hereinafter *Firestone II*].

plaintiffs' claims under the *de novo* standard was aptly brought into play in *Aubrey v Aetna Life Insurance Co.*,⁹³ where policy language demonstrated internal contradiction.⁹⁴ By examining the entire policy in light of its own "plain and dispositive language" and placing this language in the context of statutory principles that the carrier claimed to uphold,⁹⁵ the court was able to allocate benefits in a manner that not only aided the plaintiff beneficiary, but arguably resulted in "lower long-term cost to the Plan,"⁹⁶ and thus to all potential beneficiaries.

A distinction must be drawn between the therapeutic interventions for which argument is made in cases recently decided under the *de novo* standard and the claims of "ersatz or self-proclaimed healers or figures from the fringes of medicine"⁹⁷ that characterize many appeals of health benefit denials.⁹⁸ The current discourse in the federal district courts has been directed toward areas of genuine controversy. Issue definition is clouded, however, by administrative problems such as imprecise plan language,⁹⁹ failure to disclose current plan exclusions,¹⁰⁰ and ambiguous statements by plan administrators.¹⁰¹

Unlike the *de novo* review in *Aubrey* and *Firestone*, the application of this standard in a suit challenging benefit denial on the

⁹³ 886 F.2d 119 (6th Cir. 1989).

⁹⁴ In *Aubrey*, language granting benefits for costs associated with pregnancy, regardless of its diagnosis at the time of employment, conflicted with "pre-existing condition" language requiring that no diagnosis or treatment of a condition be made within three months of employment. *Aubrey v. Aetna Life Ins. Co.*, 886 F.2d 119, 120-21 (6th Cir. 1989).

⁹⁵ Aetna contended that the apparently exceptional language for pregnancy was included to establish compliance with the Pregnancy Discrimination Act of 1978, amending Title VII of the Civil Rights Act of 1964. *Id.* at 122.

⁹⁶ *Id.* at 123.

⁹⁷ *Pirozzi v. Blue Cross & Blue Shield*, 741 F. Supp. 586, 594-95 (E.D. Va. 1990).

⁹⁸ *Shumake v. Travelers Ins. Co.*, 383 N.W.2d 259 (Mich. Ct. App. 1985) (Laetrile and other forms of nutritional therapy found to be a necessary and required treatment for lung cancer); *Jacob v. Blue Cross & Blue Shield*, 758 P.2d 382 (Or. 1988) ("Gerson therapy" case decided in plan's favor on both medical necessity and "experimental or investigational" grounds).

⁹⁹ See *Pirozzi*, 741 F. Supp. at 590 (the terms "experimental" and "investigative" were not explicitly defined, but could be construed with reference to adjacent language); *DiDomenico v. Employers Co-op. Indus. Trust*, 676 F. Supp. 903, 907-08 (N.D. Ind. 1987) (liver transplants were excluded from reimbursement in one section of the plan and authorized in another).

¹⁰⁰ *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416 (7th Cir. 1988); *Egert v. Connecticut General Life Ins. Co.*, 900 F.2d 1032 (7th Cir. 1990).

¹⁰¹ *McKinnon v. Blue Cross-Blue Shield*, 691 F. Supp. 1314 (N.D. Ala. 1988); *McGee v. Equicor-Equitable HCA Corp.*, No. 87-1721-K (D. Kan. Mar. 27, 1990) (LEXIS, Genfed library, Dist. file).

grounds that the procedure is experimental or investigational goes beyond the judicial application of law to a specific set of facts.¹⁰² When a court addresses the question whether a specific procedure is in fact experimental, it must investigate and rule on the validity of medical opinion.¹⁰³ The court is then vulnerable to the influence of medical experts called to testify on behalf of the validity of their own procedures of choice.¹⁰⁴ In the highly competitive biomedical research environment,¹⁰⁵ significant support may be marshalled for procedures that have not achieved acceptable levels of efficacy.¹⁰⁶ The intellectually challenging nature of these decisions is exacerbated by the urgency of judicial determinations when procedures are presented as being the last possible course of treatment for dying patients.¹⁰⁷ The cases that have arisen under the *de novo* standard illustrate this problem.

A. The "Experimental or Investigational" *De Novo* Cases

Among the many experimental or investigational procedures subject to *de novo* review, the most frequently litigated thus far has been the use of autologous bone marrow transplants for high dosage chemotherapy ("HDCT-ABMT") in persons with recurrent cancer.¹⁰⁸ Other treatments brought into the judicial arena have

¹⁰² *Pirozzi*, 741 F Supp. at 590 ("[T]he Court must resolve the ambiguity by reference to the Plan's structure and to the testimony of experts. ").

¹⁰³ *Zweig & Perry*, *supra* note 12, at 5.

¹⁰⁴ *Id.*

¹⁰⁵ *See, e.g., Healy, Innovators for the 21st Century: Will We Face a Crisis in Biomedical Research Brainpower?* 319 *NEW ENG. J. MED.* 1058-64 (1988); *Palca, Hard Times at NIH*, 246 *SCIENCE* 988-90 (1989).

¹⁰⁶ *See infra* notes 112, 124-30, 134-36 and accompanying text.

¹⁰⁷ *See, e.g., Rollo v. Blue Cross & Blue Shield*, No. 90-597 (D.N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist. file) ("When the parties were first before me less than six weeks ago, I was called upon to decide whether eight year old Tishna Rollo could live or whether she must die, a humbling and sobering decision."); *Pirozzi*, 741 F Supp. at 587 ("Plaintiff pointed out that her condition was one well-documented to progress rapidly and that only an expedited resolution of this dispute could be effective. Left on this Division's normal five to six month trial docket, the dispute likely would be overtaken by events and rendered irrelevant."); *Dosza v. Crum & Forster Ins. Co.*, 716 F Supp. 131, 140 (D.N.J. 1989) ("If a preliminary injunction is not granted, ultimate relief for the plaintiff will come too late Failure to provide treatment will probably result in death in a matter of months.").

¹⁰⁸ HDCT-ABMT is a procedure by which bone marrow is extracted ["harvested"] from the patient's body, frozen, and stored while the patient receives large, near lethal doses of chemotherapy. In some cases the chemotherapy is administered in doses in excess of one thousand times the standard dose. This high dose chemotherapy kills not only the cancer, but much of the patient's

included radial keratotomy¹⁰⁹ and "coma arousal" programs.¹¹⁰

The first case testing HDCT-ABMT against the experimental/investigational criterion in the federal courts was decided in the plan administrator's favor, using the "arbitrary and capricious" standard, in June 1988.¹¹¹ At that time, there was no debate regarding the investigational status of the procedure for recurrent metastatic breast cancer.¹¹² Thus, the issues were confined to denial of coverage for bone marrow transplantation following coverage for precautionary extraction of bone marrow ("harvesting").¹¹³ Authorization for coverage had apparently been granted in a similar case, but that case was clearly distinguished by the plan administrator and the court.¹¹⁴ The court engaged in something approaching a *de novo* analysis despite its stated reliance on the "arbitrary and capricious" standard. Specific investigation of the language associated with the plaintiff's consent to bone marrow harvesting, which repeatedly emphasized the experimental and contingent nature of this procedure, buttressed the court's finding in favor of the plan administrator's denial.¹¹⁵

remaining bone marrow as well. This secondary effect, untreated, could well be lethal to the patient. Thus, after the chemotherapy is completed, the patient's stored bone marrow is returned to the patient's body to replace the damaged bone marrow and thereby "rescue" the patient. A patient undergoing HDCT-ABMT is hospitalized, often in intensive care, for approximately 10 days of the treatment and requires full-time medical attention. The entire procedure costs approximately \$100,000. Most health care facilities that provide the treatment require pre-payment, or a substantial deposit.

Pirozzi, 741 F Supp. at 588; see also Beck, *The Politics of Breast Cancer*, NEWSWEEK, Dec. 10, 1990, at 62, 65 (discussion of federal funding for cancer research and court battles for insurance coverage of AMBT treatment); Cowley, *In Pursuit of a Terrible Killer*, NEWSWEEK, Dec. 10, 1990, at 66, 67 (discussion of effectiveness of new breast cancer treatments).

¹⁰⁹ *Stringfield v. Prudential Ins. Co. of America*, 732 F Supp. 69 (E.D. Tenn. 1989).

¹¹⁰ *McGee*, No. 87-1721-K (LEXIS).

¹¹¹ See *Thomas v. Gulf Health Plan, Inc.*, 688 F Supp. 590, 595 (S.D. Ala. 1988).

¹¹² *Id.* at 592. "Agreed Fact No. 5: It is undisputed that autologous bone marrow transplantation for the treatment of breast cancer is still considered experimental or investigative, even though such treatment is no longer considered experimental by Blue Cross for certain other types of cancer." Blue Cross is currently funding this treatment for participants with breast cancer who qualify for a National Cancer Institute study of its efficacy. See *supra* note 58 and accompanying text.

¹¹³ *Thomas*, 688 F Supp. at 593-94. Plaintiff contended that because Blue Cross had paid for the bone marrow harvesting, it should also cover the transplantation, although the contingent nature of the harvesting procedure was amply explained and documented.

¹¹⁴ *Id.* at 595. The precise nature of this claim is not discussed in the opinion, and the court does not find it to be relevant to plaintiff's argument.

¹¹⁵ *Id.* at 592-94.

One year later, another HDCT-ABMT case advanced the transition from the "arbitrary and capricious" to the *de novo* standard. In *Dosza v. Crum & Forster Insurance Co.*,¹¹⁶ the court applied a *de novo* standard following *Firestone*, but noted that "whether the *de novo* or abuse of discretion standard was applied, defendants' determination of noncoverage did not conform with the specific terms of this particular Medical Plan."¹¹⁷

Dosza is particularly troubling in light of the court's analysis of an apparent conflict between the definition of experimental procedures in the plan as presented to the plaintiff and that applied by the organization that provided technical consultation to the plan administrator.¹¹⁸ The consultant's policy required that a treatment be supported by a consensus in peer-reviewed literature, while the plan language itself merely required that it be "commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment of the sickness or injury," and "neither *educational nor experimental* in nature nor provided primarily for research purposes."¹¹⁹ In finding for the plaintiff, the court stated that ABMT "is commonly and customarily recognized throughout [the plaintiff's expert witness's] profession, i.e., those administering ABMT treatment."¹²⁰ Discounting peer-reviewed publications contesting this endorsement, the court in effect decided that the enthusiasm of researchers regarding their area of investigation amounted to irrefutable evidence of its validity.¹²¹

Two reported 1990 cases have subjected HDCT-ABMT to *de novo* review in the federal district courts. *Pirozzi v Blue Cross-Blue Shield of Virginia*¹²² again examined the procedure for breast cancer, while *Rollo v Blue Cross-Blue Shield of New Jersey*¹²³

¹¹⁶ 716 F. Supp. 131 (D. N.J. 1989). The procedure had been recommended for the treatment of recurrent multiple myeloma.

¹¹⁷ *Id.* at 140.

¹¹⁸ *Id.* at 142.

¹¹⁹ *Id.* at 134.

¹²⁰ *Id.* at 139. It is noteworthy that six months after the *Dosza* decision, a federal district court in Nebraska applying the "arbitrary and capricious" standard in the presence of discretionary language found that HDCT-ABMT was "in an early stage of development" and definitely within the boundaries of the "experimental or investigational" exclusion. See *Sweeney v. Gerber Products Co.*, 728 F. Supp. 594, 596 (D. Neb. 1989).

¹²¹ *Id.*

¹²² 741 F. Supp. 586 (E.D. Va. 1990).

¹²³ No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist. file); see also *Cole v. Blue Cross & Blue Shield v. Dana-Farber Cancer Inst.* 738 F. Supp. 42 (D. Mass. 1990) (preliminary injunction issued requiring reimbursement for HDCT-ABMT treatment in case of testicular cancer).

assessed its value in the treatment of Wilms tumor, a much less common condition.¹²⁴ Both courts found for the plaintiffs and rejected Blue Cross's contentions that the procedure lacked proven value.¹²⁵ The court reached this conclusion on the basis of extensive examination of evidence presented by the plaintiffs' expert witnesses.¹²⁶

The major distinction between these cases arises from the incidence of the condition for which HDCT-ABMT is proposed. The availability of research supporting or refuting the plaintiffs' claims is related to the number of persons suffering from the same type of cancer as the plaintiffs. This contrast also illustrates the difficulties encountered by insurance carriers when they undertake a determination regarding the validity of a procedure under unusual circumstances.

Breast cancer is relatively common, even in the extreme case exemplified by Mrs. Pirozzi, while Wilms tumor in children is a rare form of cancer, especially in its relapsed state.¹²⁷ While the *Pirozzi* court had ample evidence both for and against the efficacy of the treatment,¹²⁸ the studies relied upon in *Rollo* were based on small groups, the largest of which included only twenty subjects.¹²⁹ The Blue Cross Medical Director in *Rollo* was thus in the difficult position of soliciting unpublished reports of small therapeutic groups (three and four subjects) from specialists in the field whose statements had not been subjected to impartial review.¹³⁰ In *Pirozzi*, significant published evidence could be marshalled to support the procedure's efficacy in breast cancer, reducing Blue Cross to a line of defense based on the absence of randomized "Phase III" trials.¹³¹ While Phase III evidence is highly supportive of a treatment's effectiveness, it is, as the *Pirozzi* court notes, ethically difficult to

¹²⁴ See generally Breslow, *Epidemiological Features of Wilms' Tumor: Results of the National Wilms' Tumor Study*, 68 J. NAT'L CANCER INST. 429 (March 1982). Although Wilms tumor is the second most common solid tumor in children, its incidence (363 cases per year in the U.S.) is still extremely low in comparison with the leukemias. The existing standard of care has resulted in a five-year survival rate of 81%.

¹²⁵ *Rollo*, No. 90-597 (D. N.J. March 22, 1990) (LEXIS, Genfed library, Dist. file).

¹²⁶ *Id.* at 22.

¹²⁷ *Id.*

¹²⁸ *Pirozzi*, 741 F Supp. at 592 nn. 13-14. This evidence, furthermore, included peer-reviewed publications as well as testimony of expert witnesses.

¹²⁹ *Rollo*, No. 90-597 (LEXIS) (only eight of the twenty children were in complete remission at the time of the report).

¹³⁰ *Id.* at 20-21. The court criticizes the Blue Cross Medical Director harshly for failing to give credence to these anecdotal reports.

¹³¹ *Pirozzi*, 741 F Supp. at 594.

enroll patients in such studies when they believe that assignment to placebo treatment might jeopardize the patients' last chance of survival.¹³² The court's holding in *Mrs. Pirozzi's* favor thus suggests standards of acceptable benefit determination, while the *Rollo* holding leaves the carrier under the threat of moral condemnation for failure to consider scientifically questionable and unpublished research findings.

A somewhat different application of the *de novo* standard appears in *McGee v Equicor-Equitable HCA Corp.*¹³³ In *McGee*, payment was denied for treatment received in a "coma arousal program."¹³⁴ The patient was a young woman who had suffered a serious traumatic brain injury. This case can be distinguished from the three previous *de novo* reviews of experimental or investigational procedures because the patient's survival was not at issue. Furthermore, the treatment for which payment was disputed had already taken place at the time of the decision. Numerous ambiguities cloud the picture: the "coma arousal" program was mistakenly (but understandably) assumed to be inappropriate for a patient not in a state of coma;¹³⁵ the plan's language was self-contradictory with regard to coverage;¹³⁶ and the physician reviewers changed their minds about the value of the requested treatment.¹³⁷

Despite these features, *McGee* presents a clearer example of the problems inherent in *de novo* review than the cases involving HDCT-ABMT. The *McGee* court based its evaluation of the pro-

¹³² *Id.* Plaintiff's expert witness cited an HDCT-ABMT study that had failed to enroll patients for over a year. Insurer-funded participation in clinical trials may accelerate the pace of such enrollments. More innovative approaches to assessment of new medical interventions include multivariate analysis of nonexperimental data, meta-analysis, decision analysis, and economic modeling. Fuchs & Garber, *supra* note 49, at 673-76.

¹³³ No. 87-1721-K (D. Kan. Mar. 27, 1990) (LEXIS, Genfed library, Dist. file).

¹³⁴ *Id.* at 28. Like HDCT-ABMT, coma arousal programs are both expensive and controversial. According to the expert testimony of Sheldon Berrol, M.D., in *McGee*, they are also somewhat misleadingly named, as they are not of proven value for persons in a persistent vegetative state (the condition recently publicized in the case of Nancy Cruzan), but are of use for persons at higher levels of post-traumatic arousal.

¹³⁵ *Id.* The *McGee* court criticizes the plan's consulting physical medicine and rehabilitation specialist for failing to make this distinction.

¹³⁶ An exclusion for "long-term physical therapy and rehabilitation services" had apparently been deleted in a supplementary communication to the plaintiff policyholder; this finding was contested by the plan administrator. *Id.* at 7-9.

¹³⁷ *Id.* at 14-25. In summary, the court concludes that the physician's "subsequent reversal of his previous position was both unreasonable and came too late." *Id.* at 40-41.

cedure in question on the testimony of a single, albeit expert, plaintiff's witness. No publications, peer-reviewed or otherwise, were cited; no experimental trials were introduced as evidence.¹³⁸ Like the oncologists testifying on the plaintiffs' behalf in the previous cases, the McGees' expert witness had devoted his considerable energy and intellect to the improvement of coma patients, and his testimony is not discounted.¹³⁹ The defendants' failure to marshal evidence to counter his undocumented assertions is puzzling, yet it does not excuse the court's disproportionate reliance on his testimony

B. *Problems with De Novo Review*

Three problems are readily identifiable in the *de novo* review process. First, the courts themselves acknowledge that, despite the increased judicial burden created by this intensive review, decisions have not differed substantially from those that would have been made under an "arbitrary and capricious" standard.¹⁴⁰ Second, the addition of large and unanticipated areas of coverage by insurance carriers may call into question their adherence to the standards of fiduciary responsibility required by ERISA.¹⁴¹ Finally, these decisions inject an unacknowledged normative element into the judicial examination of scientific evidence.¹⁴²

In three of the four *de novo* cases previously discussed, the court states that the application of an "arbitrary and capricious" standard would have led to the same result even if the new standard had been used.¹⁴³ Despite exhaustive medical reviews in the three HDCT-ABMT cases, the courts appear to base their findings on the abuse of discretion standard when they criticize fiduciaries for

¹³⁸ See *id.* at 28. Like many rehabilitation interventions, coma stimulation does not lend itself to the type of experimental design used for medical and surgical treatments in acute care.

¹³⁹ Dr. Berrol is Director of Medical Rehabilitation at San Francisco General Hospital and editor of the *Journal of Head Trauma Rehabilitation*.

¹⁴⁰ See *infra* notes 143-46 and accompanying text.

¹⁴¹ See *infra* notes 147-50 and accompanying text.

¹⁴² See *infra* notes 151-55 and accompanying text.

¹⁴³ *Pirozzi* is the only case to date in which the decision was based solely on the results of *de novo* review. See *Rollo*, No. 90-597 (LEXIS) ("Assuming that the arbitrary and capricious standard applied, I have no difficulty in finding that Blue Cross/Blue Shield's decision falls far short and, as all of the foregoing should indicate, it surely was wrong."); *Dosza*, 716 F. Supp. at 157; ("The evidence demonstrates quite clearly that whether the *de novo* or abuse of discretion standard is applied, defendants' determination of noncoverage did not conform with the specific terms of this particular medical plan.") (italics added).

inconsistent application of review standards or questionable good faith in administrative interactions.¹⁴⁴ Likewise, although the *McGee* court applies the *de novo* standard explicitly, its review of the insurer's behavior and award of attorney fees reflect the criteria that would be applied under an "arbitrary and capricious" standard.¹⁴⁵ The sole post-*Firestone* case to date decided in favor of the insurance company also reaches a conclusion that would easily be duplicated under the older standard.¹⁴⁶ Thus, the value of *de novo* review may be called into question on the ground that it requires significant additional judicial time and resources while failing to alter the ultimate finding.

The tendency of *de novo* review, as applied thus far, to grant beneficiaries access to very costly treatments of questionable benefit may be found to violate the fiduciary duties established by ERISA § 404(a)(1).¹⁴⁷ The ERISA fiduciary is under a duty to "discharge his duties solely in the interest of the participants and beneficiaries . . . so as to minimize the risk of large losses."¹⁴⁸ When it grants a single participant disproportionate benefits dubiously related to plan provisions, the fiduciary risks jeopardizing the fiscal integrity of the plan as a whole.

Such imprudence has the obvious consequence of placing all other participants' benefits in peril of loss. This risk is most commonly illustrated in the case of the small employer whose insurance premiums rise to intolerable levels following the serious illness of a single employee.¹⁴⁹ Regulatory mechanisms that control insurers' pricing practices have the effect of spreading the cost of court-authorized treatment among the entire community of premium-payers. If the fiduciary is forced by the courts to reimburse health care providers for questionably effective treatment costing hun-

¹⁴⁴ Were the abuse of discretion standard applicable, both Prudential and Crum and Forster have a direct and conflicting interest in the determination of coverage. Prudential is not merely the impartial, disinterested administrator of Crum and Forster's Plan, as it purports to be. Its determination apparently is one which controls payments under its own medical policies.

Dosza, 716 F. Supp. at 139.

¹⁴⁵ *McGee*, No. 87-1721-K (LEXIS).

¹⁴⁶ *Stringfield*, 732 F. Supp. 69, 70 (genuine issue of material fact existed as to whether procedure was "experimental"; summary judgment denied).

¹⁴⁷ Codified at 29 U.S.C. § 1104(a)(1) (1988); see *supra* notes 21-23 and accompanying text.

¹⁴⁸ 29 U.S.C. §§ 1104(a)(1)(A), (C) (1988).

¹⁴⁹ See, e.g., *The Crisis in Health Insurance*, CONSUMER REPORTS, August 1990, at 533 (examples of small businesspersons whose insurance premiums were raised or whose carrier refused to renew insurance contracts following illness or injury of employees).

dreds of thousands of dollars, it is, in effect, forced to violate the standards of prudence established in the explicit language of ERISA.¹⁵⁰

The application of the *de novo* standard of review in cases of investigational procedures has been cast in terms of scientific assessment, but this characterization of the legal discourse ignores a strongly value-laden component. In reality, *de novo* review includes two prongs: the scientific and the normative.¹⁵¹ Judicial investigation of the risks and benefits of a given procedure for the patient leads to a choice between the positions of physician advocates and remains at least nominally within the scientific forum. However, once a procedure that falls outside the established scope of covered health services has been found to be scientifically valid, the decision that it should be reimbursed for a specific beneficiary is a normative social judgment regarding resource allocation.

While the imposition of judicial values to override a professional standard of practice is not unknown,¹⁵² it is unusual in case law. It is not inappropriate for the court to interpret plan provisions in light of the values expressed by the contracting parties within the context of trust law as manifested in ERISA.¹⁵³ Absent explicit recognition of the value-laden nature of such a determination, however, the courts may fail to account for the potential consequences of their holdings in the broader social context.¹⁵⁴ The results of *de novo* review thus far, despite expressed reliance on the interpretation of contractual intent, appear to place the insurer in the shoes of the physician. The insurer is obligated to do all it can for the patient's benefit, regardless of the interests of other plan beneficiaries or society as a whole.¹⁵⁵

¹⁵⁰ See *supra* notes 21-23 and accompanying text.

¹⁵¹ For a discussion of this problem in the context of malpractice litigation, see Hirshfeld, *Economic Considerations in Treatment Decisions*, 264 J. A.M.A. 2004 (October 17, 1990).

¹⁵² See, e.g., *Helling v. Carey*, 519 P. 2d 981 (Wash. 1974), *reaffirmed*, *Gates v. Jensen*, 595 P. 2d 919 (Wash. 1979).

¹⁵³ The terms of trusts are "determined by the provisions of the instrument as interpreted in light of all circumstances and such other evidence of the intention of the settlor with respect to the trust as is not inadmissible." RESTATEMENT (SECOND) OF TRUSTS § 4, comment d (1959).

¹⁵⁴ Such consequences include the effect of authorizing extraordinarily costly treatments on other potential beneficiaries and the plan itself. See *supra* notes 46-49 and accompanying text.

¹⁵⁵ See generally W. KEETON, PROSSER AND KEETON ON TORTS 185-93 (5th ed. 1984) (discussion of standard of conduct in professional malpractice context); Council on Ethical and Judicial Affairs, Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association (1989), Opinions 2.03 and 2.09.

CONCLUSION

De novo review has given the courts a much broader field from which to glean medical evidence than was available under the "arbitrary and capricious" standard. Beyond the adversarial postures of those testifying for and against the validity of a specific procedure, the dispassionate expressions of the scientific community should be recognized as legitimate elements of the decision making process. If courts are to be required to make *de novo* determinations regarding medical interventions, they must have access to empirical scientific findings, instead of being limited to the evidence offered by either party to the action.¹⁵⁶

Searching questions may be directed to the plaintiffs' expert witnesses: 1) To what extent is their professional advancement linked with the procedure they advocate? 2) How much of their compensation is tied to the number of such procedures performed? 3) What evidence argues against their position?¹⁵⁷ Research specialists also may lack fundamental understanding of the terms of a health insurance policy as they relate to investigational procedures.¹⁵⁸ The failure of the defendant fiduciaries' counsel to raise such obvious questions is puzzling. Their relatively passive and parochial insistence upon adherence to review protocols suggests a fundamental lack of understanding regarding the scope and potentially determinative nature of *de novo* review

The growing legitimization of practice guidelines and technology assessment programs argues in favor of their incorporation into the judicial process.¹⁵⁹ In the past, the lack of timely, reliable information has led to such anomalous situations as reimbursement

¹⁵⁶ Kinney & Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421, 442-46; Zweig & Perry, *supra* note 12, at 5; Couch & Rodríguez, *Legal Aspects of Clinical Outcome Management*, in *PHYSICIAN MANAGERS AND THE LAW* (J. B. Couch, ed. 1989); Hirshfield, *Practice Parameters and the Malpractice Liability of Physicians*, 263 J. A.M.A. 1556.

¹⁵⁷ "When expert judgment proceeds in the absence of direct empirical evidence about a particular clinical practice, a frequent circumstance, the general scientific reasoning or normative (ethical, professional) principles supporting the expert judgments should be described." INSTITUTE OF MEDICINE, *supra* note 46.

¹⁵⁸ Such misunderstanding is evidenced by the following quote from such an investigator: "I feel very strongly that when there is no good standard treatment, the best treatment is investigational treatment, and the patient should be covered." Southwick, *supra* note 59, at 37.

¹⁵⁹ Practice guidelines have been under development for several years with varying success. See Kinney & Wilder, *supra* note 156, at 424-38; INSTITUTE OF MEDICINE, *supra* note 46, at 103.

for total hip replacement by most carriers when the procedure was still classified as experimental by the Food and Drug Administration.¹⁶⁰ As a result, governmental and professional groups are moving rapidly to bridge the information gap between experimental and clinical practice.

The November 1989 amendments to the Public Health Service Act¹⁶¹ mandate the development and promulgation of "clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically,"¹⁶² a task to be completed by January 1991. These guidelines are to "be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures" and to "include treatment-specific or condition-specific practice guidelines for clinical treatments . . . for use in reviewing quality and appropriateness of medical care."¹⁶³ Medical specialty groups, health insurers, and utilization review organizations also have been involved with the development of practice guidelines.¹⁶⁴ While such guidelines are currently in a state of rapid evolution, their formulation attests to the ability of clinicians to develop criteria for the dispassionate evaluation of medical evidence in contexts such as the *de novo* review process.¹⁶⁵

As currently applied, *de novo* review of health benefit denial because a treatment is of unproven value is vulnerable to scientific partiality, emotional appeals, and inadequate intellectual grounding. By condoning this pseudoscientific debate, the courts appoint themselves as arbiters of medical decision-making. Generalization of *de novo* review would have profound effects on the efforts of

¹⁶⁰ Bunker, Fowles & Schaffarzick, *Evaluation of Medical Technology Strategies*, 306 NEW ENG. J. MED. 620, 621 (1982).

¹⁶¹ 42 U.S.C.A. § 299 (West Supp. 1989).

¹⁶² *Id.* at Part B, § 912(a)(1).

¹⁶³ *Id.* at Part B, §§ 912(b)(1), (3).

¹⁶⁴ Among these are the American Board of Medical Specialties, the American Medical Association, the Council of Medical Specialty Societies, the RAND Corporation, the Health Insurance Association of America, and the Group Health Association of America. See INSTITUTE OF MEDICINE, *supra* note 46, at 23-24.

¹⁶⁵ Recognition of these guidelines and programs also has significant implications in the area of medical malpractice litigation. Recent initiatives in the state of Maine establishing a 5-year demonstration project on practice guidelines suggest legislative sensitivity to the potential implications of this problem in a variety of medicolegal areas. See ME. REV. STAT. ANN. tit. 24, § 2857.3 (Supp. 1990).

employers, health policy analysts, and legislatures to control the proportion of national resources devoted to medical care. Cases arising thus far under *de novo* review have suggested that the “arbitrary and capricious” standard is adequate in regulating fiduciary procedures and would avoid enmeshing the courts in the process of scientific investigation. If the *de novo* standard is retained, however, the courts must have access to the full range of empirical evidence, rather than being forced to rely upon the testimony of those experts chosen by the parties in support of their positions.

The *de novo* standard of review includes both an attempt at objective assessment of medical science and a value judgment regarding the resources appropriately expended on a given patient. The recognition that *de novo* review is ultimately normative as well as scientific will encourage the courts to consider the broader social implications of their decisions.

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