Hastings International and Comparative Law Review

Volume 21
Number 3 *Spring 1998*

Article 2

1-1-1998

Health Care Rationing in the Courts: A Comparative Study

Timothy Stoltzfus Jost

Follow this and additional works at: https://repository.uchastings.edu/hastings_international_comparative_law_review

Part of the [Comparative and Foreign Law Commons](#), and the [International Law Commons](#)

Recommended Citation

Timothy Stoltzfus Jost, *Health Care Rationing in the Courts: A Comparative Study*, 21 HASTINGS INT'L & COMP. L. Rev. 639 (1998).
Available at: https://repository.uchastings.edu/hastings_international_comparative_law_review/vol21/iss3/2

This Article is brought to you for free and open access by the Law Journals at UC Hastings Scholarship Repository. It has been accepted for inclusion in Hastings International and Comparative Law Review by an authorized editor of UC Hastings Scholarship Repository. For more information, please contact wangangela@uchastings.edu.

Health Care Rationing in the Courts: A Comparative Study

By TIMOTHY STOLTZFUS JOST*

The claim of the legally insured person against his insurer for medical treatment encompasses not just traditional medicine, but also the particular schools of alternative medicine. . . . This is in accordance with constitutional requirements. The obligatorily insured patient has a right of self determination for his medical treatment pursuant to the right of personality, in connection with the [constitutionally protected] right of bodily integrity. . . . With payment of his health insurance premiums, he has also gained a property-like right to comprehensive insurance protection.¹

The augmentative communication device the State will provide Fred C. will reportedly cost about six thousand penurious dollars. Mindful of the practical need to reduce medical costs, the Court nevertheless has before it no evidence that Texas Medicaid will now be required to fund untold numbers of ACDs The Court declines the invitation to reach the callous result of denying one forty-seven year old an augmentative communication device which would routinely be provided were he under the age of twenty-one.²

I feel extremely sorry for the particular applicants in this case who have to wait a long time, not being emergency cases, for necessary sur-

* Newton D. Baker, Baker and Hostetler Chaired Professor, College of Law and Professor, College of Medicine and Public Health, The Ohio State University, Guest Professor, Universitaet Goettingen, 1996-97. The author wishes to thank Professor Dr. Erwin Deutsch, in whose institute much of this article was written, the Fulbright Foundation, which funded my research during 1996-97, and the DAAD, which funded earlier research on this topic in 1994. Numerous persons in Germany provided helpful information that contributed to this article, but the author would particularly like to thank Drs. Engelmann and Udsching of the German Supreme Social Court; Professors Ebsen, von Maydell, Heinze, Steinmeyer, Gitter, and Schulin; and Drs. Gerhard Brenner, Franz Knieps, and Dieter Barth for their help. David Hughes was very helpful with keeping me up to date with British developments. If I misunderstood anything my informants told me, the fault is all mine.

1. LSG Niedersachsen, 8/30/95, L 4 Kr. 11/95, 3 Breithaupt 1996, No. 42.

2. Fred C. v. Texas Health and Human Serv. Comm'n, 924 F. Supp. 788, 793 (W.D.Tex. 1996), *vacated by* 117 F.3d. 1416 (5th Cir. 1997).

gery. They share that misfortune with thousands up and down the country. I only hope that they have not been encouraged to think that these proceedings offered any real prospects that this court could enhance the standards of the National Health Service, because any such encouragement would be based upon manifest illusion.³

I. Introduction

This Article is a comparative study of the law's role in rationing health care in the United States, Germany, and Britain. More particularly, it examines the role of the courts and of other institutions through which these countries resolve disputes and protect rights in the context of health care resource allocation. It begins with a consideration of the role of law in health care relationships as a prologue to a discussion of law's role in resolving claims to health care resources. It next presents the problem of allocation of health care resources in the face of uncertainty and growing demands, and introduces the part law plays in this process. The focus then turns to the unique role of legal processes in each of the systems: the German social insurance system based on negotiated allocation of resources in a framework of legal obligations and rights; the British National Health Service, based on discretionary allocation of a fixed budget by payors and providers; the American public insurance system based on legal entitlements; and the American private insurance system based on contract with an ever more significant statutory overlay. It concludes with general reflections on the role of the courts and other dispute resolution mechanisms in health care resource allocation.

II. The Legal Dimension of Health Care Relationships

The relationships through which health care is provided and received have three important dimensions. Most obviously, perhaps, health care is delivered within professional relationships. One person, a professional, ministers to another person, a patient. The professional is entrusted with extensive authority over and responsibility for the patient, both on the basis of special education, training, and experience which allows the professional to understand and treat the patient's medical problems and because the ethical framework in which the professional operates is supposed to as-

3. *R v. Secretary of State for Social Services, ex parte Hincks*, 1 BMLR 93 (Ct. of App. 1980) (Opinion of Bridge, L.J.).

sure the professional's allegiance to the patient.⁴ Traditionally the patient was, as the word indicates, the passive party in the relationship. The patient trusted and was ministered to.⁵ In recent years the patient has become, at least in theory, a more active participant in the relationship. The patient is supposed to be educated regarding proposed interventions and their alternatives, and to consent to interventions before they occur.⁶ The patient has more control over his life and over the timing of his death. In reality, however, in the context of the professional-patient relationship, the professional still is largely in control.⁷

Second, the relationships through which health care is provided are also economic.⁸ The provider of health care is a merchant selling goods and services. The patient is a consumer. The patient, or the patient's insurer or employer, or the government, is a purchaser. Health care is a product provided in a market. Health care markets are governed by the laws of economics. Providers respond to incentives, providing more care when they are paid on a fee-for-service basis, and less when they are paid on a capitated or salary basis.⁹ This has always been so, but we in the United States have become much more acutely aware of health care's economic aspect in recent years.¹⁰ Other countries are also discovering this

4. See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE*, 4-17 (1982). Historically, health care institutions were also entrusted with the care of patients. They were sponsored by churches or by communities and supported by charitable contributions. They existed to provide a context in which professionals could provide care, not to make profit.

5. See Bradford H. Gray, *Trust and Trustworthy Care in the Managed Care Era*, 16 *HEALTH AFF.*, Jan.-Feb. 1997, at 34, 35.

6. BARRY R. FURROW, ET AL., 1 *HEALTH LAW* §§ 6-9, 6-11 (1995) [hereinafter "1 *HEALTH LAW*"].

7. *Id.* at §§ 6-17, 6-19.

8. The literature on health economics is vast and rapidly growing. The classic source is Kenneth Arrow, *Uncertainty and Welfare Economics of Medical Care*, 53 *AM. ECON. REV.* 941 (1963).

9. See Alan Hillman, Mark Pauly, & Joseph Kerstein, *How do Financial Incentives Affect Physicians' Clinical Decisions and the Financial Performance of Health Maintenance Organizations?* 321 *NEW ENG. J. MED.* 86 (1989). Health care institutions are also driven by the profit motive: for-profit entities seek profits for their shareholders; non-profit entities strive for prestige and growth and make sure their managers and medical staff are well provisioned.

10. See STARR, *supra* note 4, at 420-36; see, among the many proposals for reforming health care, acknowledging its economic dimension, ALAIN C. ENTHOVEN, *HEALTH PLAN* (1990); Mark V. Pauly, et al., *Incremental Steps Toward Health System Reform*, *HEALTH AFF.*, Spring 1995, at 125.

dimension of health care, although their responses to health care markets are very different from our own.¹¹

In the market environment, the purchaser of services has considerable power. The purchaser is often not the consumer (the patient), however, but the consumer's employer, or an insurer, or the government.¹² The interests of the purchaser are independent of, and not always aligned with, those of the patient. While the sick patient may want every medical intervention that may be of benefit, for example, the insurer, who actually pays for medical care, must marshal its resources carefully to assure that all of its insureds can be served, its premiums remain competitive, and its managers and shareholders are well compensated.¹³ Providers may be less powerful as sellers than they are as professionals, but they are far from powerless. They have a valuable commodity to sell, and often sell it under restricted market conditions where they are not exposed to the full force of competition.¹⁴ Under some market structures, moreover, the consumer is also not powerless, although the consumer is often the weakest participant in health care markets.¹⁵

Health care provision relationships also exist, finally, in a third dimension—they are legal relationships. In every country, legislatures have adopted a complex web of statutes that establish the framework in which health care is delivered. These statutes, for example, govern the licensing of professionals and institutions, the financing and expenditures of social insurance or national health service programs, the funding of health care education and research, and the protection of public health.¹⁶ In nations

11. See, e.g., HEALTH CARE REFORM (Chris Ham, ed. 1997); LAURENE A. GRAIG, HEALTH OF NATIONS: AN INTERNATIONAL PERSPECTIVE ON U.S. HEALTH CARE REFORM (1993) (discussing health care reforms currently underway in other developed countries, including market-based reforms).

12. In 1995, 20.8% of personal health care expenditures were out-of-pocket. Private health insurance paid 31.5% of health expenditures, the government 44.6%. Katharine R. Levit, et al., *National Health Expenditures, 1995*, 18 HEALTH CARE FINANCING REV. 175, 205 (1996). During 1994, 85.5% of privately insured Americans were insured through employer-related coverage. See HEALTH INSURANCE ASSOCIATION OF AMERICA, SOURCE BOOK ON HEALTH INSURANCE DATA, 1996, 13 (1997) [hereinafter "HIAA"].

13. This conflict has been recognized by the federal courts in private health insurance coverage litigation in the United States. See cases cited *infra* at notes 411 through 417.

14. See OCCUPATIONAL LICENSURE AND REGULATION, 7-9 (Simon Rottenberg ed., 1980).

15. See ENTHOVEN, *supra* note 10, and Pauly et al., *supra* note 10, for proposals to empower consumers in health care markets.

16. See *Medical Law*, INTERNATIONAL ENCYCLOPEDIA OF LAW (Herman Nys, ed.) (national monographs discussing how these issues are addressed in various nations).

with federal government structures, such as the United States and Germany, health laws exist at both the national and state level, and interact with each other in complex ways. In some countries, constitutions cabin the discretion that lawmakers have for designing these systems.

Administrative agencies also play an active role in most health care systems, regulating professionals and institutions and managing public programs for health care purchasing and provision. Agencies issue rules and make adjudications that govern health care relationships. Finally, in most countries the courts also oversee health care relationships by reviewing and enforcing the decisions of administrative care agencies, interpreting and enforcing contracts, and protecting those who suffer tortious or criminal injury.¹⁷

It is not surprising that health care relationships have a legal dimension. Even the most private relationships, those within families, have a public, legal dimension. The extent and density of legal intervention in health care, however, is sufficiently remarkable to require explanation. The law intervenes in health care relationships because of deficiencies that exist in professional-patient or market relationships.¹⁸ The courts are available to hear malpractice claims, for example, because professionals sometimes culpably harm rather than help patients. Licensing laws exist, at least in theory, because not all persons who would hold themselves out as professionals in fact meet minimal standards of competence and ethical conduct. Laws establish public health care financing programs because markets are only capable of making medical goods and services available to those who have money to exchange for those goods and services. Fraud and abuse laws penalize excessive and inappropriate responses of providers to the incentives offered by economic arrangements.

The legal structures through which diverse countries organize their health care systems vary greatly. They are products of different histories and different policy desiderata, and respond to different professional and

17. In many countries, including the United States, quasi-public entities exercise delegated power in governing or resolving disputes in health care relationships. The Joint Commission for Accreditation of Healthcare Organizations, for example, is one of the most important regulatory agencies in the American health care system, while the German *Krankenkassen* and *Kassenärztliche Vereinigungen*, although technically not government agencies, run the statutory health insurance system.

18. See Timothy S. Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825 (1995); Timothy S. Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525 (1988). Alternatively, laws exist because those who lack power in professional-patient relationships or economic relationships sometimes possess political power or are able to appeal to a court or agency's sense of justice.

economic arrangements. Nevertheless, legal institutions in various countries are more or less comparable; the problems and issues they address in health care are in many respects similar, and the legal structures and techniques nations have developed for addressing these problems and issues share regular patterns. Cross-national comparative analysis of legal structures in health care is both possible and instructive.

Among the most important functions that law serves in societies generally are resolution of disputes and articulation and protection of the rights of individuals. These functions are of course closely related, as disputes involve conflicting assertions of rights. In most countries courts are primarily responsible for these functions. It is the task of courts to attend to particular disputes, while legislatures and rulemaking bodies concern themselves with policymaking in general.¹⁹ However, other fora, such as administrative courts or arbitration or mediation panels, also play an important role in some nations in dealing with particular disputes. This Article focuses in particular on the role of courts and alternative dispute resolution mechanisms in health care systems. More specifically, it focuses on the part these institutions play in resolving disputes regarding resource allocation.

III. Law and the Allocation of Health Care Resources

One of the most important tasks facing modern health care systems is resource allocation. Health care resources must be allocated within health care systems in a context of scarcity and uncertainty. Health care resources are allocated through both professional and economic decisions. But the results reached through these mechanisms often cause disputes. These disputes are frequently resolved through legal institutions, and through the courts in particular.

By definition, all valuable resources are scarce, but awareness of scarcity in health care has become more acute in recent years as the demand for health care has increased. The proportion of national wealth that most developed nations spend on health care has increased in the past two decades.²⁰

The most important factor driving health care cost increases throughout the world, and particularly in the United States, is the continual prog-

19. See Lon Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353 (1978).

20. George J. Schieber, Jean-Pierre Poullier, & Leslie M. Greenwald, *Health System Performance in OECD Countries, 1980-1992*, 13 HEALTH AFF., Fall 1994, at 100, 101.

ress of medical technology.²¹ Health care is very labor intensive, often demanding expensive, skilled labor. Unlike other industries, capital investment and technological development rarely result in substantial savings of labor costs in the health care industry. The demand for health care technology is likely to continue to increase.

Another important factor inexorably driving the increase in the demand for medical care in the long run is the aging of the population. In developed countries, two trends are simultaneously increasing the average age of the population: people are living longer, and the birth rate is declining; thus at any one time there are more older people and fewer younger people.²² Assuming that most persons require periodic medical care, a longer life means a greater aggregate need for medical care. The chronic and degenerative conditions that accompany old age also result often in a greater need for medical care later in life, including in many instances the need for long term nursing care. Death is itself expensive, especially if it is repeatedly staved off. Moreover, the aging of the population not only increases the cost of a health care system, but also decreases its income, because older persons are less likely to be paying social insurance premiums or taxes to finance the services that they consume in ever-increasing volume. This inevitably leads to an imbalance of payments and income in social insurance funds or national health services, and to increased premium or tax levels.

Finally, other factors also contribute to health care cost increases. Administrative costs in health care are high and continually growing. Waste and abuse are costly and difficult to control.²³ For all of these reasons, demand for resources in health care is likely to continue to increase.

There seem to be limits, however, to the extent to which developed nations are willing to dedicate resources to health care. Virtually every

21. Joseph P. Newhouse, *An Iconoclastic View of Health Care Cost Containment*, 12 HEALTH AFF., Supp. 1993, at 152; Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525 (1996).

22. See *Gesundheitswesen in Deutschland, Kostenfaktor und Zukunftsbranche*, in SACHVERSTÄNDIGENRAT FÜR DIE KONZERTIERTE AKTION IM GESUNDHEITSWESEN (Sondergutachten ed., Nomos Verlagsgesellschaft, 1996). Aging of the population is a less important factor in explaining health care cost growth in the United States, but as the baby-boom generation reaches retirement age in the early twenty-first century, it is likely to become a more significant factor. Daniel N. Mendelson and William B. Schwartz, *The Effects of Aging and Population Growth on Health Care Costs*, 12 HEALTH AFF., Spring 1993, at 119.

23. See Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 YALE J. REG. 456 (1994).

developed nation is currently engaged in a more or less urgent debate regarding "health care reform," i.e., how to control the escalating costs of health care.²⁴ Inevitably this discussion turns to how to allocate increasingly constrained resources within health care systems.

For the past two generations, scarce resources have been allocated both to and within health care systems on the basis of professional judgment.²⁵ Health care professionals, and in particular physicians, have determined, on the basis of their professional training and experience, what diagnostic and treatment modalities would benefit their patients. In the era of fee-for-service medicine, which existed both in the United States and Germany until the recent past, the decision of a physician that a patient required a service usually meant that the service would be provided. Even British National Health Service resource allocation decisions, within the context of the national health budget, were until recently largely controlled by professionals.²⁶

These decisions regarding allocation of scarce health care resources, however, have been and continue to be made in a context of uncertainty. Though medicine is scientifically based, many medical procedures are not scientifically validated. There are significant variations in the use of medical procedures from country to country and from community to community within countries.²⁷ Even the way in which diseases are conceptualized varies from country to country.²⁸ Although outcomes studies are being pursued and practice guidelines formulated to reduce this variation, they still leave much of the territory of professional practice uncovered, and can offer only statistical probabilities, not specify what care is appropriate in particular cases.²⁹ Professional judgments regarding resource al-

24. See sources cited *supra* note 11.

25. See Elhauge, *supra* note 21, at 1536-47; Clark C. Havighurst & James F. Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. L. REV. 6, 25-30 (1975).

26. S. Harrison, *A Policy Agenda for Health Care Rationing*, in *RATIONING HEALTH CARE* 885, 889 (R.J. Maxwell, ed. 1995).

27. LYNN PAYER, *MEDICINE & CULTURE: VARIETIES OF TREATMENT IN THE UNITED STATES, ENGLAND, GERMANY, AND FRANCE* (1988); John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF., Summer 1984, at 6, 9.

28. See PAYER, *supra* note 27.

29. Arnold M. Epstein, *The Outcomes Movement-Will it Get us Where we Want to go?*, 323 NEW ENG. J. MED. 266 (1990); David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, HEALTH AFF., Spring 1988, at 19. See also Sandra J. Tanenbaum, *Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research*, 19 J. HEALTH POL., POL'Y & L. 27 (1994) (noting that doctors do not think in terms of statistical probabilities in making decisions).

location do not, therefore, reach predictable or even consistent results. Professional judgment as the basis of resource allocation tends to benefit some patients, but slights the needs of others.³⁰ Perhaps more importantly, professional judgments also err on the side of providing more, rather than fewer, procedures, as there is virtually no limit to the resources that can be allocated to health care with some beneficial effect.³¹ In the end, therefore, professional judgment must be supplemented, limited, and directed by other forms of decision-making that serve other ends.

Decisions allocating health care resources allocation are also, and ever more prominently, economic decisions. In most sectors of the economy, innumerable individual purchasing decisions determine the ultimate allocation of resources. These purchasers, applying their own value calculations, make discrete purchases, which in aggregate determine resource allocation within an economy. Uncertainty as to value is, therefore, a problem for individuals, not for society. It has long been believed, however, that individual purchasing decisions also have their limits as a resource allocation tool in health care markets.³² For this reason, markets have traditionally played only a limited role in health care resource allocation.

For market forces to work, purchasers must be relatively well informed. They must be able to evaluate the capacity of the product to meet their needs and to weigh comparatively a range of products with differing prices and values. Most consumers have a limited ability to judge their need for medical care and an even more limited capacity for evaluating

30. A fascinating example of this is the waiting lists of the national health service. It is well known that in Britain scarce health resources are allocated by the assignment of patients to waiting lists through professional judgment. Year after year, however, these waiting lists tend to be limited to patients with "varicose veins, hernias, painful or immobile joints, cataracts and enlarged tonsils, or they are women awaiting sterilization." STEPHEN FRANKEL AND ROBERT WEST, *RATIONING AND RATIONALITY IN THE NATIONAL HEALTH SERVICE: THE PERSISTENCE OF WAITING LISTS* 6 (1993). What these conditions have in common is that they are of little interest to doctors—the procedures that address them are routine, boring, and have little research potential. *Id.* at 7-12. They are thus continually shoved behind more glamorous and interesting conditions and procedures. See also David Hughes & Lesley Griffiths, "Ruling in" and "Ruling Out": Two Approaches to the Micro-Rationing of Health Care, 44 SOC. SCI. MED. 359 (1997) (describing doctor's decision-making behavior in deciding who gets cardiac surgery or neurological rehabilitation services in British NHS units.)

31. See Elhauge, *supra* note 21, at 1547.

32. See CONGRESSIONAL BUDGET OFFICE, *ECONOMIC IMPLICATIONS OF RISING HEALTH CARE COSTS* (1992) [hereinafter "CBO"] (discussing basic failures in health care markets.)

particular medical goods and services.³³ Not only, as noted above, are objective standards often lacking to this end, but even the standards that exist are not readily understandable by consumers. In fact, consumers have traditionally depended on providers, especially physicians, to act as agents in advising them what and how much medical care they need.³⁴ It is only to be expected, however, that permitting suppliers to direct purchasing decisions will result in excess demand. An additional obstacle to relying on the decisions of individual consumers to reach an efficient allocation of health care resources is the prevalence of health insurance.³⁵ Individual instances of the use of medical care are often very expensive, and are uncertain in frequency and extent. The high cost of medical care makes it difficult for most persons to pay for anything other than routine health care out of current income.³⁶ Moreover, most persons are risk averse, and are willing to pay sizable insurance premiums to avoid the uncertain risk of catastrophic liability for medical care costs. Further, most nations have concluded that individual health is a benefit to the state and that because poor health is a risk to which all are exposed, its costs should be borne by all.³⁷ Thus, in all developed countries, health care is to a greater or lesser degree financed by society or by the state. For all of these reasons, medical care tends in most countries to be covered by insurance, either social insurance provided by the community or by commercial insurance.

Insurance, however, permits individuals to obtain health care at less than market cost (often without cost altogether). This results in moral hazard: insureds obtain health care of questionable value, that they would probably not purchase themselves at full cost, because the care is essentially free.³⁸ But it is not free, of course. All insureds must collectively

33. *Id.* at 13.

34. *Id.* at 13-14.

35. *Id.* at 17-18.

36. The uncertain occurrence and tremendous and unpredictable variation of medical care costs make financing through individual savings problematic. In 1996 and 1997, Congress adopted legislation encouraging experimentation with medical savings accounts (MSAs) to stimulate market competition in health care by encouraging consumers to pay for health care out of special savings accounts. Whether MSAs in fact will result in a reduction of medical costs, however, is strongly contested. Compare Pauly, *supra* note 10, with J. SHIELDS, ET AL., CHANGES IN MEDICARE PROGRAM SPENDING UNDER ALTERNATIVE MEDICAL SAVINGS ACCOUNT MODELS (1995). Debt financing of health care, though common in the United States, puts providers at high risk, particularly when they provide care for the elderly.

37. DIANE LONGLEY, HEALTH CARE CONSTITUTIONS 1 (1996).

38. See Arrow, *supra* note 8 at 961-62; CBO, *supra* note 32 at 17-18. Insured persons face incentives to use more health care than they actually "need" either because they do not understand how to use health care appropriately or because the insured may derive

pay for it. The availability of insurance also lowers the cost to the individual of non-compliance with treatment requirements, again often imposing costs on the community. On the provider side, insurance encourages professionals to expand the demand for their services—to resolve uncertainty in favor of action—particularly where insurance pays the provider on a per-service basis.³⁹ Where insurance pays on a charge or cost basis (as was formerly often the case in many countries) not only the volume of services, but also the price of services expands continually.⁴⁰ In sum, the prevalence of insurance builds on the other market failures already present to weaken the incentives that individual consumers face for limiting their own demand for services, while at the same time creating incentives for providers to encourage increased demand for health care resources.

The limited ability of individual consumers to assure the efficient use of health care resources is only one problem with relying on markets to allocate resources in health care.⁴¹ Another problem is that markets cannot, without more, reach an equitable allocation of health care resources. Markets require purchasers with purchasing power. Insured consumers have such power (within the limits of their insurance policies), but in most countries a significant proportion of the population lacks the money that would be needed to pay the full premiums of insurance out of their own funds. In the United States, for example, nineteen percent of the adult population currently lack health insurance, and most of these are not insured because they cannot afford it.⁴² All developed countries, therefore, have created either social insurance systems or national health insurance systems to assure equitable access to health care. In the United States, over one quarter of the population are covered by public health insurance programs.⁴³

an advantage from the medical service beyond its actual benefit for improving health (such as paid release from work, gratification of a drug dependency, satisfaction of an abnormal psychiatric need for medical treatment, for example).

39. Havighurst & Blumstein, *supra* note 25, at 27-28.

40. PHYSICIAN PAYMENT REVIEW COMMISSION, REPORT TO CONGRESS: MEDICARE PHYSICIAN PAYMENT REFORM: AN AGENDA FOR ACTION 26-28 (1987) [hereinafter "PPRC"].

41. See, discussing other concerns regarding market-based approaches to reforming health care delivery and finance, Thomas Rice, *Can Markets Give us the Health System we Want?*, 22 J. HEALTH POL., POL'Y & L. 383 (1997); Robert G. Evans, *Going for the Gold: The Redistributive Agenda behind Market-Based Health Care Reform*, 22 J. HEALTH POL., POL'Y & L. 427 (1997).

42. Karen Donelan, et al., *Whatever Happened to the Health Insurance Crisis in the United States*, 276 JAMA 1346 (1996).

43. HIAA, *supra* note 12, at 13.

Even if we cannot, in the end, rely totally on the decisions of individual consumers to allocate resources in health care, markets nonetheless play a key and ever more important role in resource allocation. As noted earlier, the real purchasers of health care are often not patients, but employers who purchase health insurance and insurers, managed care organizations, or health benefit plan administrators who purchase health services. These purchasers are increasingly aware of their market power and increasingly savvy in bringing it to bear on resource allocation decisions.⁴⁴ The interests of purchasers, however, are not necessarily congruent with the interests of consumers (patients), on the one hand, and are often contrary to the interests of providers, on the other. Economic resource allocation decision-making, therefore, often result in conflicts that must be resolved through other means.⁴⁵

In developed nations, professional judgment and economic decisions interact in complex ways to yield health care resource allocation decisions. Many actors play a role in resolving uncertainty in health care. First, and most obviously, individual professionals continue constantly to make decisions as to the appropriateness and necessity of the use of health care resources in particular situations, based of course on professional judgment, but also with an eye to economic limitations and incentives. Second, health care institutions make resource allocation decisions, both by deciding how to allocate resources among particular types of equipment or facilities, and, in many countries, by allocating resources among particular patients.⁴⁶ Again, these decisions are influenced both by economic concerns and by pressure from the professionals that practice within the institutions. Third, purchasers and insurance administrators make resource allocation decisions.⁴⁷ In the United States, for example, employers that

44. See, e.g., PHYSICIAN PAYMENT REVIEW COMMISSION, ARRANGEMENTS BETWEEN MANAGED CARE PLANS AND PHYSICIANS (1995) (describing arrangements through which managed care organizations purchase services from physicians); Elizabeth W. Hoy, et al., *A Guide to Facilitating Consumer Choice*, 15 HEALTH AFF., Winter 1996, at 9 (describing health care purchasing arrangements of major corporations).

45. See, e.g., discussing conflict resolution issues in managed care, Eleanor D. Kinney, *Resolving Consumer Grievances in a Managed Care Environment*, 6 HEALTH MATRIX 147 (1996); Marc A. Rodwin, *Managed Care and Consumer Protection: What are the Issues?*, 26 SETON HALL L. REV. 1007 (1996).

46. This is obviously true in public health systems such as the British National Health Service, but is also true in the United States as well. See ANSELM STRAUSS, ET AL., SOCIAL ORGANIZATION OF MEDICAL WORK 189 (1985) (describing resource allocation processes in American health care institutions).

47. See Emily Friedman, *Managed Care, Rationing and Quality: A Tangled Relationship*, 16 HEALTH AFF., May-June 1997, at 174.

provide health insurance as an employment benefit negotiate policy coverage with health insurers and managed care organizations.⁴⁸ In most countries, governments are major purchasers of health care services, and make resource allocation decisions accordingly. In Britain, District Health Authorities and Fundholding General Practices establish resource allocation priorities by negotiating coverage contracts with hospitals.⁴⁹

Governments also make resource allocation decisions, however, in their role as legislators, administrators, and adjudicators. That is to say, law also plays a major role in resource allocation decisions. The serious limitations of both professional judgment and economic decision-making necessitate the existence of legal frameworks to address and protect concerns otherwise slighted.

One of the most important functions of governments in the resource allocation context is to address the disputes that inevitably arise when resource allocation decisions are made by professionals or purchasers. Insurers deny coverage for services that patients desire or deny payment for services that doctors have provided. Hospitals lack facilities that some patients consider essential. Government national health services fail to provide services that patients believe they need. In these circumstances, claims often end up before courts. In some countries, other fora are also available to consider these disputes. How these courts and other fora respond to these disputes in three different countries is the focus of concern in this Article. Before we turn to the details, however, we will first briefly describe the health care systems of the countries we will study.

IV. National Models for Financing Health Care

The countries we will consider represent the three major models of health care financing found in developed nations. Historically, the earliest model is the social insurance model, exemplified here by the German health insurance system.⁵⁰ Under this model, employers and employees are required to pay premiums (payroll taxes) to statutory insurance funds, which in turn pay for medical care. By this means, more or less universal insurance coverage is extended to employees and to related groups, such as

48. See Gail A. Jensen, et al., *The New Dominance of Managed Care: Insurance Trends in the 1990s*, 16 HEALTH AFF., Jan.-Feb. 1997, at 125 (describing employers arrangements with insurers and managed care plans).

49. See JOHN ØVRETVEIT, PURCHASING FOR HEALTH (1995).

50. See generally RICHARD KNOX, GERMANY'S HEALTH SYSTEM: ONE NATION, UNITED WITH HEALTH CARE FOR ALL (1993); John K. Iglehart, *Health Policy Report: Germany's Health Care System*, 324 N. ENG. J. MED. 503, 1750 (1991).

employees' dependents and former employees who are now retired, disabled, or unemployed.⁵¹ Framework laws normally guide social insurance programs by defining program coverage and regulating payments to providers. This Article examines, as exemplars of legal approaches to conflict resolution within social insurance systems, four of the most common types of disputes that arise within the German health care system: disputes involving the coverage of medical equipment,⁵² disputes involving coverage of alternative (complementary) medicine,⁵³ disputes involving utilization review of the services provided by individual physicians,⁵⁴ and disputes involving the fixing of budgets for physician and hospital services.⁵⁵

A second possibility is provision of tax-financed medical care by the state, exemplified here first by the British National Health Service.⁵⁶ Direct provision could be accomplished through government ownership of health care facilities and employment of health care professionals. This is not necessary, however, and in tax-financed systems a mixture of public and private provision often exists.⁵⁷ The direct payment model commonly involves the state most intensely in direction of the payment and provision of medical care. This Article will consider resolution of coverage disputes involving individual patients and institutional providers in the National Health Service.⁵⁸

This article also examines coverage disputes in the American Medicare and Medicaid programs as further examples of public health care financing.⁵⁹ Medicare resembles closely European social insurance systems, while Medicaid is a tax-financed system. These programs are unlike both

51. See Eckhard Bloch, *Kreis der versicherten Personen*, in *HANDBUCH DES SOZIALVERSICHERUNGSRECHTS, BAND 1, KRANKENVERSICHERUNGSRECHT* 485 (Bertram Schulin ed., 1994) (describing covered groups) [hereinafter "HANDBUCH SVR"].

52. See *infra* text accompanying notes 108-29.

53. See *infra* text accompanying notes 130-60.

54. See *infra* text accompanying notes 161-219.

55. See *infra* text accompanying notes 220-44.

56. Although this Article refers throughout to the British National Health Service, there are some differences in administration of the NHS between England and the rest of Britain, and, where these exist, we describe the English variant. See, describing the NHS, JUDITH ALLSOP, *HEALTH POLICY AND THE NHS TOWARDS 2000* (2d ed. 1995); CHRISTOPHER HAM, *HEALTH POLICY IN BRITAIN* (3rd ed. 1992).

57. In Britain, for example, the NHS is financed from central tax revenues, purchasing decisions are made at the district level by government health authorities, secondary and tertiary care are provided by non-profit "NHS trusts," and primary care is delivered by private general practitioners who contract with the government.

58. See *infra* text accompanying notes 261-84.

59. See *infra* text accompanying notes 287-380.

the German and British systems, however, in that coverage is an entitlement, not limited by a budget. This affects the nature of coverage disputes.

The third approach considered here is commercial or private health insurance. Private health insurance is available in virtually all developed nations. However, few nations (most notably the United States), rely on commercial insurance as a primary means of providing health care for the population generally. While commercial insurance exists technically by virtue of private arrangements, the relationships between insurers, insureds, and providers (including, under some circumstances, premium rates) are usually regulated by the government and commercial insurance is in some countries tax subsidized.⁶⁰ This Article examines one of the most common contexts in which commercial insurance disputes come before legal tribunals: the resolution of coverage disputes involving private health insurers in the United States, focusing in particular on disputes regarding the necessity or experimental nature of treatment.⁶¹

V. Germany: Social Courts and Arbitration Panels

The German health insurance program is an employment-based social insurance system. When Bismarck originated the system in the nineteenth century, its goal was to provide support for sick workers.⁶² Over the past century, however, the system has evolved into a comprehensive health insurance program, financing not only the health care needs of workers, but also of their dependents and of formerly employed persons, be they retired, disabled, or simply unemployed. All workers who earn less than DM 72,000 per year in the former western zone or DM 61,200 per year in the former eastern zone (1996 figures) are legally obligated to be insured.⁶³ About eighty-eight percent of the population is currently enrolled in the social insurance system, seventy-five percent being mandatory enrollees

60. In 1995, employer-provided health benefits were subsidized in the United States to the extent of \$90 billion. Alain C. Enthoven & Sara J. Singer, *Market-Based Reform: What to Regulate and by Whom*, HEALTH AFF., Spring 1995, at 105.

61. See *infra* text accompanying notes 381-435.

62. Iglehart, *supra* note 50, at 504-05; PETER ROSENBERG, THE ORIGIN AND DEVELOPMENT OF COMPULSORY HEALTH INSURANCE IN GERMANY, in POLITICAL VALUES AND HEALTH CARE: THE GERMAN EXPERIENCE 105 (Donald W. Light and Alexander Schuller, eds. 1986).

63. Reinhard Busse, et al., *The Future Development of a Rights Based Approach to Health Care in Germany: More Rights or Fewer?* in HARD CHOICES IN HEALTH CARE, 21, 26 (Jo Lenaghan, ed. 1997).

and their families and thirteen percent voluntary enrollees.⁶⁴ Nearly nine percent of the population is covered by private health insurance and two percent by government programs, and less than one percent are uninsured.⁶⁵ Health insurance premiums for employees are paid half by the worker and half by the employer.⁶⁶

The health insurance program is administered by self-governing, quasi-public, non-profit health insurance funds (*Krankenkassen*, here referred to as KKn, or KK in the singular). There are several hundred KKn, some of which are firm-specific (similar to our self-insured ERISA plans), some occupation-specific (such as special funds for craft-workers, miners, sailors, farmers), and some specific to particular geographic areas.⁶⁷ Historically Germans had only a limited ability to choose among these funds, but as of 1996, they have virtually unlimited freedom to choose among available insurers.⁶⁸ The populations insured by the various funds still vary significantly in terms of their age, income, and health status. Although Germany instituted a risk adjustment scheme several years ago to transfer income among the funds to compensate for this variance, premiums still vary from fund to fund.⁶⁹ The funds are organized at the state and federal level into associations.

Providers are also organized in corporate bodies. In particular, all doctors who provide services to members of the sickness funds are members of their state *Kassenärztliche Vereinigung* (KaV, plural KaVn), the union of insurance doctors,⁷⁰ and all dentists are organized into the *Kasenzahnärztliche Vereinigung* (KzV).⁷¹ The hospitals are also organized at

64. Friedrich Schwartz and Reinhard Busse, *Fixed Budgets in the Ambulatory Sector: the German Experience*, in *FIXING HEALTH BUDGETS*, 93, 95 (Friedrich Schwartz, et al. eds., 1996) [hereinafter, "Fixing Health Budgets"].

65. BUNDESMINISTERIUM FÜR GESUNDHEIT, *DATEN DES GESUNDHEITSWESENS*, 1995, 278.

66. § 249(1) SGB V (Sozialgesetzbuch chapter 5).

67. Busse, et al., *supra* note 63, at 26.

68. § 173 SGB V.

69. Busse, et al., *supra* note 63, at 27; *see*, describing the German risk adjustment system, Ashley Files & Margaret Murray, *German Risk Structure Compensation: Enhancing Equity and Effectiveness*, 32 *INQUIRY* 300 (1995). During the first 6 months of 1996, DM 10.4 billion was transferred through the risk adjustment mechanism, mainly from the white collar insurance funds to the local, blue-collar, funds. *See* H. Korzilius, *Risikostrukturausgleich behindert Wettbewerb*, 93 *DEUTSCHES ÄRZTEBLATT*A-2440 (1996).

70. §§ 77, 95 SGB V.

71. § 77 SGB V.

the state and national level.⁷² The genius of the German system is that resources for health care are allocated through the means of negotiations between these corporate entities representing providers on the one side, and the KKn, their organizational entities on the other, within a statutory framework but without direct government intervention.

Three principles are at the base of German coverage and payment policy. The first is a principle of comprehensiveness: the insurance system covers a comprehensive list of preventive and curative health care services, described below. The second is the *Sachleistungsgrundsatz*, or principle of direct payment of providers by the KKn or by the provider corporate organizations which are in turn paid directly by the KKn.⁷³ Until a 1997 amendment to the law, which is now being implemented, patients treated by a doctor received no information as to what services the doctor had billed for or how much he had billed. The level of these direct payments are established through negotiations between the corporate organizations and the KKn.⁷⁴ These negotiations take place in the context of the third principle, *Beitragsstabilität*, or premium stability.⁷⁵ Health insurance premiums are not supposed to rise faster than the incomes on which they are based. Payments to providers, therefore, should not be more generous than those that can be funded through stable premiums.

The German system of paying for health care is a result of the interaction of these principles. The principle of direct payment makes possible the use of budgets. For the major sectors of health care (ambulatory physician care, hospital care, drugs, and dental care), resources are allocated through budgets between representatives of the health insurance funds and representatives of the providers. The regional KaVn, for example, have, for the past twenty years, annually negotiated budgets with the sickness funds for funding all physicians' services within the region. At first these budgets were voluntary, and then from 1989 until 1997 they were mandatory.⁷⁶ The budgets are negotiated with reference to the principle of premium stability, within guidelines established by the Concerted Action in

72. § 108a SGB V. This provision was added by the second *Neuordnungsgesetz* of 1997. Prior to that time the hospital associations were private and had no legal status.

73. §2(2) SGB V. This principle is not absolute however, and various exceptions are provided for indemnification. See *Rechtliche Grundprinzipien der gesetzlichen Krankenversicherung und ihre Probleme*, in *HANDBUCH SVR*, *supra* note 51, at 177, 211-24.

74. See, e.g., describing this process with respect to physician payment, Schwartz & Busse, *supra* note 64.

75. §§ 71, 141(2) SGB V.

76. Schwartz & Busse, *supra* note 64, at 96-100.

Health Care organization, an organization representing all of the major interest groups in health care, established to guide these negotiations.⁷⁷

The KaVn pay doctors from these budgets on a fee-for-service basis based on a national relative value scale, the *Einheitlicher Bewertungsmaßstab für ärztliche Leistungen* (EBM), which assigns a point value to each procedure.⁷⁸ The weight of points for particular services or specialties is further modified by each regional KaV using its own *Honorverteilungsmaßstab* (HVM) to reach a total quarterly point value for each member physician.⁷⁹ These point numbers are summed to yield a total number of points for all services billed during the quarter by all physicians, which is then divided into the quarterly budget to yield a point value.⁸⁰ This point value is then multiplied by the number of points billed by each doctor to determine the amount each particular doctor is paid. Under the EBM implemented in 1996, payments are also limited on a per patient basis by what are known as *praxisbudgets*, subject to a variety of exceptions.⁸¹

Hospitals are also paid on a negotiated basis. The operating costs of German hospitals have in recent years also been financed through budgets negotiated with the KKn, while the capital costs have been financed by the states.⁸² Operating costs are funded in part through diagnosis-determined

77. *Id.* at 97; § 87 SGB V.

78. Winfried Funk, *Vertragarztrecht*, in *HANDBUCH SVR*, *supra* note 51, at 852, 888-90. Traditionally the EBM was further modified under the *Bewertungsmaßstab für ärztliche Leistungen* (BMÄ) for the primary sickness insurance funds, which essentially covered blue collar workers, and the *Ersatzkassen Gebührenordnung* (E-GO) for the substitute funds, which provided somewhat more generous payments for the coverage of white collar workers. Reimbursement is now essentially identical for both types of insurance.

79. *Id.* at 892. Each regional KaV establishes its own HVM for dividing up its own budget, and in some regions separate sub-budgets are established for various specialties, resulting in different specialists receiving more or less per point billed than others. See GÜNTHER SCHNEIDER, *HANDBUCH DES KASSENARZTRECHTS* 435-41 (1994).

80. Klaus-Dirk Henke, et al., *Global Budgeting in Germany: Lessons for the United States*, *HEALTH AFF.*, Fall 1994, at 7-21. In the recent past, moreover, attempts have been made to improve compensation for primary care physicians and to decrease payment for technical services. There has also been a movement toward grouping some services, which are billed together for a lump sum.

81. See Thomas Ballast, *Mengenbegrenzung im EBM: Praxisbudgets*, *DIE ERSATZKASSE*, Dec. 1996, at 440.

82. A brief English description of the program is found in U.S. GENERAL ACCOUNTING OFFICE, 1993 GERMAN HEALTH REFORMS 32-34, 45-46 (1993). For an exhaustive description of the system, see KARL HEINZ TUSCHEN & MICHAEL QUAAS, *BUNDESPFLEGESATZVERORDNUNG: KOMMENTAR MIT EINER UMFASSENDEN EINFÜHRUNG IN DAS RECHT DER KRANKENHAUSFINANZIERUNG* (3. Auflage 1996).

per-case (*Fallpauschal*) and procedure-specific (*Sonderentgelt*) payments.⁸³ The classification scheme for these payments is established through negotiations between the hospitals and regional KKn at the national level, while the payment level is based on KKn/hospital association negotiations.⁸⁴ Hospital expenses for patients not covered by the case or procedure specific payments, and other expenses, are covered by flexible budgets negotiated between the individual hospitals and the KKn.⁸⁵ When negotiations are unsuccessful in establishing budgets, disputes are often submitted to arbitration panels, known as *Schiedsstellen*, discussed below.

The German health insurance system is actively supervised by a system of special courts, the *Sozialgerichte*, or social courts. Individual disputes regarding coverage of services or payment of providers and arbitration panel decisions are often appealed to the social courts.⁸⁶ Sixty-nine social courts of the first instance, which hear social insurance disputes, exist throughout Germany.⁸⁷ Appeals from decisions of these disputes are made to the *Landessozialgerichte*, which exist in each of the sixteen German states.⁸⁸ In some instances, appeals from the *Landessozialgerichte* can be taken to the *Bundessozialgericht* (BSG), which sits in Kassell.⁸⁹ In 1996, 131 of the 775 appeals resolved by the BSG involved sickness insurance claims, and another ninety-eight involved the claims of insurance doctors, making health insurance issues the second largest category of cases decided by the BSG after pension cases.⁹⁰ Germany is a civil law country, and court decisions do not have precisely the same precedential weight and effect that they have in the United States. Nevertheless, the decisions of the social courts, and of the BSG in particular, are taken very se-

83. See TUSCHEN & QUAAS, *supra* note 82, at 72.

84. *Id.*

85. *Id.* at 73-75.

86. See Peter Kummer, *Das sozialgerichtliche Verfahren*, in *SOCIALRECHTSHANDBUCH* 603 (Bernd Baron von Maydell and Franz Ruland eds., 1996). Germany has a number of systems of special courts, in addition to its general jurisdiction civil and criminal courts (headed by the *Bundesgerichtshof*) and its constitutional court (the *Bundesverfassungsgericht*). These courts have jurisdiction over tax law, employment law, administrative law and social law. See *GESCHÄFTSVERTEILUNGSPLAN DES BUNDESSOZIALGERICHTS FÜR DAS JAHR 1997*, reprinted in *50 NEUE JURISTISCHE WOCHENSCHRIFT* [NJW] 35* (1997).

87. Kummer, *supra* note 86, at 609-11.

88. *Id.* at 611-13.

89. *Id.* at 613-15.

90. *DIE TÄTIGKEIT DES BUNDESSOZIALGERICHTS IM JAHRE 1996: EINE ÜBERSICHT* 29 (Bundessozialgericht ed., 1997).

riously and play a major role in defining the contours and boundaries of German health insurance law.

Panels of judges preside over the social courts. In the courts of the first instance there are usually three judges, a professional judge and two lay judges.⁹¹ In disputes regarding insurance coverage, one of the lay judges represents insureds, and the other represents the employers.⁹² In matters concerning the relationship between health insurance companies and insurance doctors, one of the lay judges represents the insurance companies, the other the doctors; in matters concerning the internal relationships of insurance doctors, both represent the doctors.⁹³ At the state and national social court level, the panel consists of three professional judges and two lay judges.⁹⁴ The BSG is divided into a number of panels of judges, called senates, each of which has jurisdiction over a particular body of cases. The Sixth Senate, for example, hears disputes involving insurance doctors.

The courts hold oral proceedings in which the parties are often, though not always, represented by attorneys. The judges take an active role in the proceedings, interrogating the parties and their attorneys. They have, in fact, an obligation to investigate the facts thoroughly, and to assist the parties in effectively presenting their cases.⁹⁵ Access to the social courts has traditionally been free (though public law entities such as insurance companies must pay a fee), and the victorious claimant has the possibility of receiving his litigation costs from the losing insurance company.⁹⁶ Disputes involving social insurance programs end up, therefore, in court with great frequency.⁹⁷

In general, the social courts have been very receptive to the claims of insureds and providers. Benefit coverage claims, however, only come before the courts in marginal cases. As noted above, the KKn are required by law to offer a comprehensive range of services. Social Insurance is governed by *Sozialgesetzbuch V* (the fifth Social Law Book, abbreviated SGB V). Section 2 SGB V requires the Social Insurance Funds to make avail-

91. § 12(1) SGG (*Sozialgerichtsgesetz*).

92. SGG § 12(2).

93. SGG § 12(3).

94. SGG §§ 33, 40.

95. Kummer, *supra* note 86, at 657-59.

96. *Id.* at 695-700.

97. During 1994, 178,636 complaints were filed in the social courts of the first instance, 17,954 appeals filed in the *Landessozialgerichten*, and 713 appeals and 1511 requests to file an appeal were filed in the BSG. Kummer, *supra* note 86, at 611, 612, 615. Only a minority of these, of course, were health insurance cases.

able to their insureds (usually through direct arrangements with providers) the services listed in chapter 3 of SGB V.⁹⁸ The first section of chapter 3⁹⁹ specifies as covered under the insurance program services for the prevention, early diagnosis, and treatment, as well as rehabilitation services needed to prevent or reduce a handicap or need for nursing care. The chapter goes on to identify specifically medical care, dental care, medications, dressings, various therapists and treatments, medical devices, hospital care, and rehabilitation or occupational therapy as covered services for the treatment of illness.¹⁰⁰ The statute imposes a general limitation that services must be necessary and economically provided and must correspond with the general state of medical knowledge and attend to medical progress.¹⁰¹ Additional sections impose a host of limitations on particular procedures, including cost-sharing obligations that have increased significantly under recent legislation. Payment for dental prostheses in particular has been increasingly limited in recent years.¹⁰²

The structure of the German health care system, as described above, minimizes opportunities for disputes between insureds and insurers or between patients and providers over benefit coverage issues. The fee-for-service physician payment system, for example, rewards physicians for delivering as many services as possible to their patients. The physician has until recently also faced only limited incentives for controlling prescribing. From 1993 until 1996, the law imposed budgets (first fixed, thereafter negotiated) on prescribing by region.¹⁰³ These prescribing limits only applied to physicians as a group, however. Although they were substantially exceeded in 1996,¹⁰⁴ sanctions for exceeding the limits have not in fact yet been imposed.¹⁰⁵ Physicians who substantially exceed their peers in providing services or prescribing medications risk cutbacks in their payments under the German utilization review system, discussed below. This only

98. § 2(1) SGB V.

99. § 11 SGB V.

100. § 27(1) SGB V.

101. § 2 SGB V.

102. § 30 SGB V.

103. GENERAL ACCOUNTING OFFICE, *PRESCRIPTION DRUG SPENDING CONTROLS* (1994); Reinhard Busse & Chris Howorth, *Fixed Budgets in the Pharmaceutical Sector in Germany: Effects on Costs and Quality*, in *FIXING HEALTH BUDGETS*, *supra* note 64, at 109, 114-16.

104. Josef Maus, *Massive Ärzteproteste zeigen Wirkung*, 93 DEUTSCHES ÄRZTEBLATT A-3235 (1996).

105. For a discussion of the difficulties of imposing the sanctions, see Wolfgang Spellbrink, *Rechtsfolgen der Budgetüberschreitung nach § 84 SGB V*, 15 MEDIZINRECHT 65 (1997).

occurs after relatively extreme limits are reached, however, and the income-maximizing strategy of the individual physician is to provide the greatest possible number of services up to point where utilization review is triggered.

Other factors in addition to the payment system also limit conflicts over insurance benefit coverage. Patients have essentially free choice of physician. Any patient refused services by a physician is free to find another. All insureds, moreover, have free choice of insurer as of January 1, 1996, and white collar employees have had free choice for much longer.¹⁰⁶ In the past, insurers have competed in terms of serving their insureds, including making services available, rather than by limiting premiums.¹⁰⁷ Insurance companies, therefore, deny coverage requests only relatively infrequently.

A. Coverage Disputes: *Hilfsmittel*

Coverage disputes do arise, however, even in the German system. One of the most common objects of coverage disputes is *Hilfsmittel*, which is covered by statutory health insurance under SGB section 33. *Hilfsmittel* is roughly analogous to the category of durable medical equipment in the United States, but includes more broadly, "[v]ision and hearing aids, prostheses, orthopedic and other medical equipment, that in particular cases is necessary to assure the success of treatment of the sick or to compensate for a disability, so long as the equipment is not an article used generally by people in daily life (or excluded by other code sections)."¹⁰⁸ Examples from recent opinions include hand-held devices that detect color for the blind or fax machines for the deaf.¹⁰⁹ The BSG issued twenty published decisions regarding *Hilfsmittel* between 1990 and 1996, making this area one of the most hotly contested areas considered by the BSG.

Cases normally come to the court when an insured requests coverage of a particular device from a KK and the request is denied. Because KKs rarely deny coverage with respect to other treatments and services, it is cu-

106. See Johann Behrens, *Die Freiheit der Wahl und die Sicherung der Qualität (Versuch einer Antwort auf [nicht nur] amerikanische Fragen)*, in *GESUNDHEITSSYSTEMENTWICKLUNG IN DEN USA UND DEUTSCHLAND 197, 199* (Johann Behrens et al. eds., Nomos Verlagsgesellschaft 1996).

107. See Sabine Richard & Karl-Heinz Schönbach, *German Sickness Funds under Fixed Budgets*, in *FIXING HEALTH BUDGETS*, *supra* note 64, at 187, 191 (describing competition among sickness funds to offer more services).

108. § 33 SGB V.

109. BSG, 1/17/96, 3 RK 39/94, SozR 3-2500, § 33, No. 19 (fax machine); BSG, 1/17/96, 3 RK 38/94; SozR 3-2500, § 33, No. 18 (color detection apparatus).

rious that denials arise so often in this area. Disputes frequently involve very expensive equipment, however, which often might be useful to sizable categories of disabled persons (the blind, deaf, paralyzed, and so forth).¹¹⁰ *Hilfsmittel* disputes can be seen as test cases, therefore, involving potentially large sums of money, and when the KKn believe that a denial is justified, appeals of the denial will be vigorously resisted by the KKn.¹¹¹

The insureds win a surprising proportion of appellate decisions involving *Hilfsmittel* claims, and in many cases where the lower court upholds the KK denial of coverage, the appellate court remands for reconsideration of additional factors not attended to by the lower court. The social court decisions give only cursory attention to several statutory coverage requirements. Although SGB V, section 128, requires the sickness funds to publish jointly a list of covered *Hilfsmittel*, together with maximum prices to be paid for each item, the courts routinely treat this list as advisory rather than as binding; the fact that a specific item is not on the list is of no consequence.¹¹² Second, although SGB section 33(1) on its face requires that a device have curative potential and or completely compensate for a handicap, the courts find this requirement satisfied if a device will partially compensate for a handicap.¹¹³

Disputes normally center around three other *Hilfsmittel* coverage requirements. First, the statute excludes coverage for objects requested by handicapped persons that non-handicapped persons use regularly in their daily life.¹¹⁴ The question here is not whether the item is widely used—glasses and hearing aids, for example, are covered despite the fact that millions of persons use them.¹¹⁵ Rather, the question is whether the item is widely used for non-medical purposes. The court tends to take a statistical approach to this question. Computers (sought as perception or communi-

110. See, e.g., BSG, 2/6/97, 3 RK 1/96 (unpublished) (computer systems costing DM 9100 sought as communications device for handicapped child) (on file with author).

111. In some cases the KKn also resist paying for a piece of equipment, not because it is not needed, but because some other entity (most often vocational rehabilitation insurance) is responsible for paying for it. See, e.g., BSG, 7/26/94, 111 RAr 115/93, SozR 3-2500 § 33, No. 10 (orthopedic shoes used only for work not covered by sickness funds).

112. See BSG, 1/17/96, 3 RK 16/95, SozR. 3-2500, § 33, No. 20.

113. See *id.* (fact that air filter only made one room in dwelling suitable for handicapped person not decisive if room was bedroom and made it possible for person to sleep.) The fact that the device does not directly substitute for a body part is also not important, if the device in fact compensates indirectly for the loss of a bodily function; BSG, 1/17/96, 3 RK 38/94, Breithaupt 633 (1996) (color recognition device that does not cure or totally compensate for blindness, but assists a blind person to perceive things).

114. § 33(1) SGB V.

115. BSG, 1/17/96, 3 RK 39/94, SozR 3-2500, § 33, No. 19.

cation devices by the handicapped) were owned by twelve percent of the population in 1995, and were thus held to be objects widely used in daily life.¹¹⁶ Fax machines (sought by a deaf person for communication) were owned by only 2.3% of private persons in 1994, and were therefore held not to be excluded.¹¹⁷ Obviously, the extent of use of objects such as computers and faxes changes over time, generally in the direction of moving objects from covered to uncovered status as they become more widely used by the general public. The coverage exclusion for widely used devices is itself subject to two exceptions, however. First, even items that are in wide use may be covered, at least in part, if they are very expensive and thus not affordable by the insured.¹¹⁸ Second, to the extent that items are similar to items in general use, but cost more because they have been adapted for the handicapped, such as hypoallergenic mattresses and pillows, the additional costs will be covered.¹¹⁹

A second requirement, found in SGB V section 12, provides that coverage is extended only to items the coverage of which are cost-effective. In applying this requirement, the BSG tends to perform a cost-benefit analysis, considering both the cost of the item and how useful it would actually be to the handicapped person in practice.¹²⁰ The fact that costs for ever more sophisticated devices for aiding the handicapped have dropped dramatically in recent years is relied on by the courts to support a continual expansion of coverage for these devices. Indeed, sometimes the BSG explicitly acknowledges that it ruled against coverage of a particular device when it was earlier disputed, but that costs have now dropped to the extent that coverage is warranted.¹²¹ Also relevant in some of these cases are issues of whether the item is in fact necessary, or whether it might be a luxury. The BSG tends to interpret "need" expansively, however, finding that

116. BSG, 8/23/95, 3 RK 7/94, SozR 3-2500, § 33, No. 16. The BSG followed this determination in a later case, 2/6/97, 3 RK 1/96 (unpublished).

117. BSG, 1/17/96, 3 RK 39/94, SozR 3-2500, § 33, No. 19.

118. BSG, 10/15/95, 1 RK 18/94, SozR 3-2500, § 33.

119. BSG, 1/17/96, 3 RK 39/94, SozR 3-2500, § 33, No. 19 (though fax paid for by insurance, costs of using it are similar to ordinary telephone costs, and must be paid by insured); BSG, 1/25/95, 3/1 RK 63/93, SozR 3-2500, § 33 (bed adapted for handicapped child covered).

120. BSG, 11/21/91, 1 RK 43/89, SozR 3-2500, § 33 No. 4 (electric reading device that costs DM 5900). In some of these cases this consideration is almost mechanical. In the color detection device case, the court found that the object would be used 10 times a day, and was thus justified given its cost of DM 1470. BSG, 1/17/96, 3 RK 38/94.

121. See discussion of coverage of writing telephones for the deaf in BSG, 10/25/95, 3 RK 30/94; SozR 3-2500, § 33, No. 17.

the blind have a right to be able to read,¹²² that persons who are deaf have a right not to be isolated from others,¹²³ and that persons who are paralyzed have a right to move freely in the environment.¹²⁴ The BSG has also found, moreover, that disabled persons have a right to have equipment provided to compensate for their handicaps rather than to be expected to rely on family members or others around them for help.¹²⁵ Sometimes the BSG invokes the human rights sections of the Constitution as a source of these rights.¹²⁶

Finally, the BSG inquires under SGB V section 34 whether the items are so inexpensive that they are readily affordable without insurance assistance, or whether their therapeutic value is disputed.¹²⁷ Here again, the court tends to be generous, rejecting, for example, the policy of a KK that excluded a breast milk pump that cost DM 255 from coverage as an item of minimal cost.¹²⁸ On the other hand, the BSG has upheld exclusion of hearing aid batteries, which are cheap enough to be affordable by most insureds, and are covered by welfare for those who truly cannot afford them.¹²⁹

In sum, the decisions of the social courts have continually supported expansion of coverage in this area. This may explain, in part, why *Hilfsmittel* costs have been one of the fastest growing areas of insurance coverage.

B. Coverage Disputes: Alternative and Experimental Medicine

The decisions of the BSG also appear to be a factor in expanding coverage of experimental and alternative medicine. On their face, the health insurance sections of the German Social Code would appear to strictly limit the services for which the health insurance funds are required to pay.

122. BSG, 8/23/95, 3 RK 7/95, SozR 3-2500, § 33, No. 16. The court also observed in this case that to force a blind person to rely on others to read to him would violate his constitutional right to privacy in communication.

123. BSG, 10/25/95, 3 RK 30/94, SozR 3-2500, § 33, No. 17.

124. BSG, 6/8/94, 3/1 RK 13/93, SozR 3-2500, § 33, No. 7.

125. BSG, 1/17/96, 3 RK 38/94, SozR 3-2500, § 33, No. 18. The Court also considers whether the device is necessary for assisting the handicapped for leading normal lives in general, or whether it is rather needed to permit the pursuit of a particular vocation. If an item is vocation specific, it is not the responsibility of the sickness funds, but might be paid for by the vocational rehabilitation insurance program.

126. See BSG, 2/26/91, 8 Rkn 33/90, SozR 3-2500, § 33, No. 3 (constitutional right of freedom of movement justifies payment for adaptive seat for auto).

127. § 34(4) SGB V.

128. BSG, 9/28/93, 1 RK 37/92, SozR 3-2500, § 34, No. 2.

129. BSG 6/8/94, 3/1 RK 54/93, SozR 3-2500, §33, No. 9.

Section 2, which defines the scope of services generally, provides that services must be provided effectively and economically, and only to the extent necessary,¹³⁰ further specifying that quality and efficiency of services must comply with the general state of medical knowledge.¹³¹ Section 12 states even more emphatically that providers may not provide, insureds request, or insurers pay for services that are unnecessary or that are not economically provided, a directive repeated in sections 70 and 72.¹³² Section 28 again obligates doctors to provide services according to the standards of medical practice, while section 34 excludes payment for ineffective medications.¹³³ Finally, section 135 provides that new diagnostic and treatment methods may not be ordered at the cost of the sickness funds until the Federal Commission of Insurance Doctors and Health Insurance Funds at the request of a KaV or the federal organization of KKn has made recommendations regarding the recognition of the new procedure and qualifications for doctors who may deliver it.¹³⁴ Under 1997 amendments to the health insurance law, these recommendations must consider the medical necessity and efficiency of the procedure as well as its effectiveness.¹³⁵

The legislative history of the SGB supports a restrictive interpretation of these provisions. The report accompanying the 1989 Health Reform Law, the last major revision of coverage provisions, emphasized that payments by the health insurance funds must be limited to truly needed services, specifically excluding services

... that are provided with methods that are not generally accepted. New procedures, that are not sufficiently researched, or exotic treatment methodologies (paramedical procedures), that are recognized, but that have not been proved, are not within the responsibility of the health insurance funds. It is not the task of the health insurance funds to finance medical research. This is also true when new methods in particular cases can lead to a healing of the disease or to a diminution of a disability.¹³⁶

130. § 2(4) SGB V.

131. § 2(1) SGB V.

132. §§ 12(1), 70(10), 72(2) SGB V.

133. §§ 28(1), 34(2) SGB V.

134. § 135(1) SGB V; see ANDREAS SCHMIDT-RÖGNITZ, DIE GEWÄHRUNG VON ALTERNATIVEN SOWIE NEUEN BEHANDLUNGS-UND HEILMETHODEN DURCH DIE GESETZLICHE KRANKENVERSICHERUNG 92-93, 96-97 (1996).

135. Horst Dieter Schirmer, *Das Kassenarztrecht im 2. GKV-Neuordnungsgesetz* —BGBl. 1997 I S. 1520—, 15 MEDIZINRECHT 431, 447 (1997).

136. Bundestag Print, 11/2237, 148, 157.

In practice, however, the restrictions imposed by SGB V, as interpreted by the BSG, are far less onerous than would first appear. As long as a code exists under the EBM, the codebook under which procedures are billed, a service can be provided and the doctor paid for it; it is subject only to retrospective review for excessive provision of care under the *Wirtschaftlichkeitsprüfung* process described below.¹³⁷ The EBM applies primarily to traditional medicine, however, and only covers new and experimental treatments to the extent they have been reviewed under the section 135 new diagnostic and treatment procedure approval process.

Where services are either experimental or non-traditional, and thus not yet recognized in the EBM, coverage policy becomes more complicated, although the service may still ultimately be paid for by the KKn.¹³⁸ First, section 2 SGB V states that alternative therapeutical modalities cannot be excluded from coverage.¹³⁹ Section 34, which deals with covered drugs, refers to "alternative therapeutic modalities such as homeopathy, phytotherapy, and antroposophy" and requires drugs from these therapeutic modalities to be evaluated according to the standards of these modalities.¹⁴⁰ This section does not explicitly limit alternative therapeutic modalities to these three schools, however, and other schools of treatment may be covered by sections 2 and 34. A provision in the recently adopted 1997 health reform law goes even further, amending section 135 to provide that new procedures are supposed to be reviewed according to the state of knowledge "in the particular school of therapy."¹⁴¹ This provision was clearly added to encourage the extension of coverage to non-traditional medicine.

The rulings of the BSG interpreting the coverage of alternative or experimental medicine have been complex and contradictory. For a decade, the Third Senate of the BSG, which decides issues of coverage policy, has

137. See Bertram Schulin, *Alternativ Medizin in der gesetzlichen Krankenversicherung*, 40 ZEITSCHRIFT FÜR SOZIALREFORM 546, 553 (1994).

138. See generally SCHMIDT-RÖGNITZ, *supra* note 134.

139. § 2(1) SGB V.

140. § 34(2) SGB V; see also § 92(2) SGB V (requiring drug guidelines for drugs from the separate therapy modalities to be evaluated by experts from these modalities). For a description of these modalities, see Rüdiger Zuck, *Der Standort der Besonderen Therapierichtungen im deutschen Gesundheitswesen*, 44 NEUE JURISTISCHE WOCHENSCHRIFT 2933, 2934 (1991).

141. Zweites Gesetz zur Neuordnung von Selbstverwaltung und Eigenverantwortung in der gesetzlichen Krankenversicherung (2.GKV-NOG), § 50, to be codified at § 135(a)(1).1 SGB V. Alternative medical procedures, however, must be evaluated in terms of their effectiveness, necessity, and efficiency, and must be evaluated in terms of comprehensible scientific knowledge. Schirmer, *supra* note 135, at 447.

recognized the extension of coverage to alternative or experimental treatment methods in cases of severe illness of unknown origin where traditional treatment methods are ineffective or where recognized treatments are not appropriate for the particular case.¹⁴² In either case, the court has required a plausible case to be made that the treatment can be effective.¹⁴³ The court has been willing to order the sickness fund to indemnify the patient, however, where a disputed treatment proves in fact to be effective.¹⁴⁴ The 14a Senate also supported alternative medicine in a decision rejecting the discipline of a dentist who refused to use amalgam fillings with mercury in them because of his adherence to natural healing.¹⁴⁵ The BSG relied in this decision on the constitutional arguments discussed below. A recent decision of the social appeals court for Lower Saxony went even further, recognizing coverage for plausible alternative treatment, even though the disease is not life threatening and traditional treatment may be available.¹⁴⁶

Arguments that SGB V should be interpreted to cover alternative and experimental treatments not yet evaluated under the section 135 procedures are based in part on the structure of the Social Code. SGB V governs both the relationships between insurers and their insureds and between insurers and providers. It is argued that provisions like section 135 may limit payment of providers to particular procedures, but do not limit the independent and higher right of insureds to receive other procedures where such procedures are otherwise covered by SGB V.¹⁴⁷ Even though providers may not bill directly for services not covered by the EBM, it is argued, patients may receive such services and then claim indemnification from their insurer.¹⁴⁸ In short, the commentators argue that the direct payment principle is subordinate to the comprehensiveness principle.

142. SCHMIDT-RÖGNITZ, *supra* note 134, at 98-99, 107; Rolf-Ulrich Schlenker, *Die Außenseitermedizin und das System der gesetzlichen Krankenversicherung*, 39 DIE SOZIALGERICHTSBARKEIT 530 (1992); Matthias von Wulffen, *Besondere Therapiemethoden in der Rechtsprechung des Bundessozialgerichts*, 43 DIE SOZIALGERICHTSBARKEIT 250 (1996).

143. SCHMIDT-RÖGNITZ, *supra* note 134, at 100-01.

144. Stephan Biehl and Heinz Ortwein, *Sind Außenseitermethoden Maßnahmen außerhalb des Leistungskataloges der gesetzlichen Krankenversicherung (GKV)?*, 38 DIE SOZIALGERICHTSBARKEIT 529, 531-32 (1991).

145. BSG, 9/8/1993, 14a RKa 7/92, SozR 3-2500, § 2, No. 2.

146. LSG Niedersachsen 8/30/95, L 4 Kr 11/95, Breithaupt 191 (1996).

147. See SCHMIDT-RÖGNITZ, *supra* note 134, at 104-06; Schulin, *supra* note 136, at 558-59.

148. SCHMIDT-RÖGNITZ, *supra* note 134, at 101.

Further, some commentators have argued that the German Constitution would be violated if SGB V were interpreted to permit decisions of a commission of doctors and insurers to establish rules that would limit the rights of insureds.¹⁴⁹ The delegation doctrine is much more robust in Germany than in the United States, and the German Constitution limits the entities to which authority for making generally binding rules can be delegated and the forms such rules can take. It has been forcefully argued that the commission that reviews experimental procedures is not an agency that can constitutionally limit the rights of insureds.¹⁵⁰

It is also more broadly argued that a total ban on coverage for services not listed in the EBM would violate other constitutional rights. First, it would arguably violate the constitutional right of doctors to professional freedom.¹⁵¹ Second, it would violate the constitutional right of self-determination and personal integrity of persons who are required by law to be insured.¹⁵² Finally, it has been argued that the property and equal protection rights of persons required by law to be insured would be violated if there were major gaps in their coverage, because supplemental commercial insurance is neither affordable nor available to fill the gaps.¹⁵³ A recent decision of the German constitutional court, holding that the constitutional right to self-determination, although applicable in the health insurance setting, is subject to the statutory responsibility of the health insurers to limit access to medication to promote efficiency, calls these arguments into question.¹⁵⁴ Nevertheless, they continue to be plausible.

In sum, the law has traditionally supported the claims of insureds to alternative and experimental medicine, and the limitations found in SGB V have been largely ineffective. Belief in alternative medicine is widespread in Germany, and some believe that the costs of alternative medicine impose a significant cost on the German health care system.¹⁵⁵

There may, however, be a trend toward greater restriction of coverage of alternative and experimental treatment. In recent years, the BSG has

149. Thomas Clemens, *Verfassungsrechtliche Anforderungen an untergesetzliche Rechtsnormen*, 14 MEDIZINRECHT 432, 438-39 (1996).

150. Raimund Wimmer, *Verfassungsrechtliche Anforderungen an untergesetzliche Rechtsetzung im Vertragsarztrecht*, 14 MEDIZINRECHT 425 (1996); cf. Horst Dieter Schirmer, *Verfassungsrechtliche Probleme der untergesetzlichen Normsetzung im Kasernenarztrecht*, 14 MEDIZINRECHT 404 (1996).

151. See Zuck, *supra* note 140, at 2933.

152. Art. 1 & 2 GG; see Zuck, *supra* note 140.

153. Schulin, *supra* note 137, at 562.

154. See BVerfG 3/5/97, 1 BvR 1068/96, 15 MEDIZINRECHT 318 (1997).

155. *Rückfall ins Mittelalter*, DER SPIEGEL, May 20, 1997, at 22; Schlenker, *supra* note 142, at 530.

become less receptive to alternative medicine, requiring at least a plausible understanding of the method of operation of a particular medical intervention.¹⁵⁶ A 1995 decision of the First Senate went further, requiring statistical evidence of effectiveness.¹⁵⁷ The most important development, however, is a 1996 decision of the Sixth Senate, which holds that claims of insureds are in fact limited by the section 135 coding rules.¹⁵⁸

The Sixth Senate of the BSG is responsible for reviewing the claims of insurance doctors. As claims for coverage of alternative or experimental treatment have usually been brought by insureds, it has been generally silent on these issues. In 1996, however, it considered a case involving a doctor who had been refused permission to treat an addicted patient with Methadon because the drug's treatment guidelines were not met in the particular case. The decision is long and carefully argued, and reaches the conclusion that insureds are entitled only to receive insurance funds for services for which providers are authorized to bill, and that this situation does not violate the constitutional rights of insureds or providers or constitutional limitations on delegation.¹⁵⁹ The decision has been sharply criticized,¹⁶⁰ but has been followed in another Sixth Senate decision, which upheld the refusal of a KK to pay for extracorporeal shockwave lithotripsy outside the hospital before it was approved for ambulatory coverage under the new therapy guidelines.¹⁶¹

It remains to be seen whether these decisions will extend beyond the situations they addressed, where a federal commission representing both providers and insurers (and thus derivatively insureds and employers) had either already considered a particular treatment and issued guidelines regarding it or, alternatively, first issued guidelines regarding the therapy after the service was rendered for which the claim was submitted. It also remains to be seen whether other senates of the BSG will follow the decisions of the Sixth Senate. The fundamental argument of the decision, however, is compelling. The legislature is not capable of reviewing every

156. BSG, 2/9/89, 3 RK 19/87; BGG 2/10/93, 1 RK 17/91, noted in Wolfgang Wölk, *Paramedizinische Therapie und Rechtsprechung*, 13 MEDIZINRECHT 492 (1995).

157. BSG, 7/5/95, 1 RK 6/95, 14 MEDIZINRECHT 373 (1996), noted in von Wulffen, *supra* note 142, at 252.

158. BSG 3/20/96, 6 RKa 62/94, noted in 15 MEDIZINRECHT 123 (1997).

159. *Id.* at 129.

160. Raimund Wimmer, *Substitution mit Methadon nach den NUB-Richtlinien*, 15 MEDIZINRECHT 224 (1997). In another recent decision involving methadon, the First Senate denied coverage because it was being used for a drug addiction maintenance program, not for the treatment of a sickness. BSG, 3/12/96, 1 RK 33/94, Breithaupt 824 (1996).

161. BSG, 11/13/96, 6 RKa 31/95 (unpublished) (on file with author).

treatment that could possibly be covered by the social insurance funds and deciding on a case by case basis whether or not it should be covered. This decision must either be delegated or left to the courts. It makes a great deal of sense to delegate it to a commission that represents providers, insureds, and those who pay for insurance. Judicial review must continue, but only with respect to the reasonableness of decisions made by the experts best capable of deciding. Whether the German social courts will take this approach, however, or whether they will continue to independently review the coverage of experimental and alternative medicine is not yet clear.

C. Efficiency Review Cases

In terms of sheer number of cases, probably the greatest involvement of the social courts in health care financing is with respect to the process of *Wirtschaftlichkeitsprüfung* (WP), or economic monitoring, established by section 106 SGB V. WP is essentially what we would think of as utilization review. In contrast to the cases just considered, it does not address the claims to particular types of coverage by individual patients, but rather the aggregate provision or ordering of services for patients by particular doctors. It is a process through which doctors and dentists who perform unnecessary procedures or who order unnecessary drugs or therapy are first warned and then, if they persist, have their payments reduced or are subjected to fines.¹⁶² Committees composed of representatives of the KKn and the KaVn assess these penalties, which are subject to appeal to the social courts.¹⁶³ Decisions are frequently appealed and are frequently reversed by the social courts or settled after appeal. The WP process generates a great deal of work for lawyers, and a host of books have been written describing the WP process.¹⁶⁴

The process of WP can only be understood in the context of the German system of sector-specific medical care budgets. For two decades, first

162. §106(5) SGB V. This discussion focuses primarily on the process as it is applied to physicians. The process as it is applied to dentists is in most instances almost identical.

163. *Id.*

164. ALEXANDER P.F. EHLERS, ET AL., *PRAXIS DER WIRTSCHAFTLICHKEITSPRÜFUNG* (1996) [hereinafter "EHLERS, ET AL."]; ALEXANDER P.F. EHLERS, *DIE WIRTSCHAFTLICHKEITSPRÜFUNG IM VERTRAGARZTRECHT* (looseleaf, 1993); DIETER RADDATZ, *DIE WIRTSCHAFTLICHKEIT DER KASSENÄRZTLICHEN UND KASSENZAHNÄRZTLICHEN VERSORGUNG IN DER RECHTSPRECHUNG—WKR* (1993); WOLFGANG SPELLBRINK, *WIRTSCHAFTLICHKEITSPRÜFUNG IM KASSENARZTRECHT NACH DEM GESUNDHEITS—STRUKTURGESETZ* (1994); Thomas Clemens, *Honorkürzung wegen Unwirtschaftlichkeit*, in *HANDBUCH SVR*, *supra* note 51, at 910-60.

voluntarily and then under the compulsion of law, the German sickness funds and insurance doctors have negotiated annual budgets for physicians' services.¹⁶⁵ In recent years, budgets have also been established for prescribed drugs and therapies.¹⁶⁶ The regional KaVs pay their physicians on a quarterly basis, with their payments depending on the number of points they billed for services during the quarter based on the point values assigned to services by the EBM.¹⁶⁷

The obvious incentive created by this system is for each doctor to bill as many points as possible to obtain the largest possible slice of the fixed pie. Thus, a doctor's billings are reviewed by the KaV, to determine, first, whether they are honest and accurate, and, second, whether they are for services that are truly necessary. The honesty and accuracy of a doctor's billings are reviewed through the *sachlich-rechnerische Richtigstellung*, which reviews whether a service billed could in fact legally have been provided by the billing doctor considering his specialty and type of practice, whether the service is correctly coded, and, at the margins, whether it was in fact rendered.¹⁶⁸ The doctor's bills are also reviewed using a daily profile program that assigns a plausible minimum number of minutes to each of the services billed by physicians and reviews billing to determine whether the number of services billed by the doctor could in fact have been provided in a reasonable working day.¹⁶⁹ Doctors also have an obligation not to serve so great a number of patients that they cannot reasonably care for each patient, and doctors with unreasonably large practices may have their payments reduced accordingly.¹⁷⁰ These reviews are performed by the KaVn prior to the point when formal WP begins.

Doctors (and dentists) have an obligation under the SGB to provide services sufficiently, effectively, and economically, and in no greater volume than necessary.¹⁷¹ Section 106 SGB V, and the extensive body of caselaw interpreting section 106 and earlier provisions of the *Reichsversicherungsordnung* (RVO) which preceded it, provide a variety of methods

165. See *supra* text at notes 76 through 77, Schwartz & Busse, *supra* note 64.

166. See *supra* text accompanying notes 103-05; Busse & Howorth, *supra* note 103.

167. See *supra* text accompanying notes 78 through 81.

168. See Thomas Clemens, *Sachlich-rechnerische Richtigstellung*, in HANDBUCH SVR, *supra* note 51, at 899-909.

169. *Id.* at 904-07; see Hermann Müller, *Allgemeinarzt war mit 25, 2 Stunden pro Tag der Spitzenreiter beim Abkassieren*, ÄRZTE ZEITUNG, Feb. 28, 1997, at 23 (reporting on doctors who billed for obviously impossible numbers of points during the second quarter of 1996).

170. Funk, *supra* note 78, at 892-93.

171. §§2(4), 12 SGB V.

that the KaVn and KKn may use to assure that services are economically provided. The favored approach to economic monitoring for billing for doctors' services is currently statistical review.¹⁷² The key variable in this review is cost per patient, i.e., the average amount the doctor bills per patient.¹⁷³ A doctor's billings are reviewed to determine how many points the doctor has billed for each patient. For comparison purposes, doctors are grouped by specialty and locality.¹⁷⁴ The group must be both sufficiently homogenous and sufficiently large to permit meaningful statistical comparison.¹⁷⁵ Doctors are also generally compared by patient group, specifically considering separately older, retired patients and younger patients.¹⁷⁶ Doctors with extraordinarily high billings are subject to sanctions.

The statistical comparison usually encompasses a doctors' total billing, but it can be limited to particular services or categories of services.¹⁷⁷ Two different statistical approaches have been taken for comparison. Originally the comparison focused on percentage deviation from the average. Under this approach, doctors whose total billings exceed the average of their comparison group by fifty percent are considered to be obvious outliers, subject to sanctions unless they can explain the deviation.¹⁷⁸ Doctors whose billings lie in the twenty to fifty percent range are subject to scrutiny for uneconomic conduct.¹⁷⁹ Physicians whose billings lie less than twenty percent above the mean are considered to be within the range of random variation, and are not subject to further examination.¹⁸⁰ Where the review focuses on individual services or groups of services, rather than on total billings, a wider range of deviation is permitted, recognizing that ranges of variance will be broader with respect to individual services than for an entire practice.¹⁸¹

In recent years, the percentage deviation approach has been called into question. Some have argued that a more accurate approach is to consider distribution around the mean, i.e., location on the so-called Gaussian

172. BSG, 11/15/95, 6 RKa 43/94, SozR 3-2500, § 106, No. 33.

173. SPELLBRINK, *supra* note 164, at 195-212.

174. *Id.* at 212-15.

175. *Id.* at 215-16.

176. RADDATZ, *supra* note 164, at 254-55.

177. SPELLBRINK, *supra* note 164, at 198-203.

178. *Id.* at 239.

179. *Id.*

180. *Id.*

181. BSG, 4/8/92, 6 RKa 34/90, SozR 3-2500, § 106, Nr. 11.

curve.¹⁸² This approach recognizes that in very homogenous groups, a doctors' billings could be exceptional even though they lie only a small percentage above the norm, while in less homogenous groups a much larger percentage deviation could be unexceptional. Under this approach the determining factor is the number of standard deviations from the norm, with physicians whose billings lie over 1.6 standard deviations above the norm considered obvious outliers.¹⁸³ Neither the statute nor the decisions of the BSG endorse either approach. In a series of recent decisions, however, the BSG has criticized lower courts that have strictly relied on the Gaussian distribution approach without further evidentiary evaluation.¹⁸⁴

A doctor who is found to be a statistical outlier has two primary lines of defense. First, and most importantly, the doctor may argue that there are exceptional circumstances respecting his or her practice that justify the deviation.¹⁸⁵ The possibilities here are rather limited because (1) some exceptional circumstances are accounted for in the original comparison process (high proportion of elderly patients, for example, is not an excuse since elderly patients are compared separately); (2) others are accounted for by the permitted deviation from the mean (exceptionally sick patients); and (3) still others are not acceptable excuses as they are precisely the problem at which WP is aimed (particularly frequent use of expensive equipment). Some exceptional circumstances, however, are regularly recognized, such as the fact that a doctor is just beginning a practice and must perform an exceptional number of initial interviews and examinations, or that the doctor practices in a particular subspecialty or with a particular method that results in the treatment of more expensive patients.¹⁸⁶ Doctors such as pathologists who perform services primarily on a referral basis may also argue that they were simply performing services requested by other doctors.¹⁸⁷

Second, doctors subject to sanctions for deviation from the norm with respect to particular services or groups of services may claim that the high

182. See WILHELM GAUS, PRÜFUNG DER WIRTSCHAFTLICHKEIT DER BEHANDLUNGS-UND VERORDNUNGSWEISE DES KASSENARZTES (1988).

183. Clemens, *supra* note 164, at 935.

184. BSG, 3/15/95, 6 RKa 37/93, reported at 49 NEUE JURISTISCHE WOCHENSCHRIFT 2448 (1996); Wolfgang Nofitz, *Wirtschaftlichkeitsprüfung im Vertrags(zahn)arztrecht zwischen Statistik und Intellektualität?—Aktuelle Tendenzen der neueren Rechtsprechung*, NEUE ZEITSCHRIFT SOZIALRECHT 207 (1997).

185. RADDATZ, *supra* note 164, at 374-444; SPELLBRINK, *supra* note 164, at 137, para. 274.

186. Clemens, *supra* note 164, at 937-38; SPELLBRINK, *supra* note 164, at 278-80.

187. SPELLBRINK, *supra* note 164, at 286-87.

use of certain services is compensated for by low usage in other areas.¹⁸⁸ Doctors may argue, for example, that they gave a high number of injections because they prescribed fewer oral medications.¹⁸⁹

The individual cases of doctors may also be subjected to review on a case by case basis. For a long time, the BSG held up individual case review as the preferred form of economic review,¹⁹⁰ but it quickly became obvious that it was generally not practical. The BSG decided quite early that for an individual review to be truly accurate and reliable, it would have to go beyond the doctor's records, perhaps including an actual examination of the individual patient to determine the patient's actual condition.¹⁹¹ Moreover, the examination would have to focus not on the patient's condition at the time of the review, but on the patient's condition at the time of the treatment. Individual review is difficult because the WP commissions do not have the resources to perform such examinations, and have no means to require patients to submit to them.¹⁹² Individual review based on the doctor's records is permitted but is regarded skeptically by the courts. Extrapolations based on individual reviews are also permitted, allowing sanctions to exceed the levels warranted by the individual cases reviewed but only once a relatively large group of cases have been reviewed.¹⁹³ Only in the dental area, where review can readily be performed on the basis of x-rays, does individual review play a major role.¹⁹⁴

188. RADDATZ, *supra* note 164, at 330-73.

189. Clemens, *supra* note 164, at 941-42.

190. RADDATZ, *supra* note 164, at 146.

191. See BSG, 6/2/87, 6 RKa 19/86, SozR 2200, § 368n, No. 54; Hans-Siegmund Danckwerts, *Kassenzahnärztliche Versorgung: Überwachung der Wirtschaftlichkeit durch Einzelfallprüfungen*, 70 DIE ORTSKRANKENKASSE 458 (1988).

192. SPELLBRINK, *supra* note 164, at 315-16.

193. At least 100 cases or 20% of the total, with a discount from the extrapolated result of 25% to account for uncertainty. SPELLBRINK, *supra* note 164, at 320-21.

194. SPELLBRINK, *supra* note 164, at 315. The 1989 health reform law introduced a new form of economic monitoring based on sampling. § 106(2)2 SGB V. The idea grounding this random review is that doctors who avoid being obvious outliers often also have uneconomical practices, and should be subject to review. Under the sampling review, two percent of non-outlier physicians are supposed to be randomly selected each quarter for review. § 106(2) SGB V; see Ursula Spiolek, *Das Wirtschaftlichkeitsgebot des SGB V und die beiden neuen Formen der Wirtschaftlichkeitsprüfung—Stichproben- und Richtgrößenprüfung—nach § 106 II 1 SGB V*, 38 ZEITSCHRIFT FÜR SOZIALREFORM 209 (1992). Statistical review is not appropriate as a method for sampling review, both because sampling review is by definition a statutory alternative to statistical review, and because sampling is used precisely because the doctors it affects are not statistical outliers. Comprehensive case by case review of individual patients, on the other hand for two percent of all doctors would quickly exhaust the resources of the economic review

Not only are services provided by doctors subject to economic monitoring, but prescriptions, bandages, and therapy are also reviewed.¹⁹⁵ These reviews are normally carried out, again, through a statistical review of prescriptions.¹⁹⁶ They result in sanctions much less frequently than billing reviews,¹⁹⁷ but are of more interest to the KKn as they result in actual recoveries by the KK, not simply in reallocation of funds among doctors. Under the 1992 reform law, reviews are also supposed to be performed based on deviations from prescribing volume guidelines to be agreed to by the KaVn and KKn.¹⁹⁸ Between 1994 and 1997, however, implementation of these guidelines would have resulted under the terms of the law in termination of the prescribing budgets imposed by the 1992 law, and was resisted by the KKn who preferred to preserve fixed budgets.

Economic review committees consisting of an equal number of members from the KKn and the KaVn initially perform economic review.¹⁹⁹ A doctor who is sanctioned may have a hearing before an appeal committee, the *Beschwerdeausschuß*, which also contains members drawn equally from the KKn and KaVn.²⁰⁰ If the sanction stands, the doctor may go to court.²⁰¹

On the whole, doctors face fairly substantial incentives to appeal WP decisions. Access to the social court is free,²⁰² and a doctor whose com-

commissions. SPELLBRINK, *supra* note 164, at 325. Sampling review, therefore, has to date played virtually no role in EHLERS, ET AL., *supra* note 164, at 92.

195. § 106(2)1 SGB V.

196. SPELLBRINK, *supra* note 164, at 333.

197. Statistics regarding the use of WP nationwide are not available generally in Germany. The author wrote to all KVn in Germany, therefore, requesting information regarding WP statistics. A number of KVn responded, but most did not have the requested data available. A fee of the KVn provided data with response to the relative frequency of sanctions involving fee claims compared to those involving prescribing. In 1994, one KV had 36 prescribing WP cases, 123 fee WP cases; a second had 19 prescribing and 76 fee cases; a third in 1995 had 61 drug prescribing and 325 fee cases.

198. §§ 84, 106(2)1 SGB V.

199. § 106(4) SGB V.

200. § 106(5) SGB V.

201. *Id.* In the responses returned to the author's questionnaire, noted *supra* note 196, one KV stated that in 1995 during the first quarter of 1995 it sanctioned 213 doctors for excessive fees, 138 of which appealed internally, and 21 of whom ended up appealing to the social court. A second KV sanctioned 361 doctors during the first quarter of 1995, of whom 108 appealed internally and eight appealed to the social court. A third KV had 127 internal appeals in 1995, followed to date by six social court appeals. Finally, a fourth small KV had nine to eleven sanctions per quarter during 1995, of which two to four were appealed internally in each quarter, and one case was filed in the social court in each of three quarters.

202. § 183 SGG (*Sozialgerichtsgesetz*).

plaint is successful is entitled to have costs incurred in the appeal, including the costs of a necessary attorney, reimbursed.²⁰³ Although since 1993 the doctor who loses a WP proceeding is obligated to reimburse a WP panel for necessary attorney costs it has incurred, panels do not usually retain attorneys unless a case goes to court, and they are not entitled to reimbursement for their administrative costs or the costs of internal legal staff.²⁰⁴ On the other hand, an appeal to court does not generally stay the imposition of the sanction,²⁰⁵ and therefore if a considerable sum of money is involved, a doctor may be better served by a settlement than by an appeal, which could last several years. Thus, doctors appeal WP decisions relatively often, but then settle the case on appeal.

In reading WP cases, one cannot help but be struck with the intensity of judicial supervision of the process. Section 106 of SGB V, which governs WP, is relatively short. Yet the BSG has developed an extensive body of caselaw governing in minute detail the methods that are available for WP, in what order they must be applied, the statistical methods that must be employed, the defenses doctors may raise, and the procedures through which the whole process is applied. As noted above, early decisions of the BSG imposed such rigorous demands on individual case review as to make this form of review, perhaps the most common form of utilization review in the United States, not viable. More recent decisions involving statistical review involve highly technical mathematical questions, difficult for the layman to understand.²⁰⁶ This body of judge-made law applies nationwide, and cannot be varied by agreement by the regional KKn and KaVn.²⁰⁷

In the end, doctors have rights—rights enshrined in the Constitution, though these cases rarely advert to the Constitution. Article 12, section 1 of the Constitution protects the freedom of professionals to practice their profession, while Article 19, section 4 guarantees access to the court by those whose rights are violated by public institutions. Individual doctors must be treated fairly—the level of arbitrariness common in American utilization review decisions would not be tolerated in Germany.²⁰⁸ This does not mean that doctors always bring or win WP appeals. Appeals are

203. EHLERS, ET AL., *supra* note 164, at 118-20.

204. *Id.* at 120-21.

205. *Id.* at 135-42.

206. *See, e.g.*, BSG, 8/5/92, 14a/6 RKa 4/90, SozR 3-2500, § 106, Nr. 13.

207. *See* BSG, 11/30/94, 6 RKa 16/93, SozR 3-2500, § 106, Nr. 25.

208. *See* Donald Light, *Life, Death, and the Insurance Companies*, 330 N. ENG. J. MED. 498 (1994); William P. Peters & Mark C. Rogers, *Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer*, 330 N. ENG. J. MED. 473 (1994).

often brought by the KaVn or KKn, and they often win. The more recent cases have emphasized the expertise and discretion of the WP panels, and have loosened the grip that some of the social courts were imposing on their decisions.²⁰⁹ But one has the impression that the many demands and requirements imposed on WP by the courts have made it difficult both for doctors to know what to expect from the process and for the panels to know how to apply it. In the end, more and more cases are settled either before the *Beschwerdeausschuß* or at the first level of judicial review, probably leaving both the doctors and the payors feeling that the best result was denied.

Economic review has not been very successful in limiting unnecessary services or prescribing. First, it effects only a relatively small number of doctors, and an even smaller proportion of expenditures.²¹⁰ Because sanctions are generally limited to statistical outliers, the system has no effect on unnecessary services so long as most doctors provide them.²¹¹ If it is true, as is generally believed, that doctors use practice computers to protect themselves from becoming outliers, the effect of sanctions on controlling the use of unnecessary procedures or prescribing is even less significant.²¹² Even when doctors are sanctioned, the sanctions are quite mild. If the doctor is a first time offender, the most likely sanction is a warning.²¹³ When financial sanctions are imposed, the doctor's payments are usually only reduced to the level of obvious outlier status,²¹⁴ and thus the doctor remains well-paid. Doctors can lose their permission to practice as insurance doctors for repeated offenses, but this rarely occurs.²¹⁵

As long as the tight physicians services and prescribing budgets of the 1992 reform law were in place, the KKn had fairly minimal interest in the WP process, which mainly involved reallocation of restricted budgets among providers. The significant increase in service billing that accompa-

209. See *supra* text accompanying note 184; Wolfgang Spellbrink, *Die "Intellektuelle Wirtschaftlichkeitsprüfung,"* 3 MEDIZINRECHT 125 (1996).

210. In response to the author's questionnaire, *supra* at note 196, one large KV reported reviewing between 5.61% and 6.31% of its doctors in each quarter in 1995, but in each quarter cut only between .53% and .6% of total payments to doctors through WP. Another KV reported reviewing between 2.1% and 3.9% of its doctors during four quarters in 1993 and 1994. A third reviewed between 9.81% and 12.16% of its doctors during the four quarter of 1995.

211. SPELLBRINK, *supra* note 164, at 306-08.

212. RADDATZ, *supra* note 164, at 167; but see SPELLBRINK, *supra* note 164, at 308-13.

213. § 106(5) SGB V.

214. See SPELLBRINK, *supra* note 164, at 302.

215. §§ 81(5), 95(6) SGB V; EHLERS, ET AL., *supra* note 164, at 255-63.

nied the fall of the point value during 1996 unleashed a flood of WP sanctions. Under the second *Neuordnungsgesetz* (NOG2), which took effect on June 12, 1997, fixed global budgets for both provider services and drugs were abolished, though more flexible budgeting will continue.²¹⁶ Praxis Budgets instituted for provider service billing effective July 1, 1997, basically capitate most services on an individual patient basis, diminishing the importance of WP, but the KaVn have committed themselves to abolishing Praxis Budgets, probably returning to a fee-for-service system.²¹⁷ Doctors have also fought hard for a fixed-point value based system, which is recognized to a degree by the NOG.²¹⁸ The NOG2 also requires prescribing volume guidelines to be put into place, and abolish the prior fixed budgets.²¹⁹ These prescribing guidelines are supposed to be specialty-specific. Doctors whose prescribing varies more than fifteen percent above the guidelines are supposed to be subjected to review automatically; those whose prescribing lies twenty-five percent above the average must pay the KKn for the difference, unless they can justify their prescribing based on exceptional circumstances peculiar to their practice.²²⁰ This provision is likely to result in a flood of economic monitoring proceedings.

Fixed point value billing would make a vigorous WP system absolutely essential to the KKn. The institution of drug prescribing guidelines will also require tight WP oversight. It is likely that the importance of WP will greatly increase in the not too distant future. The question remains, therefore, whether the courts will permit the development of an effective WP process or whether they will interpret the statute narrowly and technically, making utilization review difficult.

D. Review of the Decisions of Arbitration Panels

To this point we have been discussing the role of the courts, especially the social courts, in resolving disputes regarding the allocation of resources in the German health care system. The primary means of resolving resource allocation disputes in the German health care system, however, is negotiation. In Germany, resource allocation policy over a wide range of issues, and in particular budgets that determine resource allocation to particular health care sectors, are determined through negotiations involving

216. 2 GKV-NOG, *supra* note 141 at § 20, to be codified at § 85(2) SGB V and § 27 to be codified at § 84 SGB V.

217. Josef Maus, *Praxisbudgets: Nur noch ein Modell für den Übergang*, 93 DEUTSCHES ARZTEBLATT A-1536 (1997).

218. 2 GKV-NOG, *supra* note 140, § 28 (amending § 85(2) SGB V).

219. *Id.* at § 27 (amending § 84 SGB V).

220. § 106(5a) SGB V.

the KKn on one side and provider organizations on the other.²²¹ Payments for hospitals, for example, are determined through negotiations between the representatives of the insurance funds and of the hospitals.²²² Budgets for payment of physicians have been negotiated between the KaVn and the state KKn associations.²²³ In the past, drug budgets have been negotiated between the KaVn and the associations of *krankenkassen* (or *ersatzkassen*); in the future these same institutions will negotiate prescribing guidelines.²²⁴ A wide range of issues other than budgets are also settled through institutional negotiations.²²⁵

If disputes must be settled through negotiations, however, there is always the problem of what to do when negotiations break down—when the parties can not or do not reach an agreement. The mechanism provided generally in German health insurance law is the *Schiedsstelle*.²²⁶ *Schiedsstelle* are essentially arbitration panels. They exist at both the national and Land level in Germany, and address a wide variety of issues and problems both within and outside of the health insurance sector.²²⁷ They impose a solution to disputes when the parties who are supposed to negotiate a solution are unable to do so. During 1996, for example, ten of the seventeen negotiations to establish the conversion value for the case and procedure payments for hospitals, discussed above, ended up before *Schiedsstelle*.²²⁸

Schiedsstelle generally have two types of members, partisan and non-partisan. Each side of the contract dispute has an equal number of partisan members, who represent the interests of their institutions. The number of partisan members is usually determined by the number of sorts of insur-

221. See Marian Döhler & Philip Manow-Borgwardt, *Korporatisierung als gesundheitspolitische Strategie*, 3 STAATSWISSENSCHAFTEN UND STAATSPRAXIS 64 (1992).

222. § 18 KHG (*Krankenhausfinanzierungsgesetz*).

223. §§ 82, 83, 85 SGB V.

224. § 84 SGB V.

225. See, e.g., § 87 SGB V, describing the contents of the national structural contract that is to be negotiated between the KaVn and the KKn national association to establish the framework of health insurance medical practice.

226. See, e.g., §§ 89, 114 SGB V; § 18 KHG; see generally Ruth Düring, *Das Schiedswesen in der gesetzlichen Krankenversicherung*, 21 ARBEITS-UND SOZIALRECHT (1992); WOLFGANG GITTER AND MEINHARD HEINZE, *DIE SCHIEDSSTELLE DES KRANKENHAUSFINANZIERUNGSGESETZS* (1989).

227. See, e.g., Timothy Jost, *Schlichtungsstellen und Gutachterkommissionen: The German Approach to Extrajudicial Malpractice Claims Resolution*, 11 J. ON DISPUTE RES. 81 (1996) (describing the use of *Schiedsstelle* in medical malpractice cases).

228. TUSCHEN & QUAAS, *supra* note 82, at 84-85. All of the *Schiedsstelle* decisions in these cases were appealed to the administrative courts.

ance funds affected by the negotiations, with an equal number of representatives of the provider or provider organizations. *Schiedsstelle* generally have three "non-partisan" members, including a chair, who are supposed to be appointed by both sides by agreement.²²⁹ Neither the partisan nor the non-partisan members are bound by the instructions of those who appoint them—all are technically free agents.²³⁰ If the parties cannot agree on an impartial chair, one is chosen by lot from the nominees of both sides.²³¹ As a practical matter, each side usually picks one sympathetic "impartial" member, and the chair—usually an eminent professor or retired judge—is the only member who is truly impartial.

Schiedsstelle proceedings are initiated when the parties reach an impasse in negotiations, or, with respect to hospital budget negotiations, when six weeks pass without negotiations resulting in agreement.²³² *Schiedsstellen* must act quickly—*Shiedsstelle* dealing with contracts between the KKn and doctors must resolve the issues before them and issue a final order within three months.²³³ *Shiedsstelle* proceedings are not open to the public, although the parties may be present while evidence is taken.²³⁴ Only the members of the *Schiedsstelle* are present for its deliberations, although the members may consult their constituents.²³⁵ The *Schiedsstelle* conducts an oral hearing, hearing witnesses and experts and assembling evidence.²³⁶ The parties have an obligation to work together with the *Schiedsstelle* and to expedite the proceedings.²³⁷ Decisions are reached by majority vote, with each party having one vote.²³⁸

The chair plays a major role in the proceedings, clarifying the issues in a written opening summary, ensuring that the parties submit appropriate documents, overseeing the proceedings, and writing the decision of the panel, with appropriate justification.²³⁹ The *Schiedsstelle* have jurisdiction only to decide issues to the extent that the parties cannot themselves reach

229. §§ 89(3), 114(2) SGB V. Under § 18 of the KHG, there is only one neutral party, the chair, who is appointed by agreement of the parties, or, failing that, by the Land.

230. § 18(3) KHG; § 114(3) SGB V.

231. §§ 89(3), 114(2) SGB V.

232. § 18(4) KHG.

233. § 89(1) SGB V.

234. Düring, *supra* note 226, at 108-09.

235. *Id.* at 111.

236. *Id.* at 107-08, 109-10; Meinhard Heinze, *Verfahren und Entscheidung der Schiedsstelle*, in GITTER & HEINZE, *supra* note 226, at 61, 66-67.

237. *Id.* at 65-67.

238. § 114(3) SGB V; § 18a(3) KHG.

239. GITTER & HEINZE, *supra* note 226, at 70-84.

agreement, and the chair and other nonpartisan members often propose settlements for the parties to consider themselves before proceeding to impose a settlement.²⁴⁰ In the final vote, the partisan and party-affiliated nonpartisan members quite often take the position of their constituents, leaving the chair the deciding vote.

The decision of the *Schiedsstelle* must comply with governing law. Setting of budgets for doctors' compensation, for example, must observe the principle of premium stability, but must also assure adequate compensation.²⁴¹ The *Schiedsstelle's* decisions that set hospital budgets must first be approved by the state administration before they become legally binding.²⁴² In the end, decisions of the *Schiedsstelle* can be appealed to court: hospital budget decisions are appealed to the administrative courts because they affect the Länder; other health insurance decisions are appealed to the social courts. The *Schiedsstelle* have considerable discretion in reaching their decisions, however, and the bodies that review their decisions can only reject them if they violate the law.²⁴³ *Schiedsstelle* decisions are appealed fairly often, but are usually affirmed at the trial court level and rarely appealed to higher courts.

The *Schiedsstelle* play a vital role in resolving disputes in the German health insurance system, and, ultimately in resource allocation questions. Their existence assures that negotiations will reach a conclusion. If one party fails to cooperate in the negotiation process, the dispute will go to the *Schiedsstelle* which will resolve it. Thus, parties are always under pressure to negotiate disputes when negotiation is possible. On the other hand, as budgets have become tighter in recent years, an ever increasing number of cases are ending up in the *Schiedsstelle* process.²⁴⁴ The legitimacy of the process depends to a certain extent on it being a last resort. If *Schiedsstelle* resolution of disputes becomes the norm, and if disputes are consistently sufficiently divisive that most are resolved by the chair, the whole institu-

240. Interviews between the author and Günter Spielmeier, head of the *Bundesschiedsamt*, June 9, 1997, and Professor Wolfgang Gitter, May 22, 1997.

241. Andreas Hustadt, *Blockieren oder Gestalten? Zur Entscheidungspraxis und Rolle der Schiedsämter*, 77 *DIE ERSATZKASSE* 117, 118 (1997)

242. Gunter Kisker, *Verwaltungsrecht dogmatik zwischen Vereinbarungsprinzip und direktionsprinzip—Zur Rechtsnatur der Schiedsstelle und zur Kontrolle ihrer Entscheidungen durch Genehmigungsbehörde und Gericht*, in GITTER & HEINZE, *supra* note 226, at 21; Dieter Krauskopf, *Das Genehmigungsverfahren durch die Verwaltungsbehörde*, in GITTER & HEINZE, *supra* note 226, at 39.

243. BVerwG 6/22/95, 3 C 34-93; BVerwG 1/21/93, 3 C 66.90; see Kisker, *supra* note 242, at 30-33.

244. A recent article reports that in 17 of 22 KzV regions, *Schiedsverfahren* were necessary to establish dental budgets in 1996. Hustadt, *supra* note 241, at 118.

tion may be called into question. One way in which *Schiedsstelle* can retain legitimacy is to limit their efforts to preservation of the status quo, to avoid innovation that would provoke controversy. The *Schiedsstelle* have indeed been criticized for their lack of creativity and for their dedication to status quo preservation.²⁴⁵ Nonetheless, their contribution to maintaining a system of resource allocation based on corporate negotiation and for reducing dependence on litigation must not be overlooked.

E. Conclusion

In summary, the German courts take a very activist role in overseeing the German statutory health insurance system. On the whole, they have tended to expand coverage, as with *Hilfsmittel* and alternative and experimental treatment, and to protect the rights of individual insureds and providers, as is evidenced in judicial review of *Wirtschaftlichekeitsprüfung* decisions. When discretion is clearly and properly delegated to another decisionmaking body, as with the *Schiedsstelle*, or perhaps with the commission of doctors and insurers responsible for updating the EBM to account for new technology, the courts defer to the decisions of such bodies.

VI. The British National Health Service: Allocating by Administrative Discretion

The British National Health Service offers a striking contrast to the German systems of health care finance—in the simplicity of its organization, in its economy, and in its freedom from judicial oversight. The NHS has for five decades provided tax-financed health care in Great Britain. It is centrally organized, headed by the NHS Executive, a Branch of the Department of Health, which operates within the framework established by the Department of Health and the Policy Board.²⁴⁶ Both of the latter are headed by the Secretary of State for Health, who in turn answers to Parliament.²⁴⁷ Operationally, the NHS is administered through District Health Authorities located throughout Britain, which purchase health care with funds allocated to them by the NHSE.²⁴⁸ The DHAs contract with local NHS Trust hospitals and with private providers to purchase secondary and tertiary health care services for their constituents, and in a very few in-

245. *Id.* at 119-20.

246. LONGLEY, *supra* note 37, at 110-13.

247. *Id.*

248. RUTH LEVITT, ANDREW WALL, & JOHN APPLEBY, *THE REORGANIZED NATIONAL HEALTH SERVICE*, 68-73 (1995).

stances manage their own provider units directly.²⁴⁹ The DHAs have recently been merged with the Family Health Service Authorities (FHSAs), which contract with independent general practitioners (GPs) to provide primary care, either independently or as fund-holding general practices.²⁵⁰ The NHS is slated for further reorganization under a plan recently put forth by the new Labor government, but will retain a separation between purchasers and providers, with purchasing power moving toward new, larger, groups of primary care providers.²⁵¹

Resource allocation decisions are made at every level of the NHS, beginning with the initial government budgetary decision as to how much to allocate to the NHS as compared to other government departments, followed by allocations among the districts by means of a weighted capitation formula, then by distribution of funds among providers according to District priorities and purchasing arrangements, and finally rationing of resources among patients by hospital management, "consultants" or hospital doctors, and general practitioners.²⁵²

The NHS operates arguably one of the most efficient health care systems in the world. In 1995 Britain spent 6.9% of its GDP on health care, 5.9% in NHS spending, and 1% in private.²⁵³ This is about one half the percentage of GDP that the United States spent on health care in the same year.²⁵⁴ In terms of real spending, the difference is even more dramatic: in 1995 Britain spent \$1300 per person, Germany \$2840 per person, and the United States \$3830 per person.²⁵⁵ Every resident in the United Kingdom, however, has access to NHS care, which though it does not always meet public expectations or the standards found in countries that spend more, is on the whole adequate and in some sectors quite good. Health care in the United Kingdom must explicitly compete head to head with other public services for resources in the budget process. The NHS budget represents in a very real sense a choice taken by elected representatives of the public as to what share of the nation's resources should be dedicated to health care. By contrast, health care in the United States is paid for by a host of private and public sources (including hidden public subsidies such as tax

249. *Id.*; see Timothy Stoltzfus Jost, et al., *The British Health Care Reforms, the American Health Care Revolution, and Purchaser/Provider Contracts*, 20 J.HEALTH POL., POL'Y & L. 885 (1995) (examining the contracting process and contracts).

250. LONGLEY, *supra* note 37, at 124, 128-29.

251. See NATIONAL HEALTH SERVICE, NHS WHITE PAPER, THE NEW NHS (1997).

252. RUDOLF KLEIN, ET AL., MANAGING SCARCITY 45-48, 55-60 (1996).

253. *Britain: An Unhealthy Silence?*, ECONOMIST, March 15, 1997, at 37.

254. *Id.*

255. *Id.*

exclusions and deductions), making effective control over health care expenditures far more difficult.

The existence of and need for rationing is openly acknowledged and discussed in Britain, and much of rationing theory and technology stems from Britain.²⁵⁶ One small indication of the rationality of the NHS is a recent study that found that ten of the fifty most often sold pharmaceutical products in Italy and France and six of the fifty most often sold products in Germany had no clear evidence of therapeutical effectiveness; none of the fifty most prescribed drugs in Britain fell in this category.²⁵⁷

Rationing is carried out in the United Kingdom through a host of explicit and implicit methods. Among the best known British tools for rationing are waiting lists (delay) and standards of practice that deny many persons, particularly elderly persons, services that would be available in other nations. Waiting lists for certain surgical services have existed in the United Kingdom since the foundation of the NHS, and are often seen simplistically by economists as evidence that excess demand is inevitable when supply is artificially constrained. A recent reexamination of the waiting list phenomena reveals a much more complex explanation, in which waiting lists result on the one hand from the fact that the patients on waiting lists (mostly elderly) and the conditions from which they suffer (hernias and hemorrhoids, for example) tend to be unattractive and uninteresting to hospital doctors, and on the other from the fact that physicians are often rewarded for maintaining long waiting lists by opportunities for private practice and by access to new resources.²⁵⁸ Waiting lists are, nonetheless, an important tool for allocating scarce resources within the NHS.

Denial of some services, often by simple failure to mention their potential availability or usefulness, was first documented by Aaron and Schwartz in their 1984 comparison of medical practice in the United King-

256. See, e.g., FRANKEL & WEST, *supra* note 30; KLIEN, ET AL., *supra* note 252; RATIONING HEALTH CARE (R.J. Maxwell, ed., 1995); BILL NEW & JULIAN LE GRAND, RATIONING IN THE NHS: PRINCIPLES AND PRAGMATISM (1996) (recent British publications discussing rationing). The classic American book which initiated discussion of rationing in the United States was a study of the NHS. HENRY J. AARON & WILLIAM B. SCHWARTZ, THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE (1984). The quality-adjusted life year (QUALY) approach to valuation of health care interventions was developed in England, and is now being considered throughout the world. See, e.g., Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015 (1997).

257. S. Garattini & L. Garattini, *Pharmaceutical prescriptions in four European Countries*, 342 THE LANCET 1191 (1993).

258. FRANKEL & WEST, *supra* note 30, at 1-14.

dom and the United States.²⁵⁹ Particularly well-documented is the denial of renal dialysis to the elderly, but many coronary care units also limit admission on the basis of age.²⁶⁰

Under the internal market reforms introduced by the Conservative government in the early 1990s, rationing became more explicit. Allocations are being made under these reforms (still largely in place under the new Labor government) in the first instance by the district health authorities and reflected in their purchasing plans. Purchasing plans of the District Health Authorities increasingly explicitly exclude certain procedures, though they tend to be marginal procedures which are not major expenditure concerns, like tattoo removal and reversal of sterilization.²⁶¹ Extra-contractual referrals, referrals of patients to providers who do not have a contract with a DHA, must be approved by a DHA.²⁶² Though DHAs may not refuse ECRs in emergencies, the fact that they must be approved makes rationing again more explicit. Recent government proposals would do away with ECRs, but also affirm a commitment to planned purchasing.²⁶³

When services are denied British patients, the patients occasionally go to court. The response they meet in the courts, however, is very different from that encountered by German patients seeking judicial relief. Cases directly challenging resource allocation decisions in the NHS have almost always been unsuccessful.²⁶⁴ The National Health Services Act of 1977 recognizes a principle of comprehensiveness much like that governing the German health insurance system. The Act imposes on the Secretary of State a:

... duty to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement (a) in the physical and mental health of the people in those countries, and (b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide and secure the effective provision of services in accordance with this Act.²⁶⁵

259. AARON & SCHWARTZ, *supra* note 256.

260. KLEIN, ET AL., *supra* note 252, at 87-88.

261. *Id.* at 68-73, 140-42.

262. LONGLEY, *supra* note 37, at 139-40.

263. See THE NEW NHS, *supra* note 251.

264. See DIANE LONGLEY, PUBLIC LAW AND HEALTH SERVICE ACCOUNTABILITY 79-82 (1993); CHRISTOPHER NEWDICK, WHO SHOULD WE TREAT? 119-35 (1995) [hereinafter "Newdick, Treat"]; Christopher Newdick, *Resource Allocation in the National Health Service*, 22 AM.J.L. & MED. 291 (1997) [hereinafter "Newdick, Resource Allocation"].

265. National Health Services Act, § 1 (1977) (Eng.) [hereinafter "NHS Act"].

The Statutes further provides at section 3(1) that "[i]t is the Secretary of State's duty to provide . . . to such extent as he considers necessary to meet all reasonable requirements . . .," and then proceeds to list specific medical services, such as hospital accommodation, medical, dental, and nursing care, and other health services.

Although on its face the statute appears to impose upon the Secretary of State an obligation to provide medical services, the courts have generally rejected attempts to enforce the statute judicially. The first case to consider the question was *R. v. Secretary of State for Social Services, ex parte Hincks*,²⁶⁶ which challenged the failure of the Health Services to construct a new orthopaedic unit in Birmingham, which had been approved by the Secretary of State in 1971 but postponed, and then abandoned in 1978. The plaintiffs alleged that the Secretary of State had failed in his duty to provide a comprehensive health service by not constructing the unit as approved. The Court of Appeals, by Lord Denning, affirmed at trial court judgment denying relief, noting that the courts could not direct the Secretary of State's decisions as to how to allocate resources among competing claimants.²⁶⁷

Subsequent cases have denied relief in cases in which: (1) a premature baby was denied an operation to repair his heart;²⁶⁸ (2) a four year old boy, who needed an operation to repair his heart had had a desperately needed surgery scheduled and canceled three times;²⁶⁹ and (3) a woman was denied in vitro fertilization because she was over thirty-five years of age.²⁷⁰ The courts invariably in these cases review the decision of the health authority under a gross abuse of discretion standard,²⁷¹ and on this basis uphold the health authority's decision.

In the recent case of *R. v. Cambridge Health Authority ex parte B*, the lower court broke with previous deferential precedents, indicating its willingness to review the decision of a health authority. The health authority had denied B, a ten year old girl with leukemia, a bone-marrow

266. 1 BMLR 93 (1992) (decided in 1980).

267. *Id.* at 95-96.

268. *R. v. Secretary of State, ex parte Walker*, 3 BMLR 32 (1992) (decided 1987).

269. *R. v. Central Birmingham Health Authority, ex parte Collier* (unreported 1988), reprinted in part in IAN KENNEDY AND ANDREW GRUBB, *MEDICAL LAW-TEXT AND MATERIALS* 428 (1994)).

270. *R. v. Scheffield Health Authority, ex parte Seale*, 25 BMLR 1 (1994).

271. Under English law this is referred to as the *Wednesbury* standard of review. Professor Newdick describes a *Wednesbury* unreasonable decision as one "so unreasonable that no reasonable person addressing himself to the issue in question could have come to such a decision." Newdick, *Resource Allocation*, *supra* note 264, at 297.

transplant (her second), which would have cost £75,000. Judge Laws, writing for the lower court, rejected the claim of the health authority that it did not have the resources to fund the needed care, and remanded the case to the health authority to reconsider and explain its decision.²⁷² The case was appealed, however, to the Court of Appeals, which on the same day reversed the lower court judgment and upheld the decision of the health authority.²⁷³ The Court of Appeals found that the medical evidence supported the Health Authority's judgment that the treatment had a low chance of success and was not advisable. The Court of Appeals maintained the tradition of limited judicial review of NHS decisions.

In *R. v. North West Thames Regional Health Authority ex parte Rhys William Daniels*,²⁷⁴ the court went slightly further, holding that the action of a health authority had in fact violated the law. However, it then granted no relief. The case involved a three year old boy who needed a bone marrow transplant for the treatment of Batten's disease. The unit which was to do the transplant was closed before it could be done, and the family sued. The closure was technically illegal because the Health Authority had failed to consult the Community Health Council first, but the court further held that the closure was not irrational and that the patient's family did not have a right to be consulted before the closure. The court refused to order that the closure be reversed, or even to declare it illegal, because it held it had no power to do so.

Finally, in one recent case, *R. v. North Derbyshire Health Authority, ex parte Fisher*,²⁷⁵ the court actually ordered a health authority to formulate and implement a policy making a particular treatment, Beta Interferon for Multiple Sclerosis, available. The court's decision, however, merely required the health authority to implement a circular issued by the national NHS stating that it was national policy to make the drug available, and did not challenge the health authority's discretion in making rationing decisions generally. It might indicate a greater willingness of the courts to challenge NHS rationing decisions, but it more likely means simply that in

272. 25 BMLR 5 (1995). Judge Laws relied in part on the European Convention on Human Rights, which requires public bodies to provide a substantial justification for decisions infringing human rights. The European Convention on Human Rights may in time prove a grounds for challenging health care rationing decisions in the United Kingdom, although this route is as of yet largely undeveloped. See Rhonda James and Diane Longley, *Judicial Review and Tragic Choices: Ex Parte B*, 1995 PUB. L. 367.

273. 2 All. E.R. 129 (1995).

274. Reported in *Down by Law*, HEALTH SERVICES J., August 26, 1993, at 33.

275. *Health Authority Operated Unlawful Policy*, THE TIMES (LONDON), Sept. 2, 1997, at 35. The hearing date was July 11, 1997.

making rationing decisions health authorities may not violate central resource allocation policy promulgated by the NHS through regulatory channels.

On the whole, however, the British courts, in contrast to the German courts, have refused to recognize the comprehensiveness principle as judicially enforceable with remarkable consistency. They do not interfere with rationing decisions. The courts also play no role in resource allocation disputes between payors and providers. Under the 1990 Conservative reforms, the Health Authorities, which previously had provided services through their own hospitals and other provider units, were reconstituted as purchasers. Hospitals, on the other hand, were spun off into independent NHS trusts.²⁷⁶ The health authorities are now supposed to contract with the trusts (as well as with private institutions and institutions directly managed by health authorities) to purchase services.

Disputes often arise regarding the formation or interpretation of these contracts. The NHS statute states, however, that an NHS contract "... shall not be regarded for any purpose as giving rise to contractual rights or liabilities, but if any dispute arises with respect to such an arrangement, either party may refer the matter to the Secretary of State for determination."²⁷⁷

That is, NHS contracts are not enforceable in court, although they are subject to arbitration under the auspices of the Secretary of State. As disputes between health authorities and trusts are most severe during the contract negotiation phase (that is, they are more likely to involve the terms of the contracts being negotiated rather than enforcement of breached contracts) judicial enforcement of contracts would be of limited value in any event. In fact, not only are the terms of NHS contracts not litigated, they have only rarely resulted in formal arbitration. The Secretary of State has issued regulations establishing an arbitration procedure, but the procedure has almost never been used.²⁷⁸ Rather, the parties usually rely on mediation, conciliation, or informal arbitration.²⁷⁹ A major impediment to the use of arbitration seems to be the form of arbitration used—pendulum arbitration.²⁸⁰ Under pendulum arbitration, the arbitrator must adopt either the solution offered by one side or that offered by the other. This approach

276. LONGLEY, *HEALTH CARE CONSTITUTIONS*, *supra* note 37, at 117-19.

277. NHSA, *supra* note 265, at § 4(3).

278. David Hughes, et al., *Settling Contract Disputes in the National Health Service: Formal and Informal Pathways*, in *CONTRACTING FOR HEALTH* 98, 106 (R. Flynn and Gareth Williams eds., 1997).

279. *Id.* at 104-10.

280. *Id.* at 111.

does not afford enough flexibility to reach the essentially management solutions necessary for resource allocation. Recent proposals for restructuring the NHS seem to contemplate even less formal arrangements between purchasers and providers, making judicial involvement even less likely.²⁸¹

Although British courts are generally not open to complaints of patients who believe they have been improperly denied care, there are host of other avenues.²⁸² Procedures are available for complaints against general practitioners and there are separate procedures for complaints against hospitals.²⁸³ The Health Service Commissioner is available as a general ombudsman when more specific complaint procedures do not apply.²⁸⁴ Other specialized authorities are available for investigating other specific problems, such as mental health care.²⁸⁵ The number of complaints to all sources has risen sharply in the recent past.²⁸⁶

The existence of complaint procedures underscores the fact that the NHS is a public service, answerable to the public. In some cases complaints have, in fact, made a difference. One complaint to the Health Services Ombudsman, for example, regarding a stroke patient who was refused long term care within the NHS and had to go to a private nursing home, resulted in the Ombudsman condemning the NHS policy, the health authority agreeing to pay for the cost of the patient's care, and a change in NHS policy accepting responsibility for caring for patients requiring specialist nursing care.²⁸⁷ Complaint procedures, like conciliation and mediation procedures for resolving disputes with providers, allow health authorities to respond to resource demands without constraining them to respond to particular demands in precise particular ways.

The NHS also, in the end, remains accountable through malpractice litigation when resource shortages result in patient injury.²⁸⁸ In *Bull v. Devon Health Authority*, for example, a hospital was found liable when lack of staffing in maternity care resulted in child suffering serious damage when its mother had to wait for over an hour for a doctor to arrive during a complicated delivery of twins.²⁸⁹

281. See THE NEW NHS, *supra* note 251.

282. See LONGLEY, PUBLIC LAW, *supra* note 264, at 66-79.

283. JUDITH ALLSOP & LINDA MULCAHY, REGULATING MEDICAL WORK 180-86 (1996).

284. *Id.* at 55-72.

285. *Id.* at 44-47.

286. See HEALTH SERVICE COMMISSIONER FOR ENGLAND, FOR SCOTLAND, AND FOR WALES, ANNUAL REPORT, 1996-97 (1997).

287. Newdick, Resource Allocation, *supra* note 264, at 305-06.

288. Newdick, Treat, *supra* note 261, at 77-118.

289. Eng. C.A. Feb. 2, 1989, available in LEXIS, Enggen Library, Cases File.

On the whole, however, the courts respect the discretion granted the NHS by Parliament to make its own rationing decisions free from judicial oversight. The courts defer to NHS decisions, retaining only the right, largely theoretical, to intervene if resource allocation decisions are indefensibly irrational.

VII. American Public Health Care Entitlements: Medicare and Medicaid

In contrast to the freedom the British National Health Service enjoys from judicial oversight, America's national health programs are more subject to judicial supervision. Although the United States is not commonly regarded as having "socialized medicine," it in fact operates two of the largest public health care financing systems in the world. Medicare is America's health care social insurance program. In 1995 Medicare insured about 38 million Americans, 33.4 million of who are over 65 and 4.6 million of whom are disabled, and spent about \$187 billion.²⁹⁰ Medicaid funds health care services for the poor: in 1995 it covered 36.3 million recipients and spent \$133 billion.²⁹¹ Medicare and Medicaid program decisions limiting coverage are both subject to judicial review. The courts have taken a very different approach, however, to reviewing decisions under the two programs.

A. *Medicare*

Medicare is a social insurance program, resembling in many respects the social insurance programs of central Europe. It is, on the whole, more parsimonious than its European cousins. It is not based on a comprehensiveness principle: Part A (financed by payroll taxes) basically covers hospital care and related institutional services (home health, hospice services, very limited nursing facility care), and Part B (financed by general revenue funds and premiums) covers physician care, treatment by clinical psychologists or social workers, outpatient hospital care, dialysis, durable medical equipment and prosthetic devices, home health, and a few other services; but neither program covers dental care, vision care, or most prescription drugs.²⁹² A new Medicare Part C, established in 1997, recognizes a variety of "Medicare+Choice" managed care plans that might expand services for some Medicare beneficiaries, but are unlikely to dramati-

290. PPRC, *supra* note 40, at 126, 135.

291. Levit, et al., *supra* note 12, at 196.

292. See 1 HEALTH LAW, *supra* note 6, at §§ 13-5, 13-6.

cally expand coverage except insofar as they charge supplemental premiums.²⁹³ Moreover, Medicare imposes much larger copayments than are common in Europe, as well as deductibles and length of hospital or nursing home stay time limits that are unknown in Europe.²⁹⁴ Medicare is also, however, in a limited sense more generous: unlike the British National Health Service and certain sectors of the German health insurance system, it does not have a fixed budget—Medicare must pay for whatever covered services its beneficiaries consume. Medicare has thus proved very expensive.

The courts play a very limited role in the Medicare program.²⁹⁵ The Medicare statute combines a strict exhaustion requirement (from which the Supreme Court has repeatedly and almost without exception refused to deviate) with an exhaustive array and exhausting sequence of administrative remedies, effectively keeping most disputes from ever reaching the courts.²⁹⁶ A number of important issues, moreover, are simply removed from the jurisdiction of the courts by judicial review preclusion provisions.

Private insurers and data processors, called carriers in Part B and intermediaries in Part A, pay Medicare claims; they contract with the Health Care Financing Program to carry out this function.²⁹⁷ A beneficiary or physician who has treated the patient on an assignment basis (i.e. has agreed to present the claim directly to Medicare) who is dissatisfied with a carrier decision must first request reconsideration from the carrier, and then, if \$100 or more is at issue, appeal to the carrier hearing officer.²⁹⁸ If the carrier's decision remains unsatisfactory, and if \$500 or more is involved, the appeal can be taken to a Health and Human Services Administrative Law Judge, and ultimately to the HHS Appeals Council.²⁹⁹ An in-

293. See Balanced Budget Act of 1997, Title IV, Pub. L. 105-33, 111 Stat. 251, 270, §§ 4000-4041 (1997).

294. Medicare beneficiaries spent \$29.7 billion on Medicare copayments and deductibles for covered services in 1996, 12.9% of the total expenditures for covered Services. PPRC, *supra* note 40, at 136.

295. During 1996, the CCH Medicare and Medicaid Guide reported 109 Medicare-related cases, many of which involved fraud and abuse issues and most of which were trial court decisions. During the same year, the BSG entered judgments in 464 appeals (*Revisionen*). TÄTIGKEIT, *supra* note 90, at 24. As nearly 30% of the appeals considered by the court involved health insurance member or provider issues, *id.* at 32, the BSG almost certainly decided more cases than all reported Medicare decisions. Of course, the lower social courts decided thousands more.

296. 1 HEALTH LAW, *supra* note 6, at § 13-32.

297. 42 U.S.C. §§ 1395h, 1395u.

298. 42 C.F.R. §§ 405.807, .820.

299. 42 C.F.R. § 405.8.

dividual dissatisfied with a Part A decision can request reconsideration from the Health Care Financing Administration, followed by, if \$100 or more is at stake, a hearing from an Administrative Law Judge and Appeals Council Review.³⁰⁰ In most instances, an appeal can reach a federal court only after these administrative remedies have been exhausted and when \$1000 or more is at stake.³⁰¹ Few do so.

Coverage disputes arise in a number of contexts under the Medicare program, three of which will be addressed here: coverage of new technology, medical necessity determinations, and determinations regarding long term care.³⁰² Every year, many new technologies—drugs, devices, and procedures—become available. The Medicare statute excludes from coverage services “not reasonably necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part,”³⁰³ and has been interpreted to exclude experimental procedures.

Decisions as to whether to cover new technologies are in most instances made by carriers and intermediaries applying their own policies and criteria.³⁰⁴ Decisions regarding a small number of major new technologies are made at the national level. A panel of HCFA physicians and health professionals reviews the technology and determines whether to (1) allow individual Medicare carriers or intermediaries discretion to cover or not to cover a service, (2) commission a special study (as was done with heart transplants), or (3) ask the Public Health Service to assess the technology.³⁰⁵ If a technology is referred to the Public Health Service for assessment, the assessment is done by the PHS Office of Health Technology Assessment, which will publish a notice in the Federal Register asking for

300. 42 C.F.R. §§ 405.710, .720, .722, .724.

301. 42 U.S.C. §§ 405(h), 1395ff(b)(2), 1395ii; see *Heckler v. Ringer*, 466 U.S. 602, 606-07 (1984). Where only a constitutional challenge to a statute is involved, the appellant can proceed directly to federal court without exhausting remedies once the issue at stake has been presented to the government. 42 C.F.R. §§ 405.717 - 405.718c.

302. See 1 HEALTH LAW, *supra* note 6, at § 13-7.

303. 42 U.S.C. § 1395y(a)(1).

304. See Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869 (1988); PHYSICIAN PAYMENT REVIEW COMMISSION, REPORT TO CONGRESS, 1994, 113-34; GENERAL ACCOUNTING OFFICE, MEDICARE TECHNOLOGY ASSESSMENT AND MEDICAL COVERAGE DECISIONS (1994) [hereinafter “GAO MEDICARE”].

305. Louis Hays, *From the Health Care Financing Administration: Medicare Coverage*, 262 JAMA 2794 (1989). See Proposed Rule, Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989).

comments, do a literature search, and reach a conclusion.³⁰⁶ Although approval by the Food and Drug Administration of a drug or device does not guaranty that Medicare will pay for its use, HCFA published a rule in 1995 committing Medicare to cover devices not yet FDA approved but described as "non-experimental/investigational," i.e., devices that are modifications or improvements on existing approved devices and that are known to be safe and effective, if they otherwise meet Medicare payment requirements, such as reasonableness and necessity.³⁰⁷

Administrative and judicial review of national coverage determinations has been strictly limited since the Omnibus Budget Reconciliation Act of 1985. Administrative Law judges may not review the validity of national coverage determinations on administrative appeals.³⁰⁸ Courts may not hold national coverage determinations to be invalid for failure to comply with the publication and comment requirements of the Administrative Procedure Act.³⁰⁹ If a court determines that the record supporting a national coverage determination is incomplete or that information supporting the decision is otherwise lacking, the court must remand the case to HHS for further consideration, and can only determine that the item or service is covered on review of the supplemental record.³¹⁰ The cases reviewing national coverage decisions pursuant to these provisions have generally upheld the challenged coverage determination with minimal scrutiny.³¹¹ For example, *Bosko v. Shalala*, a case challenging the refusal of HHS to reconsider its seven year old policy refusing coverage for autologous bone marrow transplantation, held that the HHS decision was supported by substantial evidence, claiming that "[t]he Medicare statute 'unambiguously vests final authority in the Secretary, and no one else, to determine whether a service is reasonable and necessary, and thus whether reimbursement should be made.'"³¹² In a few cases, HCFA coverage policies not considered to be national coverage determinations have been set aside for failure

306. GAO MEDICARE, *supra* note 304. The staffing of the OHTA permits it to only do fewer than 10 studies a year.

307. 42 C.F.R. §§ 405.203, .205, .207, .209, .211.

308. 42 U.S.C. § 1395ff(b)(3)(A).

309. 42 U.S.C. § 1395ff(b)(3)(B).

310. 42 U.S.C. § 1395ff(b)(3)(C).

311. See *Friedrich v. Secretary of Health and Human Services*, 894 F.2d 829, 838 (6th Cir. 1990), *Mathews v. Shalala*, No. 93 Civ. 1408 DC, 1997 WL 124106, *5 (S.D.N.Y. Mar. 18, 1997); *Bosko v. Shalala*, No. 95-1608, 1996 WL 895356, *4 (W.D. Pa. Aug. 28, 1996).

312. See [1997-1 Transfer Binder] Medicare & Medicaid Guide (CCH) para. 45,139 at 53,524 (W.D. Pa. Aug. 28, 1996) (quoting *New York v. Secretary of Health and Human Serv.*, 903 F.2d 122, 125 (2d Cir. 1990)).

to comply with the notice and publication requirements of the Administrative Procedure Act,³¹³ or a court has remanded a case to supplement the rule-making record.³¹⁴ Consistent with congressional intent, however, the courts have stayed on the sidelines with respect to Medicare determinations with respect to technology coverage.

A second category of coverage cases involves utilization review: review of the claims of professionals and institutions regarding the treatment of individual patients, often involving routine and non-experimental modalities. Carriers review claims made under Part B are reviewed, and Medicare Peer Review Organizations review claims regarding inpatient hospital care.³¹⁵ Claims are reviewed on both a pre- and post-payment basis, with denial resulting in non-payment for the service. Reviews are based on computer algorithms, and vaguely resemble the German efficiency review system. The appeal procedures and judicial review procedures outlined above are available for adverse utilization review determinations, and a handful of cases have ended with judicial review overturning the original denial.³¹⁶

Two factors combine, however, to keep medical necessity issues out of both the appeal and judicial review process. The first is the "waiver of liability" provisions of the Medicare statute.³¹⁷ If a Medicare beneficiary receives services ultimately determined not to have been "reasonable and necessary," Medicare will still pay for the services if neither the beneficiary nor the person who provided the service "knew, or could reasonably have been expected to know," that the services were excluded from coverage.³¹⁸ Beneficiaries are presumed not to have knowledge of noncoverage absent written notice,³¹⁹ but providers are expected to know that services are excluded from coverage on the basis of "HCFA notices, including manual issuances, bulletins, or other written guides or directives from in-

313. See *Linoz v. Bowen*, 800 F.2d 871, 878 (9th Cir. 1986); *Cedars-Sinai Med. Ctr. v. Shalala*, 939 F. Supp. 1457, 1465 (C.D.Cal. 1996).

314. See *American Lithotripsy Soc'y v. Sullivan*, 785 F. Supp. 1034, 1037 (D.D.C. 1992).

315. See Timothy P. Blanchard, "Medical Necessity" Denials as a Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make it Right or Rational, 34 ST. LOUIS U. L.J. 939 (1990); Alice G. Gosfield, *Slouching Toward the Millennium: False Claims in Medicare Physician Billing*, in HEALTH LAW HANDBOOK, 1997, 51, 76-82 (Alice G. Gosfield ed.) [hereinafter "1997 Handbook"].

316. See Alice G. Gosfield, *Part B Physician Reimbursement Development, Limits, and Pitfalls*, in 1990 HEALTH LAW HANDBOOK 275, 308-09 (Alice G. Gosfield ed.).

317. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400.

318. 42 C.F.R. § 411.400(a)(2).

319. 42 C.F.R. § 411.404.

intermediaries, carriers or PROs," Federal Register notices of national coverage decisions, or "acceptable standards of practice in the local community."³²⁰ If the provider is deemed to have knowledge of noncoverage, but the patient is not, the provider may neither bill Medicare nor the patient for the cost of the service, and must refund any money collected from the patient.³²¹ A physician who believes that a service is not covered by Medicare may inform the patient of that fact, and provide the service at the patient's cost if the patient agrees to pay for it independently,³²² but there are, of course, risks in telling a patient that he or she must pay for a service because Medicare considers it unreasonable or unnecessary.³²³ In the end, the most likely effect of the "waiver of liability" provisions is to create an incentive for physicians to err on the side of not providing, or even offering, services when necessity might become an issue.

This incentive is strengthened by a second phenomena, the recent dramatic increase in Medicare fraud prosecutions. Federal law provides a plethora of criminal, civil, and administrative penalties for false claims. A doctor who submits a false claim commits a felony,³²⁴ is subject to both civil and administrative fines of three times the amount claimed plus \$5000 to 10,000 per claim,³²⁵ and, if convicted of a felony, can be excluded from the Medicare program and from other federal and state health care programs for five years or more.³²⁶ Claims submitted for unnecessary services are false claims. The false claims acts are increasingly being used to police billing practices.³²⁷ A recent Office of Inspector General investigation involving over 100 teaching hospitals challenged as fraudulent the hospital's billing for the use of investigational devices for treating Medicare patients.³²⁸ There are undoubtedly many professionals and providers who continue to bill for services of questionable necessity; the payment system still rewards this. But the risks of doing so are increasing, as are the incentives to deny services. Patients denied care, however, because the doctor simply fails to mention the possibility of a service (because the doctor fears denial of payment and of liability waiver on the one hand or

320. 42 C.F.R. § 411.406(e).

321. 42 C.F.R. § 411.402.

322. 42 U.S.C. § 1395u(l)(C)(ii).

323. See Blanchard, *supra* note 315, at 1015-21.

324. 18 U.S.C. §§ 287, 1347; 42 U.S.C. § 1320a-7b(a).

325. 31 U.S.C. § 3729(a); 42 U.S.C. § 1320a-7a.

326. 42 U.S.C. §§ 1320a-7(a)(1).

327. See Gosfield, *supra* note 315, at 51.

328. Sanford V. Teplitzky and S. Craig Holden, *1996 Developments in Health Care Fraud and Abuse*, in 1997 HANDBOOK, *supra* note 310, at 35-36.

false claims prosecution on the other) cannot appeal the denial, much less seek judicial review. Thus, judicial review is likely to play a smaller role in these cases, except insofar as fraud cases become trials on medical necessity.³²⁹

The courts have been most active in the final category of disputes considered here: cases involving long term care. Medicare does not pay for "custodial care,"³³⁰ and a host of cases have addressed the question of whether a beneficiary in a hospital or nursing home was simply receiving "custodial care."³³¹ These cases generally involve retroactive denials of large sums of money, and often both the provider and beneficiary have a strong incentive to appeal. The cases are fact intensive and depend on the patient's "total condition."³³² Courts tend to go along with the finding of the patient's physician that the patient needed skilled, and not simply custodial, care,³³³ but other courts recognize that the treating physician often stands to gain from a decision for the patient and that his or her testimony must therefore be discounted.³³⁴ A related issue is the meaning of a need for "part-time and intermittent care," a statutory requirement for home health services.³³⁵ *Duggan v. Bowen*,³³⁶ in which the court found HHS's restrictive definition of the term to be arbitrary and capricious and contrary to law, as well as promulgated in violation of the Administrative Procedure Act, is one of the most successful attempts to use the courts to extend Medicare coverage policy.³³⁷

Duggan and the custodial care cases, however, are the exception rather than the rule. By and large, restrictions on judicial review, layer upon layer of administrative remedies, incentives built into the system to

329. Recent fraud and abuse amendments provides civil penalties for false claims where there is a pattern of billing for services that "a person knows or should know are not medically necessary." 42 U.S.C. § 1320a-7a(a)(1)(E).

330. 42 U.S.C. § 1395y(a)(9); 42 C.F.R. § 411.15(g).

331. 1 HEALTH LAW, *supra* note 6, at § 13-7.

332. See *Ridgely v. United States*, 475 F.2d 1222, 1224 (4th Cir. 1973); *Whitman v. Weinberger*, 382 F. Supp. 256, 263 (E.D.Va. 1974).

333. See *Ridgely*, 475 F.2d at 1224; *Breeden v. Weinberger*, 377 F. Supp. 734, 737 (M.D.La. 1974).

334. See *Goodrich v. Richardson* [1974 Transfer Binder] Medicare and Medicaid Guide (CCH) para. 26,885 (E.D.Pa. 1974).

335. 42 U.S.C. § 1395x(m)(4).

336. 691 F. Supp. 1487, 1514 (D.D.C. 1988).

337. See Eleanor D. Kinney, *The Role of Judicial Review Regarding Medicare and Medicaid Program Policy: Past Experience and Future Expectations*, 35 ST. LOUIS U. L.J. 759, 783-84 (1991). OBRA 1997 enacts into law an expanded definition of coverage sought by the plaintiffs in *Duggan*. See Pub. L. 105-33, 111 Stat. 336, § 4012.

encourage providers to police coverage themselves, and the sheer mind-numbing complexity of the Medicare statute have operated in tandem to keep the courts from playing a significant role in Medicare coverage issues.³³⁸ They have mainly operated at the margins, occasionally straightening out procedural deficiencies in Medicare decision-making, but have left to Congress and the administrative agencies the job of running the program.

B. Medicaid

Compared to the limited judicial involvement in Medicare coverage decision-making, judicial involvement in the Medicaid program has been quite generous, both in terms of its extent and its results. Medicaid is the federal/state program that finances health care for some of America's poor. Historically, Medicaid eligibility was tied to eligibility for cash welfare programs—the program covered the elderly, disabled, blind, and families with dependent children. Over time, however, Medicaid has been transformed into a program that increasingly pays for care for both elderly and disabled persons with serious and chronic medical conditions who require high cost care and poor children and pregnant women, who require relatively low cost, but cost-effective care.³³⁹ The majority of program funding comes from the federal government, and federal statutes and administrative rules and issuances govern the state programs.³⁴⁰ The states participate in the program voluntarily, contributing from about twenty to fifty percent of program cost, but none have been able or willing to forgo the federal money the program brings. The federal statute requires coverage of certain eligibility groups and the provision of particular benefits, but the states have considerable discretion in deciding whether or not to cover optional groups or to provide optional benefits.³⁴¹ In fact, Medicaid programs vary significantly in size and scope from state to state.³⁴²

338. They have played a somewhat more active role in payment issues, where the considerable resources of providers and their associations are more often brought to bear.

339. See BARRY FURROW, ET AL., *HEALTH LAW* 865-67 (3d ed. 1997); Sandra J. Tanenbaum, *Medicaid Eligibility Policy in the 1980s: Medical Utilitarianism and the "Deserving" Poor*, 20 J. HEALTH POL., POL'Y & L. 933 (1995).

340. FURROW, ET AL., *HEALTH LAW*, *supra* note 339, at 881.

341. *Id.* at 870.

342. A 1995 GAO report on Medicaid reported that Nevada served 284 Medicaid beneficiaries for every 1,000 poor or near-poor individuals in the state, whereas Rhode Island served 913 per 1,000. Similarly, Mississippi spent, on average, less than \$2400 per person on Medicaid services, while New York spent an average of almost \$7,300 per person. GENERAL ACCOUNTING OFFICE, *MEDICAID, SPENDING PRESSURES DRIVE STATES TOWARD PROGRAM REINVENTION* (1995).

The Medicaid statute requires states to cover a fairly short list of services: inpatient and outpatient hospital services; laboratory and X-ray services, nursing facility and home health services for adults, physicians' services, nurse-midwife and legally authorized nurse practitioner services, and early and periodic screening, diagnostic, and treatment services (EPSDT) for children, and a few others.³⁴³ A wide range of optional services can be covered by the states, however, and because Medicaid recipients often have no other means to purchase health care services, and coverage of optional services brings federal dollars, many states cover a number of optional services.³⁴⁴

Although states have considerable discretion as to deciding what services to cover at the macro level, their discretion is much more limited with respect to provision of services to individual patients at the micro level. The federal courts, following dicta in an early Supreme Court decision, have consistently read the Medicaid statute as requiring coverage of available services deemed "medically necessary."³⁴⁵ This has generally been interpreted to mean services deemed necessary by the recipient's treating physician.³⁴⁶ Under the federal regulations, each Medicaid-covered service "must be sufficient in amount, duration, and scope to reasonably achieve its purpose."³⁴⁷ A state "may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of diagnosis, type of illness or condition."³⁴⁸ The EPSDT provisions explicitly define EPSDT, a mandatory service for children under twenty-one, to include "necessary health care, diagnostic services, treatment, and other measures . . . to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered

343. 42 U.S.C. § 1396a(a)(10)(A); 1396d.

344. See MEDICARE AND MEDICAID GUIDE, *supra* note 312, para. 15,500 for a state by state list of coverage.

345. See *Beal v. Doe*, 432 U.S. 438, 444-45, (1977) (stating that "serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage.").

346. See *Pinneke v. Preiser*, 623 F.2d 546, 550 (8th Cir. 1980) (stating that the decision of whether or not certain treatment or a particular type of surgery is "medically necessary" rests with the individual recipient's physician and not with clerical personnel or government officials"). See also *Weaver v. Reagan*, 886 F.2d 194, 200 (8th Cir. 1989); *Rush v. Parham*, 625 F.2d 1150, 1157 (5th Cir. 1980); *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990).

347. 42 C.F.R. § 440.230(b).

348. 42 C.F.R. § 440.230(c).

under a state plan.”³⁴⁹ Several courts have further held, however, that states cannot refuse to provide services to persons over twenty-one and that they must provide under EPSDT to those under twenty-one.³⁵⁰ A provision in the federal statute requiring that “assistance shall be furnished with reasonable promptness to all individuals”³⁵¹ has been interpreted to mean that provision of necessary benefits cannot be deferred or delayed by the states.³⁵² Finally, some courts have simply held state Medicaid limitations to be “unreasonable.”³⁵³

The most important factors influencing judicial involvement in Medicaid coverage disputes, however, may be jurisdictional rather than substantive. Unlike the Medicare program, where layer upon layer of administrative remedies must be exhausted before the beneficiary can get to court (if judicial review is available at all), the Medicaid recipient can go directly into federal court. The courts have long recognized the right of Medicaid recipients to sue state programs that have allegedly deviated from federal program requirements under 42 U.S.C. § 1983.³⁵⁴ In *Wilder v. Virginia Hospital Association*,³⁵⁵ the Supreme Court recognized the right of providers to sue directly as well. Some members of the Supreme Court seem eager to cut back on federal court jurisdiction over benefit program disputes,³⁵⁶ and the latest Supreme Court precedents could be interpreted as undermining direct access to the courts.³⁵⁷ However, a recent federal statute, although it is very poorly drafted, seems to support congressional intent to keep the federal courts open to recipients,³⁵⁸ and attempts in the

349. 42 U.S.C. § 1396d(r)(5).

350. See *Fred C. v. Texas Health & Human Serv. Comm'n*, 924 F. Supp. 788, 792 (W.D. Tex. 1996) (durable medical equipment); *Hunter v. Chiles*, 944 F. Supp. 914, 919 (S.D. Fla. 1996); *McDaniel v. Betit* [1996-2 Transfer Binder] Medicare & Medicaid Guide (CCH) para. 44,473 (D.Utah 1996) (organ transplantation); *Salgado v. Kirschner*, 878 P.2d 659, 660 (Ariz. 1994) (organ transplantation).

351. 42 U.S.C. § 1396(a)(8).

352. See *Smith v. Miller*, 665 F.2d 172, 174 (7th Cir. 1981); *McMillan v. McCrimmon*, 807 F. Supp. 475, 480-81 (C.D. Ill. 1992).

353. See *Skubel v. Fuoroli*, 113 F.3d 330, 336-37 (2d Cir. 1997).

354. See *Maine v. Thiboutot*, 448 U.S. 1, 5-6 (1980); Rand E. Rosenblatt, *The Courts, Health Care Reform, and the Reconstruction of American Social Legislation*, 18 J. HEALTH POL., POL'Y AND L. 439, 444-49 (1993).

355. See 496 U.S. 498, 524 (1990).

356. See Rosenblatt, *supra* note 354, at 456-68.

357. See *Suter v. Artist M.*, 503 U.S. 347, 362 (1992).

358. 42 U.S.C. § 1320a-2; see *Cherry v. Thompson*, [1995-2 Transfer Binder], Medicare and Medicaid Guide (CCH) para. 43,485 (S.D. Ohio. 1995) (interpreting statute in Medicaid claim context); see also Brian D. Ledahl, *Congress Overruling the Courts:*

1995 federal budget bill to eliminate federal jurisdiction in Medicaid disputes failed to become law.³⁵⁹

The federal courts normally do not require exhaustion of state Medicaid program administrative remedies as a condition precedent to litigation.³⁶⁰ Many benefit disputes, moreover, come before the federal courts on motions for preliminary injunctions, brought by desperate recipients who have been denied treatment that their treating physicians consider necessary.³⁶¹ These cases focus the court starkly on the irreparable injury the plaintiff faces, and often allow the plaintiff to obtain the desired service on a simple showing of likelihood of success on the merits.³⁶² Because the Eleventh Amendment prohibits damage awards against the states if benefits are improperly denied, the courts have all the more incentive to order the award of benefits prospectively to avoid the need for retrospective relief.³⁶³

Because Medicaid is a state as well as a federal program, recipients also have the option of suing in state court to obtain benefits. State court suits are most likely to be brought where state law or state judges are more sympathetic to the recipient's claim, and plaintiffs therefore win a significant proportion of these cases.³⁶⁴ A number of state courts, for example,

Legislative Changes to the Scope of Section 1983, 29 COL. J.L. & SOC. PROB. 411 (1996).

359. See Balanced Budget Act of 1995, H.R. 2491, § 2154(e)(1) (1995) (prohibiting judicial review of state Medicaid plans under federal law except by the Secretary of HHS.) A recent court of appeals decision, however, holds that federal regulations requiring the states to provide particular Medicaid services not required by statute are not enforceable under 42 U.S.C. § 1983. See *Harris v. Patton*, 127 F.3d 993, 1012 (11th Cir. 1997).

360. See *Tallahassee Mem'l Reg'l Hosp. v. Cook*, 109 F.2d 693, 702 (11th Cir. 1997); *Visser*, 756 F. Supp. at 504.

361. See, e.g., *Mair v. Barton*, [1987 Transfer Binder] *Medicare & Medicaid Guide* (CCH) para. 36,692, available in 1987 WL 108989 (D Kan. July 27, 1987).

362. See, e.g., *DeSario v. Thomas*, 963 F. Supp. 120, 132 (D. Conn. 1997).

363. The courts also recognize that Medicaid recipients lack the financial capacity to pay for services up front and sue for reimbursement later. See *Dodson v. Parham*, 427 F. Supp. 97, 108 (N.D.Ga. 1977).

364. Cf. state court cases granting denied benefits: *Jackson v. Stockdale*, 264 Cal. Rptr. 525, 532 (Cal. Ct. App. 1989) (root canal treatment and crowns); *Persico v. Maher*, 465 A.2d 308, 322 (Conn. 1983) (orthodontic dental services for minor); *McCoy v. Idaho*, 907 P.2d 110, 115 (Idaho 1995) (gastric bypass surgery for obesity); *Biewald v. Maine*, 451 A.2d 98, 102 (Me. 1982) (urine testing materials); *Buhs v. State Dept. of Pub. Welfare*, 306 N.W.2d 127, 132 (Minn. 1981) (chiropractic X-rays); *Kirk v. Dunning*, 370 N.W.2d 113, 115 (Neb. 1985) (periodontal treatment); *Monmouth Med. Ctr. v. State Dept. of Pub. Welfare*, 403 A.2d 487, 494 (N.J. 1979) (hospital services); *A.M.L. v. Dept. of Health*, 863 P.2d 44, 48 (Utah 1993) (breast reduction for patient with lupus); with cases denying treatment: *Holmes v. Kizer*, 13 Cal. Rptr. 2d 746, 755 (Cal. App.

have held that Medicaid beneficiaries have a state constitutional right to abortion, even though federal funding for most abortions is banned.³⁶⁵

The federal courts have quite consistently supported recipient claims to Medicaid services. Federal courts have, for example, required state coverage of sex-change operations,³⁶⁶ access to off-formulary drugs,³⁶⁷ augmentive communication devices,³⁶⁸ Clozaril for the treatment of schizophrenia,³⁶⁹ and AZT treatment for AIDS.³⁷⁰ Even when optional services are at issue, the courts hold that the states that have opted to offer a service cannot deny it to persons who need it. States that provide eyeglasses for post-cataract surgery patients, for example, must also provide them for patients with serious refractive error.³⁷¹ Courts have also reserved the right to review state determinations that a procedure is "experimental" and thus not covered.³⁷²

Where there are specific federal limitations on Medicaid coverage, the courts have tended to interpret these quite conservatively and to order states to provide coverage where it is not prohibited. Congress has repeatedly imposed strict limits on the availability of Medicaid funding for abortions, for example, but the federal courts have consistently required the states to fund medically necessary abortions to the extent not prohibited by federal law.³⁷³ When Congress recently expanded Medicaid abortion

1992) (marijuana); *Viveros v. State Dept. of Health and Welfare*, 889 P.2d 1104, 1107 (Idaho 1995) (surgery to reduce and reshape child's ears); *Anderson v. Dept. of Soc. Servs.*, 300 N.W.2d 921, 926 (Mich. 1981) (root canal).

365. See *Right to Choose v. Byrne*, 450 A.2d 925, 941 (N.J. 1982); *Moe v. Secretary of Admin. and Fin.*, 417 N.E.2d 387, 485 (Mass. 1981); *Committee to Defend Reprod. Rights v. Myers*, 172 Cal.Rptr. 866, 886 (Cal. 1981).

366. See *Pinneke v. Preisser*, 623 F.2d 546, 550 (8th Cir. 1980).

367. See *Dodson*, 427 F. Supp. at 111.

368. See *Hunter v. Chiles*, 944 F. Supp. 914, 922 (S.D.Fla. 1996); *Fred C.*, 924 F. Supp. at 792.

369. See *Visser*, 756 F. Supp. at 507.

370. See *Weaver*, 886 F.2d at 199-200; *Mair*, [1987 Transfer Binder] *Medicare & Medicaid Guide* (CCH) para. 36,692, available in 1987 WL 108989.

371. See *Ledet v. Fischer*, 638 F. Supp. 1288, 1293 (M.D. La. 1986); see also *White v. Beal*, 555 F.2d 1146, 1152 (3d Cir. 1977); *Simpson v. Wilson*, 480 F. Supp. 97, 103 (D. Vt. 1979) (state programs that provide glasses for persons with eye diseases must also provide them for persons with refractive error).

372. See *Miller v. Whitburn*, 10 F.3d 1315, 1320-21 (7th Cir. 1993); *Meusberger v. Palmer*, 900 F.2d 1280, 1283-84 (8th Cir. 1990); *Weaver*, 886 F.2d at 198.

373. See *Elizabeth Blackwell Health Ctr. v. Knoll*, 61 F.3d 170, 184 (3rd Cir. 1995), cert. denied, 116 S.Ct. 816 (1996); *Hern v. Beye*, 57 F.3d 906, 913 (10th Cir. 1995), cert. denied, *Weil v. Hern*, 116 S.Ct. 569 (1995); *Preterm v. Dukakis*, 591 F.2d 121, 134 (1st Cir. 1979).

funding to cover abortions in rape and incest cases, for example, the courts required state expansion as well.³⁷⁴

Cases involving coverage of organ transplantation under EPSDT also illustrate this tendency. As discussed above, the EPSDT program requires the states to provide necessary medical treatment services to children, including presumably organ transplantation where necessary. 42 U.S.C. § 1396b(i)(1), on the other hand, requires the states, as a condition of federal funding, to promulgate written standards respecting coverage of organ transplantation that treat similarly situated individuals alike and that provide that restrictions on facilities and practitioners which may provide organ transplantation are "consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan." Several federal courts have interpreted these provisions as giving the states discretion over the extent to which their Medicaid programs will cover organ transplantation.³⁷⁵ Other courts, however, have read these provisions as subordinate to the general requirement that Medicaid cover necessary organ transplants, and have ordered transplants not available under state law.³⁷⁶ Still others have interpreted state standards as covering³⁷⁷ or potentially covering³⁷⁸ organ transplants in situations where the state had denied coverage.

State Medicaid agencies seeking to limit Medicaid coverage have been most successful in federal litigation challenging coverage limitations when they have imposed across-the-board utilization restrictions, for example, limiting length of coverage for hospital stays³⁷⁹ or restricting coverage to three physician visits a month.³⁸⁰ Although these usage restrictions could have an equally devastating effect on recipients as denials of specific

374. See Knoll, 61 F.3d at 184; Hern, 57 F.3d at 913.

375. See Dexter v. Kirschner, 984 F.2d 979, 987 (9th Cir. 1992); Ellis v. Patterson, 859 F.2d 52, 55 (8th Cir. 1988); see generally Lisa Deutsch, *Medicaid Payment for Organ Transplants: The Extent of Mandated Coverage*, 30 COL. J.L. & SOC. PROB. 185 (1997); C. David Flower, *State Discretion in Funding Organ Transplants under the Medicaid program: Interpretive Guidelines in Determining the Scope of Mandated Coverage*, 79 MINN. L. REV. 1233 (1995); David L. Weigert, *Tragic Choices: State Discretion over Organ Transplant Funding for Medicaid Recipients*, 89 NW. L. REV. 268 (1994).

376. See Pittman v. Florida Dept. Health & Rehab. Serv's, 998 F.2d 887, 892 (11th Cir. 1993); Pereira v. Kozlowski, 996 F.2d 723, 727 (4th Cir. 1993).

377. See Meusberger, 900 F.2d at 1283.

378. See Miller, 10 F.3d at 1320-21 (remanded to determine if liver-bowel transplant properly characterized as "experimental").

379. See Charleston Mem'l Hosp. v. Conrad, 693 F.2d 324, 330 (4th Cir. 1982); Virginia Hosp. Ass'n v. Kenley, 427 F. Supp. 781, 786 (E.D. Va. 1977).

380. See Curtis v. Taylor, 625 F.2d 645, 652-53 (5th Cir. 1980).

services, courts ultimately recognize the authority of states to place some limits on program expenditures, and tend to see this as a reasonable approach.³⁸¹ The Supreme Court has rejected challenges to such limitations based on their disproportionate effect on disabled persons.³⁸² Even in cases completely rejecting challenges to limitations of services by Medicaid agencies, however, courts have required state compliance with due process notice and hearing requirements to permit challenges to individual applications of the rule.³⁸³

Although recipients have enjoyed considerable success when they have brought judicial challenges to Medicaid coverage policy, such challenges are nevertheless relatively rare. By definition, Medicaid recipients cannot afford medical care, and they cannot afford legal representation either. Although legal services programs have represented some in the past, funding for legal services for the poor has become ever more restrictive. Medicaid is moving quickly to managed care, and is encouraged to do so by recent federal legislation.³⁸⁴ Although Medicaid managed care plans must provide grievance and appeal procedures,³⁸⁵ the structures and incentives of managed care plans will render less frequent the situation most likely to result in a favorable judicial decision: the patient and her doctor aligned against a state bureaucracy. Judicial activism in the Medicaid program has had a significant impact on the program, however, and is in marked contrast to the restrained role the courts have played in the Medicare program.

VIII. Private Insurance Coverage in the United States: From Contract to Administrative Law

The volume of litigation involving private insurance coverage in the United States, though not nearly as great as in Germany, is larger than the volume of public insurance cases, and rapidly increasing.³⁸⁶ This litigation is unlike that involved in all other programs discussed so far, because it is, at least in theory, based on contract rather than on statutes and regulations.

381. *But see* *Montoya v. Johnson*, 654 F. Supp. 511, 514 (W.D. Tex. 1987) (rejecting \$40,000 cap on inpatient hospital expense payments as impermissible).

382. *See Alexander v. Choate*, 469 U.S. 287, 308-09 (1985).

383. *See Cherry v. Thompson*, [Transfer Binder 1995-2] Medicare and Medicaid Guide (CCH), para. 43,385 (S.D. Ohio March 31, 1995).

384. Pub. L. 105-33, 111 Stat. 278, §§ 4701-4710 (1997).

385. 42 U.S.C. § 1932(b)(5).

386. *See* Mark Hall, et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L.REV. 1055, 1060-61 (1996).

For the past decade, these cases have generally involved high cost therapies sought by patients with critical illnesses (often women with breast cancer), which therapies have been refused by insurers and claims administrators who assert that the therapies are experimental and of unproven value. The rationing issues raised by the cases (as well as the issues they present regarding the appropriate role of markets, regulators, and professionals in health care resource allocation, federalism, dispute resolution, and gender discrimination) have resulted in a considerable body of academic commentary.³⁸⁷

Historically, health insurance coverage disputes were litigated only rarely. They often involved marginal therapies or dubious medical value, as insurers would normally cover therapy if it was ordered by a reputable physician.³⁸⁸ When disputes arose, they were generally decided under rather straightforward contract law principles.³⁸⁹ The insured commonly won, even in some rather extreme cases, as the courts would apply the principle of *contra proferentum* to interpret vague and ambiguous contracts in the insureds favor, or interpret clauses in light of the insured's "reasonable expectations."³⁹⁰ In some jurisdictions, the emerging law of bad faith breach of insurance contracts gave the insured the benefit of tort as well as

387. See generally MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, & ECONOMICS OF RATIONING MECHANISMS 68-73 (1997); RAND E. ROSENBLATT, ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 139-292 (1997); John H. Ferguson, et al., *Court-Ordered Reimbursement for Unproven Medical Technology: Circumventing Technology assessment*, 269 JAMA 2116 (1993); Margaret Gilhooly, *Broken Back: A Patient's Reflections on the Process of Medical Necessity Determination*, 40 VILL. L. REV. 153 (1995); Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992); Comment, Barbara A. Fisfis, *Who Should Rightfully Decide Whether a Medical Treatment Necessarily Incurred Should be Excluded from Coverage under a Health Insurance Policy Provision Which Excludes from Coverage "Experimental" Medical Treatments*, 31 DUQ. L. REV. 777 (1993); Comment, J. Gregory Lahr, *What is the Method to Their "Madness?" Experimental Treatment Exclusions in Health Insurance Policies*, 13 J. CONTEMP. HEALTH L. & POL'Y 613 (1997); Richard S. Saver, *Reimbursing New Technologies: Why are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095 (1992); Comment, Denise S. Wolf, *Who Should Pay for "Experimental" Treatments? Breast Cancer Patients v. Their Insurers*, 44 AM. U. L. REV. 2029 (1995).

388. See 1 HEALTH LAW, *supra* note 6, at § 11-2; Hall & Anderson, *supra* note 387, at 1645-46.

389. 1 HEALTH LAW, *supra* note 6, at § 11-2.

390. Hall & Anderson, *supra* note 387, at 1648-49; Saver, *supra* note 387, at 1100-03; Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525, 1549-52 (1996).

contract law, and raised the stakes for insurers who denied coverage.³⁹¹ In others, state insurance mandates denied insurers the discretion to refuse to cover certain services.³⁹²

In the late 1980s, however, several factors changed the nature of insurance contract disputes.³⁹³ For one thing, the stakes got higher: disputes became focused on cutting edge therapies that cost tens, if not hundreds, of thousands of dollars.³⁹⁴ As insurance markets became more competitive, insurers may have become more aggressive in denying coverage for such procedures.³⁹⁵ Disputes also increasingly involved preadmission or pre-procedure utilization review denials, rather than retrospective payment denials, and thus presented much more urgently and immediately the need for treatment.³⁹⁶ Disputes began to focus less on therapies commonly regarded as quackery or as excessive and unnecessary, and more on therapies that came from the mainstream of medical practice, even if they remained arguably experimental in nature.³⁹⁷ Finally, and most importantly, the disputes largely moved from state court, where they were litigated as contract and tort law claims, to federal court, where the disputes are litigated under the Employee Retirement Income Security Act of 1974.³⁹⁸

ERISA is a law adopted in the 1970s to protect the security of pensions.³⁹⁹ Incidentally, however, the law regulates employee benefit as well as pension plans, including health benefit plans. ERISA preempts any state law that relates to an employee benefit plan.⁴⁰⁰ State laws that regulate insurance, including insurance benefit mandates,⁴⁰¹ are saved from

391. See *Aetna Life Ins. Co. v. Lavoie*, 505 So.2d 1050, 1053 (Ala. 1987); *Hughes v. Blue Cross*, 263 Cal. Rptr. 850, 857-58 (Cal. Ct. App. 1989); 1 *HEALTH LAW*, *supra* note 6, at § 11-3.

392. 1 *HEALTH LAW*, *supra* note 6, at § 11-4.

393. See ROSENBLATT, ET AL., *supra* note 387, at 212-13; Hall & Anderson, *supra* note 387, at 1644-62.

394. The cost of Autologous Bone Marrow Transplantation for breast cancer, the most frequently litigated issue in recent years, ranges from \$80,000 to \$150,000, GENERAL ACCOUNTING OFFICE, HEALTH INSURANCE, COVERAGE OF AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR BREAST CANCER 3 (1996) [hereinafter "GAO COVERAGE"].

395. Hall & Anderson, *supra* note 387, at 1658-62.

396. *Id.* at 1644-57.

397. *Id.* at 1651-57.

398. 29 U.S.C. §§ 1001 *et seq.*

399. See Daniel M. Fox & Daniel C. Schaffer, *Health Policy and ERISA: Interest Groups and Semipreemption*, 14 J. HEALTH POL., POL'Y & L., 239 (1989) (setting forth history of ERISA preemption).

400. 29 U.S.C. § 1144(a).

401. See *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 758 (1985).

preemption.⁴⁰² Self-insured employee benefit plans, however, are deemed not to be insurance for purposes of state regulation, and are thus solely regulated by federal law.⁴⁰³ In large part because of this provision, sixty percent of employees in large firms are now in self-insured plans.⁴⁰⁴ ERISA also totally preempts tort claims involving denials of insurance benefits.⁴⁰⁵ These claims are regarded as based on state law that "relates to" benefit plans, and are thus preempted under ERISA. They are not, however, laws that "regulate insurance," and are thus not saved from preemption under ERISA's savings clause.⁴⁰⁶ ERISA allows defendants to remove insurance claim benefit cases to federal court, where most courts have held that they are to be tried without a jury.⁴⁰⁷ As most private health insurance in the United States is obtained as an employment benefit, insurance claims disputes are increasingly being tried in federal courts under ERISA.

Although many issues involving ERISA remain hotly contested, the outline of ERISA law as it affects insurance claims disputes is becoming clear. ERISA permits a beneficiary covered by ERISA plans to bring a civil action "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."⁴⁰⁸ It does not permit recovery of extra-contractual or punitive damages, but does allow prevailing plaintiffs (or defendants) to recover costs and attorney's fees.⁴⁰⁹ Beneficiaries must exhaust plan remedies before pursuing judicial remedies.⁴¹⁰

Under the Supreme Court's decision in *Firestone Tire and Rubber Company v. Bruch*, benefit determinations made by plan fiduciaries and

402. 29 U.S.C. § 1144(b)(2)(A).

403. 29 U.S.C. § 1144(b)(2)(B).

404. Gregory Acs, et al., *Self-Insured Employer Health Plans: Prevalence, Profile, Provisions, and Premiums*, 15 HEALTH AFF., Summer 1996, at 266, 269.

405. See *Pilot Life v. Dedeaux*, 481 U.S. 41, 57 (1987). Malpractice claims, alleging substandard medical care, are not preempted by ERISA, and can be brought against managed care plans that provide medical care directly either on corporate negligence or vicarious liability theories free from ERISA preemption. See *Dukes v. United States Healthcare, Inc.* 57 F.3d 340, 354 (3rd. Cir. 1995) cert. denied 116 S.Ct. 564 (1995). However, benefit denials, even by managed care plans, are preempted, see *id.* at 356; *Cannon v. Group Health Serv.*, 77 F.3d. 1270, 1274-75 (10th Cir. 1996).

406. See *Dedeaux*, 481 U.S. at 57.

407. See *Turner v. Fallon Community Health Plan*, 953 F. Supp. 419, 422-23 (D. Mass. 1997).

408. 29 U.S.C.A. § 1132(a)(1).

409. 29 U.S.C. § 1132(g)(1).

410. See *Hall v. National Gypsum Co.*, 105 F.3d 225, 231 (5th Cir. 1997); *Denton v. First Nat'l Bank*, 765 F.2d 1295, 1300 (5th Cir. 1985).

administrators are generally subject to de novo review by the courts.⁴¹¹ The Court adopted this standard because it saw ERISA plans as fiduciaries, and considered a de novo review standard as appropriate for judicial review of fiduciary decisions.⁴¹² Where the terms of benefit plans, however, give plan administrators and fiduciaries "discretionary authority to determine eligibility for benefits or to construe the terms of the plan," however, the Supreme Court observed that a more deferential form of review was appropriate—plan decisions should be upheld unless they are "arbitrary and capricious."⁴¹³ Health plans are now customarily written, therefore, to allow substantial discretion to the health plan in determining benefits.⁴¹⁴ Health plans that retain discretion to make coverage decisions win significantly more coverage cases than those that do not.⁴¹⁵

Even where the plan retains discretion in making benefit determinations, however, the Supreme Court in *Bruch* suggested that courts should review determinations more closely where the plan administrator or fiduciary faces a conflict of interest.⁴¹⁶ This proposition poses a conundrum. From one perspective, plan administrators always face a conflict of interest, as an important part of their job is to preserve plan assets to assure coverage for other plan beneficiaries, keep premiums low, and, in some instances, to make a profit for the plan.⁴¹⁷ Even if an administrator does not bear risk, it may deny claims because its continued position as a plan manager depends to some extent on its success in keeping the costs faced by

411. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). Questions of law, including interpretation of contracts, are also subject to de novo review. See *Fuja v. Benefit Trust Life Ins. Co.*, 18 F.3d 1405, 1409 (7th Cir. 1994).

412. See *Firestone*, 489 U.S. at 113.

413. See *id.* at 113; see, e.g., *Maune v. International Bhd*, 83 F.2d 959, 962-63 (8th Cir. 1996) (applying standard).

414. Where the contract does not expressly grant the health plan discretion, the courts apply the de novo review standard to health plan decisions. See *Marro v. K-III Communications*, 943 F. Supp. 247, 250-251 (E.D.N.Y. 1996). Courts also require that plan language clearly and unequivocally give the plan discretion. See *Adams v. Blue Cross/Blue Shield*, 757 F. Supp. 661, 666-67 (D. Md. 1991).

415. Hall, et al., *supra* note 386, at 1063.

416. See *Firestone*, 489 U.S. at 115.

417. See *Pitman v. Blue Cross & Blue Shield*, 24 F.3d 118, 123 (10th Cir. 1994); *Brown v. Blue Cross & Blue Shield*, 898 F.2d 1556, 1561 (11th Cir. 1990); see, arguing that insurer's interest conflicts are not a serious problem, Hall & Anderson, *supra* note 387, at 1668-70. Treating physicians, who normally testify for plaintiffs in coverage dispute cases, also usually face a conflict of interest, as they are unlikely to be paid for a procedure unless the insurer approves it. See *Estate of Goldstein v. Fortis Benefit Co.*, available in 1996 WL 18977, *5 (N.D. Ill. Jan. 19, 1996); Hall & Anderson, *supra* note 387, at 1066-68.

the risk bearing employer under control and because it may not want to set a precedent for coverage for its risk-bearing business.⁴¹⁸ Courts have adopted several different approaches to resolving cases once a conflict is found.⁴¹⁹ Some courts have adopted a continuum approach, under which they consider the degree of conflict faced by the plan administrator or fiduciary and adjust the level of review accordingly,⁴²⁰ while other courts have adopted a two step approach, first deciding whether a substantial conflict exists, then placing the burden on the fiduciary to prove that its decision was not tainted by self-interest.⁴²¹ The Second Circuit has recently applied yet another test, considering whether the conflict of interest in fact influenced the insurers decision.⁴²²

Ultimately, whatever standard a court applies, it is left with the job of interpreting a contract and applying its terms to the facts of the case. In doing so, some courts apply common law principles, such as *contra proferentum*,⁴²³ or trust law principles, resolving ambiguities in favor of the beneficiary.⁴²⁴ Other courts, however, have concluded that state common law of insurance contract interpretation is preempted by ERISA, including the principle of *contra proferentum*, and that the courts should read insurance contracts without favoring either party.⁴²⁵

Treating private insurance coverage disputes as contract disputes is problematic, however. Coverage cases are in most instances brought by patients who have not in fact negotiated the contract directly with the insurer. Normally the contract is between the insurer and the beneficiary's

418. See *Reilly v. Blue Cross & Blue Shield United*, 846 F.2d 416, 424 (7th Cir. 1988); ROSENBLATT, LAW & ROSENBAUM, *supra* note 387, at 240.

419. See *Velez v. Prudential Health Care Plan*, 943 F. Supp. 332, 340-41 (S.D.N.Y. 1996).

420. See *Martin v. Blue Cross & Blue Shield*, 115 F.3d 1201, 1206 (4th Cir. 1997); *Doe v. Group Hosp. & Med. Servs.*, 3 F.3d 80, 87 (4th Cir. 1993); *Van Boxel v. Journal Co. Employees' Pension Trust* 836 F.2d 1048, 1052-53 (7th Cir. 1987).

421. See *Brown*, 898 F.2d at 1566-67; see also *Atwood v. Newmont Gold Co. Inc.* 45 F.3d 1317, 1322-23 (9th Cir. 1995).

422. See *Whitney v. Empire Blue Cross & Blue Shield*, 106 F.3d 475, 477 (2d Cir. 1997); *Sullivan v. LTV Aerospace & Defense Co.*, 82 F.3d 1251, 1255-56 (2d Cir. 1996).

423. See *Lee v. Blue Cross/Blue Shield* 10 F.2d 1547, 1551 (11th Cir. 1994); *Doe v. Group Hospitalization & Med. Serv.*, 3 F.3d 80, 89 (4th Cir. 1993); *Heasley v. Beldern & Blake Corp.*, 2 F.3d 1249, 1257-58 (3rd Cir. 1993); *Masella v. Blue Cross & Blue Shield*, 936 F.2d 89, 107 (2d Cir. 1991).

424. See *Blair v. Metropolitan Life Ins. Co.*, 974 F.2d 1219, 1222 (10th Cir., 1992).

425. See *Brewer v. Lincoln Nat'l Life Ins. Co.*, 921 F.2d 150, 153-54 (8th Cir. 1990); *Allen v. Adage, Inc.*, 967 F.2d 695, 701 (1st Cir. 1992); *Hammond v. Fidelity & Guar. Life Ins. Co.*, 965 F.2d 428, 430 (7th Cir. 1992).

employer, and not infrequently the dispute involves a clause added in a rider or policy modification of which even the employer may not have been fully aware.⁴²⁶ When providers sue, they are even more distant beneficiaries of the initial contract.⁴²⁷ In making some decisions, insurers apply internal policies not in fact included in their contracts.⁴²⁸ Even when an individual policy is involved, the dispute rarely involves truly negotiated terms, but rather interpretation of forms provided by the insurer.

The courts seem intuitively to recognize these facts. The cases increasingly resemble more judicial review of the reasonableness of regulatory actions imposed on beneficiaries than an attempt to interpret and apply negotiated contract terms.⁴²⁹ Cases in which insureds prevail often involve arbitrary insurer conduct, much like that condemned in administrative review proceedings. The largest number of disputes, for example, concern autologous bone marrow transplantation (ABMT) for treatment of breast or other cancers.⁴³⁰ Although insurers have more often than not approved ABMT claims,⁴³¹ insurers have often rejected claims for ABMT for breast cancer, one of the most common forms of cancer, while allowing it for treatment of less common cancers, where the success of using the ABMT might be better established, but also where fewer potential cases are involved, and thus the costs of the therapy over time are less. Therapy has been often rejected under open-ended criteria, which allow insurers to make these distinctions, but which appear suspicious to the courts.⁴³² Courts are also troubled when insurers provide minimal information to patients regarding denials, change the basis of a denial after it is challenged, or otherwise fail to address requests reasonably.⁴³³ Also, conduct of insurers who deny ABMT to women with breast cancer, while approving its use

426. See, e.g., *Martin*, 115 F.3d at 1202 (small employer claimed that Blue Cross had never provided it with a copy of the insurance contract); *Bushman v. State Mutual Life Assurance Co.*, 915 F. Supp. 945 (N.D.Ill. 1996) (plaintiff claimed to have bought policy based on representations at marketing meeting that it was "equal to or better than" prior policy, and did not get copy of policy until three months after it was in effect.).

427. See 1 *HEALTH LAW*, *supra* note 6, at § 11-9.

428. See *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 590 (E.D.Va. 1990).

429. See *Murphy v. Wal-Mart Assoc. Group Health Plan*, 928 F. Supp. 700, 705 (E.D. Tex. 1996); see, advocating this approach, *Hall & Anderson*, *supra* note 387, at 1698-709.

430. See, listing many of the cases, *Whitney v. Empire Blue Cross & Blue Shield*, 920 F. Supp. 477, 482 n.5 (S.D.N.Y. 1996), *vacated & remanded*, 106 F.2d 475 (2d Cir. 1997); see also *Saver*, *supra* note 387, at 1111-18.

431. See generally *Peters & Rogers*, *supra* note 208.

432. See *Whitney*, 920 F. Supp. at 486; *Wolf*, *supra* note 387, at 2063-72.

433. See *Velez*, 943 F. Supp. at 341-43 (S.D.N.Y. 1996); *Wolf*, *supra* note 387, at 2072-74.

for men with testicular cancer, for example, raises interesting gender discrimination issues.⁴³⁴ On the other hand, insurers that follow reasonable procedures and apply reasonable substantive criteria are likely to prevail. Health plans that use independent panels of experts for making decisions, or that rely on the decisions of external technology assessment bodies, or that have generous procedures for grievances and appeals are likely to win.⁴³⁵

Insurers seem to be winning more cases in federal court under ERISA than in the state courts under state contract and insurance law.⁴³⁶ In particular, they do significantly better in the federal appeals courts, where the courts focus more on the law, which is on the whole favorable to the insurers, and less on the pathetic facts presented by individual dying patients.⁴³⁷ At the trial court level, however, (and particularly where preliminary injunctions are sought) many courts are still concerned with the dire conditions of claimants, and put off by the callousness or ineptness of some insurers.⁴³⁸ They are also impressed by persuasive expert testimony supporting the insured's claims.⁴³⁹ Even when they rule for insurers, they often do so decrying the fact that statutory law forces them to do so.⁴⁴⁰ But as private law coverage disputes rely less on contract law, and more on in-

434. Wolf, *supra* note 387, at 2086-89.

435. See Martin, 225 F.3d at 1207-09 (insurer extensively reviewed literature before denying claim); Santucci v. Hyatt Corp., 955 F. Supp. 927, 930 (N.D. Ill. 1997) (insurer used independent expert reviewers); Healthcare Am. Plans, Inc. v. Bossemeyer, 953 F. Supp. 1176, 1178-85 (D. Kan. 1996) (elaborate contract and review procedure); Bushman, 915 F. Supp. at 946-47 (contract specifically listed covered procedures, not including that sought). See, discussing ideal experimental treatment exclusion language, David Eddy, *Benefit Language: Criteria that will Improve Quality While Reducing Cost*, 275 JAMA 650 (1996). (Proposed treatment reviewed by panel of two highly qualified experts completely independent of insurance company). Courts will also enforce policy provisions requiring disputes to be submitted to arbitration. See Davenport v. Blue Cross, 60 Cal.Rptr. 2d 641, 648 (Cal. Ct. App. 1997).

436. See Hall, et al., *supra* note 386, at 1062; Wolf, *supra* note 387, at 2062.

437. Hall, et al., *supra* note 386, at 1064; see, e.g., Parks v. Blue Cross & Blue Shield, 116 F.3d 485 (9th Cir. 1997) available in 1997 WL 303308, *3; Fuja, 18 F.3d at 1412; Maune v. International Bhd of Elec. Workers, 83 F.3d 959, 964 (8th Cir. 1996).

438. See Marro v. K-III Comm., 943 F. Supp. 247, 251-53 (E.D.N.Y. 1996); Hall and Anderson, *supra* note 387, at 1676; see Velez, 943 F. Supp. at 338 (holding that preliminary injunction ordering payment of benefits was prohibitory rather than mandatory, since it prohibited the insurer from "interference with vested contract rights.").

439. See, e.g., Pirozzi, 741 F. Supp. at 591-93.

440. See Fuja, 18 F.3d at 1407; Bushman, 915 F. Supp. at 953-54; see also Andrews-Clarke v. Travelers, available in 1997 U.S. Dist. LEXIS 17390 (Oct. 30, 1997) (court in dismissing state law suit against an insurer for wrongful denial of claim removed into federal court describes ERISA as "ridiculous" and "disturbing").

terpretation of statutes, and review of the reasonableness of the decisions of increasingly sophisticated insurers, claimants seem to be losing with increasing frequency.

IX. Conclusion

All developed nations rely on some form of third party payment—social insurance systems, national health services, commercial insurance—for financing health care services. Because such services and the resources needed to purchase them are scarce, inevitably someone is denied services he or she desperately wants, and perhaps desperately needs. Providers are often, moreover, refused payment for services they have provided to their patients or believe that their patients need. Patients and providers denied services or the funds to purchase services often have plausible legal claims—statutory, regulatory, or contractual—to the denied services or funds. Sooner or later these claims end up in court. The victims of rationing turn to the judiciary as their last hope.

The vast majority of instances of rationing are never challenged in court, of course. Rationing is often effected by mechanisms that do not present a clear refusal or denial of a service that is subject to judicial review. These mechanisms include deterrence (potential patients are discouraged from seeking services by geographic inaccessibility or unfriendly receptionists, providers are discouraged from providing services by utilization reviewers whose phone and fax lines are always busy), deflection (patients are steered away from the service they need to less expensive services or to services that some other agency will pay for), delay (including queues for services and endless requests for more information), or dilution (patients get the rationed service, only less of it).⁴⁴¹ Only a very tiny fraction of express decisions to deny or to terminate services, moreover, are challenged in court, even in countries like Germany that have an active system of judicial review.

Judicial challenges to service denials, however, have a greatly disproportionate impact on subsequent resource allocation decisions. Although many decisions to deny ABMT for the treatment of breast and other cancers were challenged in court in the United States in the late 1980s and early 1990s, most insurers in fact approved payment for this service during that time,⁴⁴² and many did so to avoid potential litigation.⁴⁴³ Judicial over-

441. See KLEIN, ET AL., *supra* note 252, at 11-12.

442. Peters & Rogers, *supra* note 208. In 1990, the national Blue Cross/Blue Shield organization agreed to fund clinical trials to be carried out under the auspices of the Na-

sight of the *Wirtschaftlichkeitsprüfung* system in Germany has largely determined the forms which that process has taken. Even in Britain, where the courts have in most instances refused to get directly involved in resource allocation decisions, the government has from time to time revised its policies once they were challenged.⁴⁴⁴

It is obvious, of course, that the courts under consideration here are not fungible. England has no written constitution, a strong civil service, and a relatively weak tradition of substantive judicial review or administrative decisions.⁴⁴⁵ German social court tribunals include representatives of insureds or insurance doctors, are specifically constituted to decide social benefits questions, and operate in an environment of strong constitutional review. American courts draw on both a heritage of judicial independence and a tradition of deference to decisions made by contracting individuals, legislatures and even administrative agencies.

Even if the courts we have considered are not fungible, they are comparable. They are trying to accomplish the same task—reviewing the coverage decisions of payors. And they going about it the same way—determining contested facts and applying law (as found in statutes, regulations, or contracts) to the facts to resolve coverage disputes.

The role of courts in resource allocation decisions in the United States with respect to private insurance has been widely noted. A number of commentators have observed that the courts tend to support insureds at the expense of insurers, and that they tend to say “yes” rather than “no.”⁴⁴⁶ This study, examining the decisions of courts in a variety of health care systems in response to a variety of claims, reveals a more complex and textured picture.

It seems to be true that if courts are asked whether a service claimed by a patient or provided by a provider is “necessary” or “appropriate,” they

tional Cancer Institute to study the effectiveness of ABMT. ROSENBLATT, ET AL., *supra* note 387, at 253-54.

443. See GAO, *supra* note 394, at 9; see also Claudia A. Steiner, et al., *Technology Coverage Decisions by Health Care Plans and Considerations by Medical Directors*, 35 MED. CARE 472, 480 (1997) (stating that potential legal challenges is a significant consideration in coverage decisions).

444. Newdick, Resource Allocation, *supra* note 264, at 303, 306.

445. See PETER SHEARS AND GRAHAM STEPHENSON, JAMES' INTRODUCTION TO ENGLISH LAW 136 (1996) (stating that to be reversed by a court on grounds of irrationality, an administrative decision must “be so outrageously unreasonable that no sensible person who had applied his mind to the question to be decided could have arrived at it.”).

446. Elhauge, *supra* note 21, at 1550-56; Hall, *supra* note 386 at 68-73; Hall & Anderson, *supra* note 387, at 1674-81; Saver, *supra* note 387, at 1100-03.

tend to answer affirmatively.⁴⁴⁷ In such decisions, the court has before it an ill or injured patient in a truly pathetic situation, whose immediate and pressing claim for services is to be weighed against the abstract and theoretical claims of persons not present, or of an impersonal organization that commands considerable resources.⁴⁴⁸ Judges are, like other decisionmakers, more sensitive to the needs of identified than statistical persons.⁴⁴⁹ Courts are also troubled by the conflicts of interest faced by payors, which are obligated to pay for care required by the claimant, but also are concerned with their own profits and the needs of other insureds. Courts are less likely to attend to the conflict faced by the treating physician, who testifies that care he offers the patient is urgently needed.

If, however, the courts are asked to defer to another decisionmaking body, they will in most instances willingly do so. The most obvious example of this is Britain, where the courts seem almost bewildered when asked to review NHS resource allocation decisions, given the high degree of discretion afforded the NHS in these matters.⁴⁵⁰ Courts seem much less likely to intervene in Medicare decisions, where there are layers and layers of administrative review, than in decisions of the Medicaid program, where there is no exhaustion requirement. In Germany, courts are much less likely to reject decisions of the *Shiedsstelle*, which are granted broad discretion by law, than the decisions of the insurers themselves. While courts sometimes protest their impotence in these situations, they nonetheless defer as the law requires.⁴⁵¹

Finally, and not surprisingly, courts are also capable of constraining their desire to help patients in need when a statute, regulation, or contract requires them to consider factors other than need. The German social courts, for example, have proved adept at applying complex criteria in deciding claims to *Hilfsmittel*; the American federal courts have enforced statutory limits on Medicaid abortion coverage and upheld state regulations limiting utilization of Medicaid services where federal regulations permit states this discretion.

447. Mark Hall's empirical study also found that insureds win well over half the time in coverage disputes. Hall, *supra* note 386, at 1062.

448. Hall & Anderson, *supra* note 387, at 1676-77.

449. See Max Mehlman, *Rationing Expensive Lifesaving Medical Treatments*, 1985 WISC. L. REV. 239, 253-56 (1985).

450. Hall's study of judicial review of insurance coverage in the United States, however, also found that the level of success of patients dropped dramatically when the insurer retained discretion in making coverage decisions. Hall, *supra* note 386, at 1063.

451. See cases cited *supra* note 440.

In the end, the most important question is what role courts should play in making coverage decisions. Institutionally, courts are particularly well adapted to particular tasks, such as resolving claims of right or involving the application of laws, regulations, or contracts to proposed conduct (e.g., is a particular medical device covered under the health insurance law) or disputes based on claims of fault involving the interpretation of past conduct (e.g., was a doctor's performance in the past "uneconomic").⁴⁵² Twenty years ago, Professor Lon Fuller in a germinal article noted that courts are less adept at resolving complex disputes regarding multiple parties and policy considerations, and "interacting points of influence," such as more global disputes regarding the allocation of resources within a health care system.⁴⁵³ Such "polycentric" disputes involve intricate networks of many persons, facts, and issues and cannot readily be presented to or resolved by a court.⁴⁵⁴ They are also focused on economic and political interests rather than on rights.⁴⁵⁵ Resolution of some disputes or issues affects others; institutions and approaches are needed that can incorporate a more global perspective on the range and relationship of issues than can courts.

Such disputes are often resolved prospectively through legislative or regulatory processes.⁴⁵⁶ Legislatures and regulatory agencies are equipped to hold hearings involving many parties and issues and to arrive at complex solutions addressing both factual and policy disputes. Each of the health care systems discussed in this article has developed administrative mechanisms for managing some resource allocation issues: the *Schiedsstelle* in Germany; the District Health Authority priority setting and negotiations processes in Britain; the Medicare technology assessment process or increasingly sophisticated technology assessment programs of major insurers in the United States.

Whether we should turn to such processes or to the courts for decisions depends on what we want to accomplish. If our primary goal is protecting the interests of patients, we should assure early and liberal access to the courts. The German statutory insurance system, imbued with a tradition of comprehensive coverage and service to patients, has traditionally embraced this alternative. If, on the other hand, we are more concerned

452. Henry H. Perrit, Jr., *And the Whole Earth was One Language: A Broad View of Dispute Resolution*, 29 VILL. L. REV. 1221, 1228 (1984).

453. See generally Fuller, *supra* note 19.

454. *Id.* at 394-395. The idea was borrowed by Fuller from the writings of Michael Polanyi.

455. Perrit, *supra* note 452, at 1229.

456. Fuller, *supra* note 19, at 398.

with limiting health care expenditures, then the role of the courts should be sharply limited, and managerial processes accentuated, as in Britain.

It is possible, however, both to retain and restrain judicial oversight of health care rationing decisions. This can be accomplished by creating expert review bodies that are responsible for reviewing denials of services in the first instance, requiring exhaustion of administrative remedies, but allowing judicial review in the end. It may be difficult to achieve the "right" level of judicial scrutiny, as courts have a tendency to withdraw from the field once administrative review becomes available, but our evidence also suggests that courts will carry out policy that is clearly articulated by legislation or contract.

This study suggests a host of models for intermediate review mechanisms: arbitration panels, complaint mechanisms, administrative law judges, and grievance panels to name a few. The technology is available. It is up to us, however, to make use of it, to construct a system that will allocate scarce resources, and that will do so justly.