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* Ph.D., University of Rochester School of Medicine and Dentistry, 1975; B. S c., St. Xavier's College, Bombay, India, 1968. Dr. Kotval is a Research Associa te Professor, at the School of Public Health, Department of Health Policy, Mana gement, and Behavior, State University of New York at Albany. Previously, Dr. K otval has been a Senior Staff Scientist for the Legislative Commission on Scien ce and Technology for the New York State Legislature. Dr. Kotval has also autho red numerous papers and reports, and given presentations on regulation and reco mbination of genes in microbial systems. This work was supported by the U.S. De partment of Energy, Office of Health and Environmental Research, Grant Number D E-FG02-97ER62430 to Jerroo S. Kotval et al., entitled: '22Confidentiality Conce rns Raised by DNA-Based Tests in the Market-Driven Managed Care Setting.'22 Th e author wishes to thank Dr. Claudia Ricci for helpful comments on the manuscri pt. \par\par\pard

SUMMARY: ... The confidentiality of the medical record has been in the fore fr ont of the national health policy agenda for the last several years. However, this policy discourse too often ignores what is troubling about confidentiality in the late twentieth century health care system, namely, the confluence of th ree elements: (1) the rise of for-profit, market-driven managed care; (2) the a vailability of computerized medical records on networked computers; and (3) th e availability of genetic tests. ... Cost-saving goals may dictate that mar ke ting strategies are developed to by-pass patients with certain high cost condit ions or that premiums for various health plans offered by MCOs are based on the prognosis of an individual's future health (as determined by a DNA-based test) especially in the absence of laws requiring community rating and prohibiting d iscrimination based on genetic information. ... Policy pro posals to address t he confidentiality of genetic test results continue to assume the paradigm of t he traditional doctor-patient relationship because of the centrality of this re lationship to pro viding care; but this relationship is no longer possible in t he MCO setting where the physician is, to a lesser or greater extent, an agent of the MCO; that is she or he is hired by the MCO and is paid by it and must ab

ide by its rules. ... \par\par\pard

TEXT: \5B*2\5D \par\par

I. Introduction\par

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The confidentiality of the medical record has been in the fore front of the national health policy agenda for the last several years. However, this policy discourse too often ignores what is troubling about confidentiality in the late twentieth century health care system, namely, the confluence of three elements: (1) the rise of for-profit, market-driven managed care; (2) the availability of computerized medical records on networked computers; and (3) the availability of genetic tests. \par

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n1. The first bill addressing the privacy of genetic information was introduced in the 101st Congress in September 1990. Referred to as the '22Human Genome Privacy Act,' it addressed only misuse of genetic information held by agencies or their contractors. H.R. 5612, 101st Cong. (1990). This bill was not enacted. The first bill to address medical privacy was introduced in May 1994 by Senator Leahy as the '22Health Care Privacy Protection Act.' S. 2129, 103rd Cong. (1994). Its intent was to preserve personal privacy with respect to medical records and health-care related information. Id. Again, this bill was not enacted. Since then, several bills have been introduced in state legislatures and in the U.S. Congress. Although several states have enacted laws to protect the confidentiality of genetic information there has been no congressional action on genetic privacy to date. Medical privacy was addressed in the Health Insurance Portability and Accountability Act of 1996 \5Bhereinafter HIPAA\5D which required that the Secretary of Health and Human Services promulgate standards to ensure the privacy of health information by February 1998 if Congress did not take action by August 1997. H.R. 3103, 104th Cong. (1996); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of \i 26 U.S.C., 29\i0 U.S.C., \i 42 U.S.C., and 22\i0 U.S.C.). For a recent overview of legislation, see Philip R.

Reilly, Laws to Regulate the Use of Genetic Information, in Genetic Secrets: Protecting Privacy And Confidentiality in the Genetic Era, 369-91, (Mark A. Rothstein ed., 1997). See also Tom. L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 8-13 (4th ed. 1994) (discussing government guidelines and public policy as well as moral dilemmas with respect to medical confidentiality); George J. Annas et al., Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations, 23 J.L. Med. & Ethics 360, 361 (1995) (describing The Genetic Privacy Act of 1995 which was aimed at prohibiting the disclosure of genetic information without consent); Paul A. Lombardo, Genetic Confidentiality: What's the Big Secret? 3 U. Chi. L. Sch. Roundtable 589, 593-94 (1996) (discussing the demise of medical confidentiality). \par\par

n2. See Inst. of Med., For-Profit Enterprise in Health Care 182-83 (Bradford H. Gray ed., 1986) (examining the commercialization of healthcare organizations) \5Bhereinafter For-Profit Enterprise\5D; see also Final Report of the Task Force on Genetic Testing, Promoting Safe and Effective Genetic Testing in the United States 25-26 (1997) \5Bhereinafter Promoting Safe and Effective Genetic Testing\5D. \par

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In this paper, I highlight the main features of each of these three elements

and then explore the implications for medical confidentiality in the new health care system. I suggest that the centrality of confidentiality to the relationship of patient to caregiver deserves to be strengthened in the age of genetic testing. Genetic information has unique properties not shared by other medical information, and only if the centrality of confidentiality is strengthened can persons of all races, ethnicities, and classes benefit from the fruits of such testing. However, in view of the aggressive cost saving imperatives of market-driven managed care organizations (MCOs), the increasing availability of DNA-based tests poses substantial threats to the maintenance of confidentiality and hence to the acceptance of the appropriate uses of these tests. Furthermore, it is not clear whether a policy can be devised which makes market-driven MCOs compatible with trust in the patient-provider relationship.

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n3. The term Managed Care Organization (MCO) is used rather than the term Health Maintenance Organization (HMO) because historically an HMO implied a specific relationship between the physician/provider and the insurer/health plan - more akin to an employer/employee relationship. The term MCO is broader and encompasses the new and varying forms of structuring this relationship between insurer and provider, including an HMO. See generally Paul Starr, *The Social Transformation of American Medicine* (1982) (providing an historical and developmental background of HMOs and MCOs). See also Aaron Coughy & James Sabin, *Managed Care*, in *Health Care Policy* 88, 88-101 (Rushika J. Fernandopulle et al. eds., 1995) (defining managed care and the rise of HMOs).

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II. Market-driven Managed Care\par
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Managed care is a unique institutional innovation of the late twentieth century health care system, born in the U.S. out of corporate concern with rising health care costs. n4 Managed care is a term that has defied simple definition because of the many ways in which clinical care is institutionally structured, organized and financed. According to one commentator, 'there is no one single definition of the term managed care that has endured in the past or will survive in the future.' n5 Nevertheless, there is a constellation of managerial features and organizational structures unified under a common goal that identifies a managed care organization: 'to control costs through improved efficiency and coordination, to reduce unnecessary or inappropriate utilization, to increase access to preventive care, and to maintain or improve the quality of care.' n6\par

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n4. See Betty Leyerle, *The Private Regulation of American Health Care* 7 (1994) (tracing the private and legislative efforts by corporate America to maintain control over health expenditures and to institute the various forms of corporate oversight and control over health care utilization that have come to be the hallmarks of market-driven managed care. 'Managed competition did not emerge out of any kind of 'free-market' logic - because it is efficient, ensures high-quality care, or controls health care costs. It certainly did not emerge because either the public or health care providers wanted it. Rather, it is t

he result of well thought out political and economic strategies that were originally planned and initiated by corporate America.\''22); see also Vicente Navarro, Why Congress Did Not Enact Health Care Reform, 20 J. Health Pol. Pol'y & L. 455, 458 (1995) (analyzing the power dynamics of health care reform in the United States). For example, the failure of any single-payor proposal for health care and the success of \''22managed competition\''22 was the cornerstone of the Clinton proposal for national health care reform. Id. at 460. According to Navarro, \''22the reality is that the United States lacks a national health care program because of its specific class relations.... For example, why did the major associations representing large employers oppose the single-payer proposal when they would most likely benefit from this proposal by paying considerably less in fringe benefits for their workers? ... As employers, members of the corporate or capitalist class, they most value control over their own labor force, and employment-based health benefits coverage gives them enormous power over their employees.\''22 Id at 458. Navarro points out that the proposal dubbed 'managed competition' that formed the cornerstone of the last national attempt at health care reform was formulated by a task force heavily representing the corporate community and the insurance industry. See id. at 456. Navarro suggests that this key feature of managed competition - namely, the creation of health plans that represent the integration of health provision and health insurance - served as the impetus for the rise of market-driven managed care. See id. at 460. \par

n5. Eric. R. Wagner, Types of Managed Care Organizations, in Essentials of Managed Health Care 24, 33 (Pete R. Kongstvedt ed., 1995). \par\par

n6. See Inst. of Med., Managing Managed Care: Quality Improvement in Behavioral Health I (Margaret Edmunds et. al. eds., 1997); see also Source Book of Health Insurance Data, 18 (32d ed. 1992) (providing an insurance industry definition of managed care as \''22a system that integrates the financing and delivery of appropriate health care services to covered individuals and has the following common elements: arrangements with selected providers to furnish a comprehensive set of health care services to members; explicit standards for the selection of health care providers; formal programs for ongoing quality assurance and utilization review; and significant financial incentives to members to use providers and procedures covered by the plan.\''22). \par

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The main management features include: capitation and other mechanisms controlling compensation to providers, thereby enforcing a sensitivity to cost of care; n7 utilization review; n8 and, to \''5B*5\''5D varying extents, restricted provider choice. n9 These features are, in the aggregate, supposed to provide the penalties and incentives to eliminate unnecessary and expensive care, streamline appropriate care, and reduce administrative costs, leading one commentator to refer to MCOs as \''22entrepreneurial agents of cost containment.\''22 n10\p

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n7. See Peter R. Kongstvedt, Compensation of Primary Care Physicians in Open Panels, in Essentials of Managed Health Care 57, 71-72 (Peter R. Kongstvedt ed. 1995). Capitation payments are fixed payments per member, per month with actuarial adjustments made for the age and gender of the client population served. See id. Since the same payment is made regardless of the services provided, capitation has been criticized as a method of payment that pits the interests of t

he physician against those of his/her patients by providing an incentive to withhold costly services from those who need them. See Marc A. Rodwin, *Medicine, Money and Morals: Physicians' Conflict of Interest* 138- 51, 215 (1993) (discussing the financial risks and incentives offered to physicians by managed care plans). \par\par

n8. See Bradford H. Gray, *The Profit Motive and Patient Care: The Changing Accountability of Doctors and Hospitals* 5, 244-51 (1991) (discussing efforts to control costs through utilization management). Utilization review programs, also referred to as utilization management or utilization control programs, seek to provide oversight to determine whether medical services are truly needed and delivered appropriately, and to profile physicians whose practices deviate from guidelines. See id.; see also Donald F. Anderson & Jeffrey L. Berlant, *Managed Mental Health and Substance Abuse Services*, in *Essentials of Managed Health Care* 150, 154-55 (Peter R. Kongstvedt ed., 1995) (distinguishing 'utilization review' and 'case management'). \par\par

n9. See Wagner, *supra* note 5, at 27 (discussing the restriction of provider choice as a means of controlling costs in health care organizations). \par\par

n10. Robert Kuttner, *Must Good HMOs Go Bad? First of Two Parts: The Commercialization of Prepaid Group Health Care*, *338 New Eng. J. Med.* 1558 (1998) (stating that 'HMOs today are widely seen as entrepreneurial agents of cost containment.'). \par

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Financial compensation for physicians serving MCOs is accomplished either through payment of a salary or is determined by a variety of contractual arrangements between the managed care plan and physicians or physician organizations. n11 Similarly, the extent to which physicians are placed at risk for the cost of care also varies with organizational type and the specific contractual arrangements. n12 In comparing the physician compensation schemes of not-for-profit MCOs with commercial MCOs, Kuttner found that market-oriented MCOs place physicians at greater financial risk. A physician stands to lose up to 50 percent of gross income. n13 Additionally, the physician risks losing part or all of bonus payments that might be earned for holding down high cost services such as hospital and emergency room admissions, and specialist referrals. In contrast, Kuttner notes that 'socially oriented' forms of MCOs, placed only approximately 15 percent of physicians' income at risk. n14\par

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n11. See Peter R. Kongstvedt, *Primary Care in Closed Panel Plans*, in *Essentials of Managed Health Care* 50, 56-58 (Peter R. Kongstvedt ed., 1995) (describing various compensation schemes for physicians). \par\par

n12. See id.; see also Marsha R. Gold et al., *A National Survey of the Arrangements Managed-Care Plans Make With Physicians*, *333 New Eng. J. Med.* 1678, 1680 (1995) (discussing risk sharing by physicians). \par\par

n13. See Kuttner, *supra* note 10, at 1561. \par\par

n14. See id. (stating 'for example, U.S. Healthcare ... puts roughly half the gross income of its physicians at financial risk. One component of the risk, affecting 10 to 15 percent of income, is a bonus system that rewards doctors for meeting clinical and marketing goals and achieving a high level of patient satisfaction.'). \par

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\5B*6\5D Managed care organizations attempt to streamline health care delivery through a 'gate-keeper' physician, who provides continuity of care and coordinates referrals. This aspect of the system is shared with the health care systems of most of the industrialized countries that provide for universal access to health care. n15 The real policy significance of the transformation of health care delivery in the United States is the shift in the locus of control of medical practice from physicians to financial managers. n16 Viewed another way, managed care in the U.S. may be thought of as the management of medicine by the insurance industry. n17 This key feature of managed care organizations is significant in addressing the ethics of medical confidentiality, in that this health care entity is both the provider and insurer/payor, since physicians are either salaried employees of the MCO or under contract to it. n18\par

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n15. See id. at 1561 (discussing the gatekeeper function of primary physicians making referrals to specialists). See generally Health Care and Reform in Industrialized Countries, (Marshall W. Raffel ed., 1997). The United Kingdom, Canada, Denmark, the Netherlands, Sweden and New Zealand all have a system in which the primary care provider is the conduit for access to specialist services. Despite the fact that France and Germany do not specifically require patients to choose a primary care doctor, universal access to health care in fact brings this about. See id. at 7, 32, 67, 86, 137, 166, 195, 242. \par\par

n16. See Leyerle, supra note 4, at 18-19 (discussing the changes in health care during the last twenty years). \par\par

n17. See id. \par\par

n18. See Kongstvedt, supra note 11. \par

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Investor-owned organizations are a relatively new phenomenon in the health care field. Originally restricted to investor-owned hospitals started in the 1960s, '22their rate of growth has exceeded that of not-for-profit systems.'22 n19 '22In 1983, U.S. Health Care Systems became the first publicly traded managed-care organization, raising \$25 million in initial stock offerings.'22 n20 While a detailed elaboration of the differences between for-profit and not-for-profit organizations is beyond the scope of this discussion, it is significant that one of the central purposes of an investor-owned organization is to generate a return on the investment. n21 This appears to create a conflict of interest between the profitability of the MCO \5B*7\5D on the one hand - and perhaps its survival - and its obligation to patient care on the other. Dr. Harris Berman, the Chief Executive Officer of Tufts Associated Health Plan (a not-for-profit plan), is quoted as saying, '22unlike a shareholder-owned HMO, \5B a n executive officer\5D can have a bad year or two and not face terrible pressures to reduce care.'22 n22 Opposed to this is the for-profit HMO, where officers and directors are under an obligation to increase shareholder wealth, even if this means cutting patient care. n23\par

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n19. For-Profit Enterprise, supra note 2, at 29. \par\par

n20. Id. at 33. \par\par

n21. See Sunny G. Yoder, Economic Theories of For-Profit and Not-For-Profit Organizations, in For-Profit Enterprise, supra note 2, at 19, 21-22 (suggesting that a for-profit firm's objective is to maximize profits); see also Gray supra note 8, at 36 (suggesting that increases in earnings and corporate growth of investor-owned companies '22were due to the managerial ability and incentives that came from their organizational form'22). \par\par

n22. See Kuttner, supra note 10, at 1560 (quoting Dr. Harris Berman, CEO of Tufts Associated Health Plan). \par\par

n23. See Gray, supra note 8, at 91 (explaining how for-profit organizations have owners who have a property right to their share of the organization's profits). \par

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Market-driven MCOs, typified by investor-owned corporations, seek to control costs by aggressively capturing market share in order to achieve economies of scale. n24 However, when operating in the same economic and competitive environment, survival dictates that not-for-profit and for-profit organizations will behave similarly. As Bradford H. Gray points out, '22the question of who is entitled to any income generated by the organization may not ... be as crucial in shaping organizational behavior as is the environment in which the organization operates.'22 n25\par

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n24. See supra notes 19-23 and accompanying text. \par\par

n25. Gray, supra note 8, at 91. \par

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The misperception that conflates the for-profit drive with a competition driven institution also needs to be addressed. Paul Menzel correctly points out that a not-for-profit provider may be fiercely competitive, and a for-profit provider who enjoys a monopoly could be insulated from competition. n26 Nevertheless, for-profit institutions that offer common stock as a means of raising capital are, at least in principle, institutionally tethered to seeking profits in the interest of paying dividends and otherwise remaining viable. n27 While competitive pressures force institutions to keep prices down in the interest of securing market share, the imperative of financial viability adds to aggressive cost-cutting practices. n28 Competition from market-driven MCOs has forced other '5B*8'5D insurers to institute similar cost control practices, such as utilization review, or risk losing business. n29\par

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n26. Paul T. Menzel, Strong Medicine: The Ethical Rationing of Health Care 132 (1990) (stating '22that the two '5Bcompetition and not-for-profit arrangements'5D are different, however, can be understood by noting that non-profit providers can heatedly compete or that for-profit providers can be insulated from competition by monopoly power.'22). \par\par

n27. See generally Kuttner, supra note 10, at 1561. \par\par

n28. See generally id. \par\par

n29. See id. (describing market forces in the health care system). \par

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Utilization review is a set of mechanisms for controlling costs incurred by MCOs. n30 In varying forms it is implemented prior to, concurrent with, and after the delivery of certain health care services; these are referred to respectively as prospective review, concurrent review and retrospective review. n31 Each has the same goal: to provide third party scrutiny over physicians' medical decisions. n32 Originated by the federal government as an oversight method for Medicare payments, n33 utilization review was soon adopted by hospitals seeking to manage costs, and later aggressively adopted by market-driven MCOs. n34 The practice used is now widely adopted in varying degrees by all health care organizations. n35 Therefore, even though this practice is not unique to market-driven managed care, it is the ethos of this industry that drives the cost-cutting practices of all health care organizations that wish to survive and retain consumers in the current health care market. n36\par

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n30. See *id.* See generally Gold et al, *supra* note 12; see also Gray, *supra* note 8, at 151, 246, 264 (pointing out that retrospective utilization review was required from the outset by Medicare regulations and the earliest tools for ongoing management of utilization were developed in response to the rising costs of Medicaid and Medicare programs). The presently implemented case-by-case review of physicians' decision-making prior to the provision of services was not part of organizational practice until self-insured plans began implementing it. See *id.* at 246, 264; see also Thomas Bodenheimer & Kip Sullivan, How Large Employers are Shaping the Health Care Marketplace, 338 *New Eng. J. Med.* 1003-1007 (1998) (chronicling the changes in decision making in health care from individuals to HMOs). \par\par

n31. See Peter R. Kongstvedt, *Essentials of Managed Health Care* 123-31 (1995) (discussing the three forms of review); see also Gray, *supra* note 8, at 247-73 (describing the different types of review and the reasons why each was created). \par\par

n32. See Kongstvedt, *supra* note 31; see also Gray, *supra* note 8, at 246-73.

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n33. See *supra* note 30 and accompanying text. \par\par

n34. See Gray, *supra* note 8, at 248. \par\par

n35. See *id.* (explaining that most utilization systems grew out of MCOs with additional development by private insurers, third party administration, and utilization management organization). \par\par

n36. See Kutner, *supra* note 10, at 1561-62 (describing various HMO plans and how they respond to market pressures). \par

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Utilization review achieved through audit trails and facilitated by relational databases on networked computers aims to discover 'unnecessary expenses' by tracking each physician's referral practices, test-ordering practices, and even treatment protocols for various diseases and conditions.

n37 Utilization review is central to our concern regarding medical confidentiality, as it exposes the medical record to several people who are not licensed professionals. n38 As such, they are not bound by the professional confidentiality laws of most states. n39 Further, utilization review exposes the medical record to persons who have, as part of their job descriptions, the imperative of

f cost cutting.\par

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n37. See Gray, *supra* note 8, at 251 (pointing out that evidence that many services which are deemed unnecessary or inappropriate strongly influenced the perceived need for utilization management). \par\par

n38. See *id.* at 297-98 (describing the variations of how information is transferred by organizations using utilization review). \par\par

n39. See *id.* (stating that utilization review management programs have done a great deal of independent inventing). The Federal Rules of Evidence recognize common law privileges, such as the doctor-patient privilege, which can be invoked by individuals at trial to prevent the disclosure of confidential patient information. See Fed. R. Evid. 501 (stating that privileges are to be extended in accordance with common law). \par

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It has been documented that traditional insurers use discriminatory practices - referred to as "cream skimming" or "cherry picking" - to control costs and to maintain market position by seeking to insure only the healthiest individuals in the population. n40 These practices include: (1) refusing new coverage for individuals with pre-existing conditions; n41 (2) terminating the policies of people with high medical costs; (3) charging substantially higher individual premium rates to individuals who are ill or have a family history of illness; (4) using experience rating n42 to set premiums for companies that have employees with high health care costs; and (5) engaging in a variety of practices that make it harder for individuals with higher health risks to obtain coverage by such practices as selective marketing so that high risk individuals are by-passed, or by tailoring health packages so that care needed for specific high-cost illnesses is not provided. n43 Therefore, consumers who most often find themselves with little or no insurance are those with a history of, or a potential for, serious illness. n44 It should be noted that all of these strategies are more easily adaptable to discrimination against persons with pre-existing genetic conditions.\par

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n40. See David Calkins et al., *Health Care Policy* 80 (1995) (describing the practice of "cream skimming," an insurance company practice that grants coverage preferentially to low-risk patients). \par\par

n41. Discrimination on the basis of a pre-existing condition is limited by HIPAA. See 26 U.S.C.A. 9801. However, ingenious methods to circumvent the intent of the law have been attempted by MCOs. These include, charges as high as five times the regular rate to cover persons with pre-existing conditions (not explicitly forbidden in the law), delaying the review of high-risk policies until more than 60 days have passed and the coverage no longer falls within the time period provided by the law, and penalizing insurance agents who sell coverage to high-risk customers by eliminating commissions for such sales. No doubt, these are methods to avoid high cost clients. See American Health Line, Oct. 6, 1997. \par\par

n42. Experience rating is a methodology for setting premiums based on the past claims experience of a group. See Calkins et al., *supra* note 40, at 81. \par

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n43. See id. at 80. \par\par

n44. See id. \par

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MCOs similarly engage in these patient selection practices to remain profitable. n45 In addition, market-driven MCOs, as a last resort, are known to sell off any unprofitable businesses leaving large groups of patients to search for new sources of care. n46 Paul Menzel predicted, on theoretical grounds, that '2 competition will increase pressures on sicker subscribers towards selection of more comprehensive plans, and insurers will attempt to skim the cream of healthy subscribers into lower-cost coverage.'22 n47\par

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n45. See Gray, supra note 8, at 107-09. \par\par

n46. See, e.g., David J. Morrow, Medicare Panacea Turns Patient: HMO's Now Must Treat Their Own Ills, N.Y. Times, Sept. 9, 1998, at C1 (describing how many HMOs who took on Medicare patients are '22heavily retreating'22 from the market because of spiraling costs). \par\par

n47. Menzel, supra note 26, at 134. \par

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In summary, the features of market-driven MCOs indicate that they must aggressively seek to control costs - even by methods that question whether the quality of care is compromised. This, of course, raises fundamental issues for the tradition of patient-centered care. MCOs that would otherwise choose to engage in different managerial decisions must adopt the aggressive cost-cutting practices of market-driven MCOs if they wish to survive in the same market. n48 This steady shift towards the predominance of competitive business practices in health care has been lamented by many because they adversely affect the fiduciary ethic of the doctor-patient relationship. n49 The result is a cultural transformation of the health care system from an ethic of care to an ethic of '5B* 11'5D cost. n50 Genetic tests, especially those which put predictive power about future health care costs in the hands of managed care organizations - such as tests for adult onset disorders, predispositional testing and presymptomatic testing of any kind - for example, prenatal tests - can be assumed to pose a serious temptation for an institution preoccupied with limiting costs, especially if market forces become even more competitive. n51 This will be discussed further below.\par

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n48. See Barry R. Furrow, Regulating the Managed Care Revolution: Private Accreditation and a New System Ethos, 43 Vill. L. Rev. 361, 363-64 (1998)\i0 (describing the legitimate fears of excessive cost-cutting by market-driven plans). \par\par

n49. See Arnold S. Relman, The New Medical-Industrial Complex, 303 New Eng. J. Med. 963 (1980);\i0 see also Jerome P. Kassirer, Managed Care and the Morality of the Marketplace, 333 New Eng. J. Med. 50, 50-52 (1995)\i0 (describing how market-driven care is likely to alienate physicians and undermine patients' trust in physicians' motives). See generally Bodenheimer & Sullivan, supra note 30 (describing why large employers have taken more of an interest in get

ting rid of reliance on managed-care insurers); see also Kuttner, *supra* note 10, at 1559 (describing how the shift from pure community rating to modified community rating has increased doctors' caseloads by about 20 percent).

n50. See Kuttner *supra* note 10, at 1561-62.

n51. See Calkins et al., *supra* note 40, at 80.

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III. Computerization and Medical Confidentiality

The organization, management, and delivery of health care has become highly information-sensitive, especially so in the case of managed care. Sharing of patient medical and financial information among physicians, hospitals, payors, employers, pharmacies and related health care entities through networked computers and relational databases is a common and permanent feature of all MCOs. Audit trails integral to the cost-saving practices of MCOs are facilitated by relational databases on networked computers. These sophisticated information systems are necessary for quality control, cost management, and increasingly for the management and decision support necessary for patient care.

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n52. See Lawrence S. Borok, *The Use of Relational Databases in Health Care Information Systems*, 21 J. Health Care Fin. 6-12, (1995).

n53. See *id.*

n54. See Gray, *supra* note 8, at 254 (stating that better documentation of unnecessary or inappropriate costs has come from medical record audits).

n55. See *id.* See generally Borok, *supra* note 52; see also Carol Primas Brennan, *Managed Care and Health Information Networks*, 21 J. Health Care Fin., 1-4, (1995).

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In addition, most large MCOs these days have within their purview testing laboratories, pharmacist services, physiotherapy and related services, and those reporting and billing circuits are all part of the patient information flow. Further, there is discussion of patient-based longitudinal health records as part of a future health information infrastructure which would contain all health-related data for a particular patient obtained over a lifetime - including any test results, diagnostic images, and research-based data. If the current congressional debate over assigning each person a medical identification number progresses towards national policy, the entire record from birth to death would be available for each citizen on networked computers.

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n56. See Lawrence O. Gostin, *Health Information Privacy*, 80 Cornell L. Rev. 451, 458 (1995) (stating that such information is part of the medical record).

n57. See *id.* (describing the shift from traditionally automated records to p

atient- specific records which would allow the lifetime databases described).

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n58. See Sheryl Gay Stolberg, Privacy Concerns Delay Medical IDs, N.Y. Times , Aug. 1, 1998, at A10 (reporting on how the Clinton administration has delayed assigning IDs to Americans until \22Congress adopts legislation to protect patients' privacy\22 and stating that some experts argue that a \22national health identification system ... could be used to develop a huge database following every American's medical history....\22). \par

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The abuses of medical confidentiality that could stem from easy access to sensitive medical information on unsecured electronic information systems have been discussed at great length and depth in the popular press, the professional literature, and in a recent report from a blue ribbon panel convened by the National Academy of Sciences/National Research Council (NRC). n59 There is unanimous agreement that institutions should take comprehensive steps to protect the confidentiality of the medical record. n60 The NRC report recommends that access to patient medical data ought to be secured from persons who are not directly involved in patient care through implementation of a variety of mechanisms that might include: technical barriers such as firewalls n61 and other methods of access control, organizational policies that ensure disciplined channels for securing and transmitting medical information, and national legislation to provide a policy framework \5B*13\5D work that protects medical privacy. n62 The NRC report also acknowledges that current institutional practices demonstrate that the security of the medical record is lax. n63 However, in making its recommendations, the NRC report does not discuss the context in which these policies and procedures will be implemented in a health care environment dominated by market-driven MCOs. Further, this report does not discuss whether there is a fundamental conflict of interest in attempting to protect medical information from abuses by an organization which has a great incentive to use it to substantially reduce or hold down costs. I will return to this later.\par

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n59. See generally National Research Council, For the Record: Protecting Electronic Health Information \5Bhereinafter NRC Report\5D(1997). See also Donna E. Shalala, Lecture: Health Care Information and Privacy, 8 Health Matrix 223 (1998). \par\par

n60. See Shalala, supra note 59, at 224 (calling for the government to \22figure out how to protect the privacy of data in this new world of technology\22); see also NRC Report, supra note 59, at 160 stating that: \par\par

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to obtain the benefits of electronic medical records, the nation must address and mitigate concerns regarding the privacy and security of electronic health care information ... health care providers have to adopt a range of technical and organizational practices to protect health care information, and the health care industry will have to work with government to create a legal framework and proper set of incentives for heightening interest in privacy and security for ensuring industry-wide protection of health information. \par\par

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Id. \par\par

n61. A firewall is a term used to describe layering of a computer network or networks to protect against unauthorized use. See NRC Report, *supra* note 59, at 162 (discussing the need for heightened security measures and the lack of incentives for vendors of health care information systems to include these security measures in their products).

n62. See *id.* at 160; see also Lawrence O. Gostin, Personal Privacy in the Health Care System: Employer-Sponsored Insurance, Managed Care, and Integrated Delivery Systems, 7 Kennedy Inst. of Ethics J. 361, 370 (1997) (describing the use of informational firewalls for security).

n63. See NRC Report, *supra* note 59, at 162-63.

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IV. Genetic Tests\par

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Discoveries spurred by the Human Genome Project have focused attention on medical confidentiality, since these discoveries are rapidly making available the capacity to examine the composition of our genes in ever finer detail. n64 A recent report by a blue ribbon panel convened to study the ethical, legal and social implications of Human Genome Research defines genetic tests as:

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n64. The Human Genome Project is a national endeavor to characterize the complete genetic material of human beings at the most fundamental level. Formally proposed in 1987 and initiated in 1990, the ultimate goal of this project is to obtain the complete sequence of human DNA and that of select model organisms by the year 2005. At its completion, the goal is to identify all of the estimated 100,000 genes in humans. See U.S. Department of Energy, Office of Research, Office of Biological and Environmental Research, Human Genome Program Report Part 1, Overview and Progress (1997), at 1, 74. According to the Human Genome Program Report, anticipated benefits of genome research are "a new era of molecular medicine characterized less by treating symptoms and more by looking to the most fundamental causes of diseases." *Id.* at 1-2. See generally Jerrold S. Kottva, New York State Legislative Commission on Science and Technology, Report No. 94-1, DNA Based Tests: Policy Implications For New York State (1994) (raising issues which may result from DNA tests including discrimination, privacy concerns, access to services, staffing needs and the potential problems so associated) "Hereinafter DNA Based Tests".

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the analysis of human DNA, RNA, chromosomes, proteins, and certain karyotypes "which" are performed for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carriers screening, as well as testing in high risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. n65

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n65. See Promoting Safe and Effective Genetic Testing, *supra* note 2, at 66.

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In brief, genetic tests reveal clinically significant traits that can be passed on from parent to child, which may be manifested at various stages of an individual's life cycle or be silent in an individual (but manifest themselves in a child only with certain partners). n66 DNA based tests allow these traits to be tested for at any stage after conception. n67 Functions of such tests in the health care system include: screening or testing for a present or future health condition, as an aid to diagnosis of a condition, and in determining treatment options and choice of drug therapy. n68 Genetic tests are expected to become part and parcel of routine health care and could become widely used in assessing the hazards posed by certain employment situations and for determining insurability. n69\par

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n66. Traits that are silent in an individual but manifest themselves in a child only with certain partners are called recessive traits. Such traits clinically manifest themselves only in individuals who carry a double dose of the abnormal gene. See Thomas D. Gelehrter & Francis S. Collins, *Principles of Medical Genetics* 308 (1990). \par\par

n67. See Karen H. Rothenberg, *Breast Cancer, the Genetic 'Quick Fix,' and the Jewish Community*, 7 *Health Matrix* 97, 104 (1997). \par\par

n68. See Promoting Safe and Effective Genetic Testing, *supra* note 2, at 61-62 (discussing how genetic testing can be used to assess risks of genetic diseases). \par\par

n69. See generally *Dna Based Tests*, *supra* note 64. See also Bryce A. Lenox, *Genetic Discrimination in Insurance and Employment: Spoiled Fruits of the Human Genome Project*, 123 *U. Dayton L. Rev.* 189, 197, 200 (1997).\i0 \par

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The interpretation of genetic tests is far from simple. n70 At present, the predictive power of DNA-based tests can vary widely depending on the genetic condition tested and the type of test used. n71 In most cases, a positive result in a genetic test for a future disease indicates only the likelihood of that disease. n72 It does not predict when, during the person's lifetime, the symptoms may appear or how severe they may be. n73 Hubbard and Lewontin '5B*15\5D have repeatedly discussed the misconceptions surrounding genetic information - especially the popular tendency to attribute a higher level of certainty to such information than is warranted. n74 Yet, in the popular imagination, genetic tests are invested with an enormous certainty and from this certainty derives the social power that can be used to discriminate and stigmatize. n75 Genetic tests are already available, or are in the developmental stage, for several high cost, socially stigmatizing conditions such as Alzheimer's disease, Huntington's disease, and some familial cancers. n76 There are thousands of clinical conditions thought to have genetic underpinnings for which genetic tests may be available in the future.\par

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n70. See DNA Based Tests supra note 64, at 9 (stating that "genetic analysis and forecasting remain complex, even though the technology for gene detection is becoming simpler."); see also Ruth Hubbard & R.C. Lewontin, Pitfalls of Genetic Testing, 334 New Eng. J. Med. 1192, 1193 (1996) (discussing how correct interpretation of genetic testing is highly complex).

n71. See DNA Based Tests, supra note 64, at 10.

n72. See id. (discussing how genetic conditions cannot provide definitive answers about how severe a condition may be and how environmental factors may influence gene-related conditions).

n73. See id. at 10.

n74. See generally Hubbard & Lewontin, supra note 70, at 1192, 1194.

n75. See Dorothy Nelkin & Laurence Tancredi, Dangerous Diagnostics: The Social Power Of Biological Information 18, 168 (1989) (stating how scientific knowledge "opens the way to discrimination, stigmatization, and vulnerability to control").

n76. See Michael Kirby, Genetic Testing and Discrimination: The Development of Genetic Testing Confronts Humanity With Urgent Challenges, UNESCO Courier, May 1, 1998, at 29.

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George Annas has aptly referred to DNA as "an individual's probabilistic future diary." n77 The significance of this lies in the stability of the DNA molecule, which remains decipherable for centuries and which contains coded biological information. n78 Some of this coded information may be expressed late in an individual's life (such as an adult onset disease), and some is not yet "decoded" by science. n79

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n77. George J. Annas, Rules For Gene Banks: Protecting Privacy in the Genetics Age, in Justice And The Human Genome Project 75, 82 (Timothy F. Murphy & Marc A. Lappe eds., 1994). See Genetic Prophecy and Genetic Privacy - Can We Prevent the Dream from Becoming a Nightmare? 85 Am. J. Pub. Health 1196-97, (1995); see also George J. Annas et al., Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations, 23 J.L. Med. & Ethics, 360 (1995) "herein after Drafting Genetic Privacy Act".

n78. See Drafting the Genetic Privacy Act, supra note 77, at 360; see also George J. Annas, Privacy Rules for DNA Databanks: Protecting Future Diaries, 270 JAMA 2346 (1993) "hereinafter Privacy Rules".

n79. See Privacy Rules, supra note 78, at 2348.

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Clearly, not all genetic information has the same social power. A genetic test predicting the future onset of leukoderma, a patchy discoloration of the skin, does not have the same stigmatizing power as a test predicting the future onset of a severely crippling, high-cost illness such as Alzheimer's disease or many neuromuscular diseases. n80 And undoubtedly, certain non-genetic medical information expected to be part of the medical record has great so

cial power, such as a record of a sexually transmitted disease or a visit to the emergency room with a drug overdose. n81\par

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n80. According to a recent study by the National Alzheimer's Association, this disease alone costs \$33 billion annually, excluding costs during the early stages of the disease and to care givers. See American Health Line Sept. 10, 1998; see also Ross Koppel, Alzheimer's Cost to U.S. Business Executive Summary <<http://www.alz.org/news/index.htm>> (last visited Sept. 9, 1998) (describing the cost not only to the person afflicted with the disease, but also the cost to business associated with caregivers); see also Kirby, supra note 76 (stating that 22 millions of people this century have lost their lives, or have suffered profoundly, because of obvious genetic distinctions. When new distinctions, previously hidden, are added to the list, we should be alert to provide effective social responses.\22). \par\par

n81. See Hugh Miller, III, DNA Blueprints, Personhood, and Genetic Privacy, 8 Health Matrix 179, 182 (1998); see also Frank Green, Putting Questions to Rest: Private Post-Mortems Booming as Insurers Cut Back on Autopsies, San Diego Union-Trib., Sept. 22, 1998 at C1 (describing how private companies are available to evaluate medical records and provide expert witnesses in court cases); see also Experts Weigh In On Privacy and HIV Professionals Would Not Go Beyond Laws Already In Place To Deal With Exposure To Aids, Indianapolis Star, June 14, 1998 at A4 (describing the challenges to opening medical records of those infected with the AIDS virus). \par

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However, genetic information differs from most other medical information, in that genetic information is permanent and is not something one recovers from. These tests can be performed soon after conception, at the earliest stages of fetal life, and tests for certain conditions can provide information years before the onset of disease. n82 Within the context of institutions such as market-driven MCOs, special concerns are raised by genetic tests that provide predictive power about future health care costs. In particular, these tests would include those for adult onset disorders, as for example, predispositional tests and presymptomatic tests, especially for those disorders with high associated costs. n83 Such tests would pose serious temptations for institutions preoccupied with saving money. n84\par

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n82. See Kirby, supra note 76 (describing how fetuses can be tested through amniocentesis for genetic abnormalities). \par\par

n83. According to a 1997 report of the Task Force on Genetic Testing, a predictive genetic test may be divided into presymptomatic tests, which are performed for conditions which have a high likelihood of expressing themselves in those who inherit the gene sequence, and predispositional tests, which are performed on conditions where inheritance of the gene may not result in expression of the condition. See Promoting Safe and Effective Genetic Testing, supra note 2.

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n84. See Kirby, supra note 76 (discussing how employers may decline to hire workers who may need sick time and disability benefits and insurance companies who may decline coverage to higher risk individuals). \par

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In addition, genetic information is unique compared to other medical information because it provides information not just about the individual tested but, with a certain probability, about ^{5B*17} close relatives. ⁸⁵ The genetic privacy of relatives may thus be unknowingly violated by DNA-based testing not directly involving them, simply because they are related to someone who has been tested. Genetic information, therefore, continues to implicate an individual's relatives long after one is dead and even implicates unborn future relatives. As such, these genetically related individuals are also parties interested in maintaining the confidentiality of this information. Equally important is the sense in the popular imagination that genetic information is fundamental and integral to the self and is immutable - that it reveals something deep, basic and final about a person - that our genes are us! This belief is a misperception with potentially serious social consequences because it does not recognize, as discussed above, that almost all genetic information is probabilistic and could wrongly stigmatize individuals who are ²²positive²² by a genetic test, but who will never get the disease.\par

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⁸⁵. See generally Rothenberg, *supra* note 67, at 99-100 (discussing genetic tests for breast cancers based upon common traits among Jewish-American women and the privacy implications it entails). See also Privacy Rules, *supra* note 78, at 2346. \par

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Genetic information is uniquely important also because our attitude towards our biological selves is culturally conditioned and fraught with personal and cultural meaning. ⁸⁶ Attitudes towards the confidentiality of genetic information vary depending on the cultural conditioning of racial and ethnic groups. ⁸⁷ Therefore, lax confidentiality policies might create conditions whereby existing racial and ethnic disparities in access to health care are exacerbated. ⁸⁸ And finally, several genetic conditions are represented disproportionately among certain racial groups and serve as very crude pointers to membership in that group. ⁸⁹ Recent history teaches us that genetic information has been abused and is the ^{5B*18} basis for much discrimination. ⁹⁰ This abuse again raises the possibility that groups which historically faced discrimination would be more cautious about availing themselves of genetic tests administered under the control of an institution that could discriminate on the basis of the results. ⁹¹\par

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⁸⁶. See Carol R. Goforth, 'What is She?' How Race Matters and Why It Shouldn't, *46 DePaul L. Rev.* 1, 9 (1996) (stating that despite little genetic variation between members of different races, racial classifications are based on ethnic heritage and background). \par\par

⁸⁷. See generally Dorothy E. Roberts, The Nature of Blacks' Skepticism About Genetic Testing, *27 Seton Hall L. Rev.* 971 (1997). \par\par

⁸⁸. See *id.* at 978 (stating that ²²black patients have less access than white patients to intensive care and specialized, high-tech medical servi

ces that may prolong life.\22). \par\par

n89. See Larry Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, 17 Am. J.L & Med. 109, 111 (stating, \22genetic diseases are sometimes closely associated with discrete ethnic or racial groups such as African Americans, Ashkenazi Jews or Armenians....\22). \par\par

n90. See Symposium: Genetics and the Law: The Ethical, Legal and Social Implications of Genetic Technology and Biomedical Ethics, 3 U. Chi. L. Sch. Roundtable 589, 595 (1996). \par\par

n91. See Discrimination Frightening Reality for People With Cancer Genes, Biotechnology Newswatch, Mar. 12, 1998, at 13 (citing statistics that approximately one third of the states do not protect individuals from discrimination based on genetic information). \par

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Discrimination by third parties outside the health care system has been widely acknowledged as a serious concern stemming from the availability of genetic information to sources outside the health care system. n92 Third parties who may have such interest in DNA-based test results include employers, financial institutions making lending decisions, marketing firms, educational institutions, governmental and private institutions seeking information about an individual's present and future lifestyle choices or reproductive decisions, and insurers of all types. n93 The strictest confidentiality has therefore been urged to ensure that the promise of the human genome does not turn into an ethical nightmare. One such nightmare exists if information about a positive DNA-based test, especially a positive test for a late-onset, high-cost, genetically influenced condition, is stored in insecurely networked computers and falls into the hands of parties interested in this information for reasons other than the medical care and welfare of the individual tested. n94 However, protecting the confidentiality of genetic tests apart from the rest of the medical record would sequester these tests to the extent that their intent in informing clinical decisions would be lost. The genetic test information can not be logically distinguished apart from other medical information on clinical grounds. n95 Therefore, medical records that contain genetic information warrant strict confidentiality protection in toto.\par

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n92. See Kirby, *supra* note 76. \par\par

n93. See *id.*; see also Biotechnology Newswatch, *supra* note 91. \par\par

n94. David V. Foster & Erica Rosa, Protecting Medical Information: Complicated Legislative Challenges, 8-SUM Experience 20 (1998) (pointing out that new telecommunications methods have increased fears of breaches in privacy). \par\par

n95. See *id.* at 22 (stating that it is impossible to determine in some cases whether traditional medical tests or genetic tests were used). \par

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\5B*19\5D Confidentiality has been urged as a safeguard against third party health insurers who, it was believed, could be prevented from accessing the results of genetic tests by means of laws and regulatory policies. n96 However, in the case of market-driven MCOs, the payor and provider functions co-exist

within one and the same organization. Cost-saving goals may dictate that marketing strategies are developed to by-pass patients with certain high cost conditions or that premiums for various health plans offered by MCOs are based on the prognosis of an individual's future health (as determined by a DNA-based test) especially in the absence of laws requiring community rating and prohibiting discrimination based on genetic information. n97 In addition, an institution concerned with saving money may be less likely to invest in high cost security software and procedures, unless public choices indicate that medical confidentiality is a market discriminator. However, regardless of negative public opinion, exposing medical information to parties outside the health care system would lead to an individual's embarrassment or even to financial ruin. n98

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n96. See DNA Based Tests, supra note 64; see also Reilly, supra note 1.

n97. See Michael S. Yesley, Protecting Genetic Difference, 13 Berkley. Tech. L. J. 653, at 657-658 (1998) (stating that laws to protect genetic information are coming but are not necessarily going to be adequate to alleviate such concerns).

n98. See Eric Mills Holmes, Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project, 85 Ky. L. J. 503, 558 (1996-97) (recognizing that the critical issue is "whether society prefers a system where the only individuals allowed to purchase reasonably priced health and health-related insurance coverages are those who were born with 'healthy genes.'").

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In summary, confidentiality of genetic tests presents uniquely delicate issues and warrants measures to heighten privacy protection for the entire medical record since the consequences for individuals whose confidential medical information is violated could be ruinous. The implications for trust in the physician-patient relationship and the care-giving institution are no less serious. Market-driven MCOs provide the institutional conditions in which cost considerations may create lax security surrounding medical records containing this information, as well as the incentives to use this information internally to shape policies that disenfranchise persons from access to health care on the basis of their genetic makeup.

V. Medical Confidentiality and the Patient-centered Ethic Examined in the Context of Market-driven ManagedCare

Traditionally, confidentiality has been the cornerstone of the fiduciary relationship between patient and physician. n99 The accepted rationale is that trust on the part of the patient is essential to a patient's willingness to reveal private, personal facts necessary to the delivery of the best possible health care. n100

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n99. See Fed. R. Evid. 501.

n100. See id.; see also Stephen Aaron Silver, Beyond Jaffe v. Redmond: Should the Federal Courts Recognize a Right to Physician-Patient Confidentiality? 11

58 Ohio St. L.J. 1809 (1998))¹⁰ (discussing how Federal Rule of Evidence 501 allows the federal courts to develop privileges to bar admission of evidence, including doctor-patient evidence, from introduction at trial, and how such a rule reflects the importance given to the relationship). \par

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In addition, the principle of medical confidentiality gives tacit acknowledgment to a core value in medical care, namely the autonomy of the patient, a value that acknowledges the right of the patient to direct the course of his/her own life. In this sense, confidentiality is tantamount to a physician's respect for a patient's dignity and humanity. ¹⁰¹ The mental ease necessary for an effective therapeutic relationship would not be possible in an atmosphere of distrust and tension between patient and physician. ¹⁰²\par

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¹⁰¹. See generally Shalala, *supra* note 59, at 224 (stating that national legislation must be enacted to safeguard and protect the privacy of medical records). \par\par

¹⁰². See Beauchamp & Childress, *supra* note 1, at 418-41. \par

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This traditional concept of confidentiality thrived in an age when the physician-patient relationship revolved around the physician's office with, at most, a few notes handwritten by the physician as a safeguard for his memory. ¹⁰³

But the modern health care institution requires that a large number of professionals view a rather comprehensive medical record in the interest of providing quality health care. ¹⁰⁴ As a consequence, the flow of patient-related information passes through many hands and resides in computerized data banks. ¹⁰⁵\par

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¹⁰³. See Shalala, *supra* note 59, at 225. \par\par

¹⁰⁴. See *id.* (suggesting that the revolution in health care delivery systems has opened the closet door that hides the '22deepest and darkest secrets'22 of those patients seeking confidentiality). \par\par

¹⁰⁵. See *id.* (stating that this flow of information endangers the privacy rights of patients and families). \par

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Mark Siegler was among the first to analyze the tensions surrounding confidentiality within modern health care institutions, a '5B*21'5D setting in which a large number of professionals, as members of a health care team, are required to view patient records in the interest of providing quality health care. ¹⁰⁶ Siegler concluded that privacy is '22a decrepit concept'22 that could for the most part be dispensed with in the interest of providing quality care. ¹⁰⁷ Gostin has expanded on this view, asserting that patient claims for privacy ought to weigh less than the broader social objectives that would be served by longitudinal health records available on networked computers. ¹⁰⁸ According to Gostin, '22'5Ba'5D sophisticated health information infrastructure is

necessary ... to achieve powerful social purposes such as patient choice, quality assurance, administrative efficiency, cost savings, governmental oversight, research, and public health.'22 n109 In both of these analyses, however, the institutional context in which the record is generated and used is ignored.\par

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n106. Mark Siegler, Confidentiality In Medicine: A Decrepit Concept, 307 New Eng. J. Med. 1518 (1982).\i0 \par\par

n107. Id. \par\par
n108. See Gostin, supra note 62, at 373-74 ('22Scholars have only begun to ponder the relevance and forms of informed consent and privacy in a transformed health care system.... Beyond consent, society must face the tradeoffs between the collective goods that are achieved from information processing and the inherent risks to individual privacy.'22). \par\par

n109. Id. at 363. \par
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Market-driven managed care poses unique confidentiality concerns because information about our future health care costs are available to managers and policy makers within a health care system that has cost-savings as its primary imperative. n110 Policy proposals to address the confidentiality of genetic test results continue to assume the paradigm of the traditional doctor-patient relationship because of the centrality of this relationship to providing care; but this relationship is no longer possible in the MCO setting where the physician is, to a lesser or greater extent, an agent of the MCO; that is she or he is hired by the MCO and is paid by it and must abide by its rules. n111 In this system, in which the payor and the provider are the same entity, there is no third party payor who may be barred from access to an individual's '5B*22'5D medical record. n112 From whom then are we to protect medical confidentiality?\par

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n110. See id. at 367 (discussing how an employer's potential use of confidential medical information to structure benefits packages that limit or exclude certain health conditions could lead to a violation of employee/patient privacy rights). \par\par

n111. See Rodwin, supra note 7, at 13-17 (discussing reduced independence and autonomy of physicians whose financial interests are linked to the health care provider organization). \par\par

n112. See id. \par
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In the modern MCO, the patient, in fact, relates to a physician who is a representative of the health care organization. This physician must serve his employer-master if he wants to maintain his job and pass his '22utilization review tests'22 - properly referred to as '22maintaining adherence to quality guidelines.'22 n113 The patient, therefore, is as much in a relationship with a health care organization as with an individual physician. n114 The objectives of this new physician who operates under global institutional guidelines, and pra

ctices as an employee of an institution that has cost saving imperatives, cannot remain in the traditional mold. The power dynamic between the institution and its physician-employee has been changed, and so must the culture of care. Now, it is actually the institution that makes decisions regarding confidentiality.

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¶13. See Siegler, *supra* note 106, at 1519. ¶

¶14. See *id.* ¶

¶15. See Gostin, *supra* note 62, at 369 (describing integrated delivery systems that enable health information to be routinely disseminated among various entities including MCOs, hospitals, healthcare provider groups, and insurers, '22without the patient's understanding or explicit consent.'22). ¶

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Institutional decision-making and its impact on individuals serving that institution are of particular relevance to the problem at hand, especially the concept - elaborated most thoroughly in the social anthropology literature - that institutions, by their very functioning, label individuals with a view to creating the stability necessary for social life. ¶16 More to the point, in being so labeled, individuals function differently. The very roles serve to label persons and define their identities. ¶17 Mary Douglas aptly describes this phenomenon:¶

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¶16. See Mary Douglas, *How Institutions Think*, 100 (1986). ¶

¶17. See *id.* ¶

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'5BThis process of labeling'5D is not like the naming that, according to nominalist philosophers, creates a particular version of the world by picking out certain sorts of things, for instance, naming stars, foregrounding some and letting others disappear from sight. It is a much more dynamic process by which new names are uttered and forthwith new creatures corresponding to them emerge.. People are not merely re-labeled and newly made prominent, still behaving as they would behave whether so labeled or not. The new people behave differently than they ever did before. ¶18¶

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¶18. *Id.* (emphasis added). ¶

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What this says about the identity of a physician in the newly forged relationship between himself/herself and the managed care organization which he/she serves

es has not been adequately explored. However, in the context of a new health care institution, the old identities - and the ethics that were an expression of those identities - cannot apply. Physicians now operate in a new cultural climate. n119\par

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n119. See Kuttner, supra note 10 (discussing how managed care was not universally developed by physicians and how currently they are torn between patients and cost controls). \par

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The major shifts in decision-making power in the managed care setting imply that significant decisions about the record-keeping and confidentiality of sensitive medical information are made by institutions rather than physicians. n120 In the case of market-driven managed care, the very assumption that an institution, which is obligated for its very survival to those who provide it with capital, can be fully trusted to discharge its fiduciary moral obligations to patients is fraudulent. Therefore, not only is there a concern regarding confidentiality because of the pressures imposed by MCOs on physicians, there is also reason to doubt whether the institutional policies and decisions themselves are rooted in ethical decision-making. n121\par

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n120. See Gostin, supra note 62, at 364-65 (discussing how sensitive health care information flows '22both vertically and horizontally'22 through organizations to various providers and billings offices). \par\par

n121. See Kuttner, supra note 10. \par
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Concepts of traditional morality cannot be applied at the institutional level since formal organizations are not moral beings. John Ladd has argued persuasively that organizational decisions are '22social decisions'22 in that these decisions are imputed to organizations rather than to the individuals making them. n122 The latter make these decisions impersonally to further the objectives set for the organization and the values implied by the decisions may not be those the individual may hold at the personal level. Organizational decisions are evaluated by the sole standard of whether or not they are effective in furthering the organization's goals. n123 It is this ideal that governs the conduct of individuals who are involved in the operations of the organization and these standards and ideals are wholly different from those that govern interpersonal '5B*24'5D morality. n124 In exploring the implications of the for-profit motive in patient care Bradford H. Gray summarizes the situation:\par

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n122. John Ladd, Morality and the Ideal of Rationality in Formal Organizations, 54 Monist 488, 492 (1970). \par\par
n123. See Richard A. Booth, Stockholder, Stakeholder and Bagholders (Or How Investor Diversification Affects Fiduciary Duty), 53 Bus. Law. 429 (1998).\n124. \par\par

n124. See Ladd, supra note 122, at 488-516. \par

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Because of the link between profitability and financial rewards to executives, and because investors who purchase equity in a company are seeking returns substantially above what they can receive from secured debt, strong pressures exist for consistent growth in earnings and for short-term economic performance...

'5Bthese pressures'5D inescapably influence managerial decisions. It is clear that the primary responsibility of management is to enhance the value of investors' equity, and this depends on profitability more than any other factor. Management will ultimately be held accountable by the board of directors and by the stock market for its ability to generate satisfactory returns on investment.

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n125. Gray, supra note 8, at 24. \par

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Keeping with this, investor-owned MCOs are known to change ownership, restructure through divestiture of unprofitable businesses, or go out of business more frequently than not-for-profit MCOs. n126 Each occurrence creates opportunities for additional exposure of the medical record. n127\par

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n126. See id. at 50-52. \par\par

n127. See id. at 52. \par

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The change in institutional ethos implies a change in the central ethical tenets guiding the relationship between patient and caregiver. The trust necessary to seeking health care - formerly assured through protection of confidentiality - is the first casualty. There are no systematic data to determine whether patients will seek the benefits of DNA-based tests from an institution that could use that knowledge to discriminate. Prudence would suggest that many, if not most, would be inhibited. \par\par

VI. Conclusion\par

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In summary, the confidentiality of the medical record needs to be strengthened in the era of genetic testing which can reveal personal and sensitive information about oneself and one's relatives. Policies requiring confidentiality of genetic information are motivated, in part, by the desire to prevent the possibility of discrimination by parties outside the caregiver-patient relationship.

In addition, confidentiality is central to the fiduciary ethic characterized by the doctor-patient relationship and is fundamental to trust on the part of the patient. However, the cost-cutting ethos of market-driven M

COs is achieved by means of a shift in the power- balance between the institution and the physician. This implies that decisions regarding confidentiality are increasingly made at the institutional level rather than by the physician, who is denied both the autonomy to protect confidentiality and the incentive to do so. This necessitates a change in the culture and ethics of the physician operating under this new institutional ethos, because the power dynamic between the institution and its physician- employee/partner has changed. The objectives of the new physician must be different. The 'new physician' must take his or her compass from the institution and must function, at some level, as an agent of the institution. However, there have been public attempts to legislate an ethic of confidentiality for market-driven MCOs by superimposing the ethics of interpersonal relationships onto the relationship between the health care organization and the patient. These are also likely to fail because we make the mistake of assuming that an institution is a moral agent with the imperatives of interpersonal duty and caring - that it can engage in a 'moral relationship.'

Interpersonal ethical decision-making cannot be translated smoothly into institutional decision-making because the imperatives of an institution are different. In the case of market-driven MCOs, the main imperative must be its profitability - i.e., its survival. It is unclear how such institutions may be entrusted with implementing ethically-based policies governing sensitive medical information, such as genetic test results, especially because what we presently know about the ability of market-driven MCOs to function ethically, are not reassuring. If protection of genetic confidentiality is decided to be a societal value, then even increasing levels of governmental regulation are likely to be inadequate to preserve it in an environment dominated by market-driven MCOs.

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ARTICLE: NEW YORK'S LEGAL RESTRICTIONS ON THE EMPLOYER'S \par

COLLECTION AND USE OF AN EMPLOYEE'S GENETIC INFORMATION

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SUMMARY: ... Advances in genetic research over the last few decades have made

it possible to identify the genetic bases for human disease. ... The only colorable basis for an ADA claim in the context of a challenge to genetic testing would require a plaintiff to stretch the existing definition of 'disability.' ... A latent genetic condition that predisposes one to disease is not an impairment that currently limits a major life activity or a record of such an impairment. ... The amendment also defines 'genetic anomaly', 'genetic predisposition', 'carrier' and 'genetic test.' ... The New York legislature has found that while genetic testing technology has improved, there is still a risk of incorrect results concerning those genetic predispositions that will result in actual disease or disability. ... There are significant legal issues raised by the interplay of existing federal anti-discrimination law generally and New York law relating to genetic information. ... This could be done by an amendment to Title VII to add genetic predisposition or carrier status to the list of protected categories or by an amendment to the ADA expanding the definition of disability to expressly encompass a genetic condition. ...

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TEXT: \5B*40\5D \par\par

I. Introduction\par

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Advances in genetic research over the last few decades have made it possible to identify the genetic bases for human disease. These scientific advances, attributable in large part to the Human Genome Project, hold great promise for the early detection and treatment of serious illnesses. For example, a \$200 blood test can detect the genetic alteration which appears to double an individual's risk of colon cancer. Obviously, scientific advances such as this can prove invaluable because once at risk individuals are diagnosed, they can receive early and aggressive treatments.\par

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n1. U.S. Department of Energy, Human Genome Project Information (last modified July 31, 1998) <[http://www.ornl.gov/Techresources/Human Genome/ home.html](http://www.ornl.gov/Techresources/Human%20Genome/home.html)> (defining and explaining the significance of the Human Genome Project) \5Bhereinafter Human Genome Project Information\5D. \par\par

n2. See U.S. Dep't of Labor, Genetic Information and the Workplace (last updated Apr. 14, 1998) <<http://www2.dol.gov/dol/sec/public/media/reports/genetics.htm>> (citing a genetic alteration most prevalent among Jewish persons of Eastern European descent that can be detected by a blood test) \5Bhereinafter Genetic Information and the Workplace\5D. \par

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While these scientific advances hold great promise for the treatment of latent diseases, in the context of the workplace they also provide information that an employer could use to discriminate against an employee. n3 For example, a 1996 survey of 917 respondents, all of whom were either susceptible to developing a genetic condition or were parents of children with an identified genetic condition, revealed that more than 200 instances of discrimination took place in the workplace. n4 Likewise, in a 1997 national telephone survey of more than 1,000 individuals, 63 percent stated that they would not take genetic tests for diseases if their employer was given access to the results. n5 The most common reason for an employer to use an employee's genetic test results would be to assess the increased costs associated with various types of illnesses (i.e. increased medical costs, early retirements, or the extra costs of new staff). n6

Spurred in part by a need to address these economic issues, the Northwestern National Life Insurance Company conducted a survey in 1989 of 400 large firms. The survey revealed that by the year 2000, fifteen percent of the companies planned to condition job offers on the results of genetic tests.

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n3. See Human Genome Project Information, supra note 1 (explaining how genetic information in the workplace can be used to discriminate against employees).

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n4. See Genetic Information and the Workplace, supra note 2 (citing, Lisa Geller et al., Individual Family and Societal Dimensions of Genetic Discrimination: A Case Study Analysis 2-1 Sci. & Engineering Ethics 71, 88 (1996)). \par\par

n5. National Center for Genome Resources unpublished survey, 1997. \par\par

n6. Id. \par\par

n7. See Larry Gostin, Genetic Discrimination: the Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, 17 Am. J.L. & Med. 109, 116 (1991); see also Shannon Brownlee & Joanne Silberner, The Assurances of Genes: Is Disease Prediction a Boon or Nightmare, U.S. News & World Rep., July 23, 1990, at 57. \par

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II. Anti-discrimination Statutes in the Workplace\par

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Numerous federal and state statutes prohibit discrimination in employment on the basis of national origin, color, race, gender, age and disability status.

Although statutes prohibit discrimination in typical hiring and firing contexts, they are generally phrased too broadly. As a result, the statutes prohibit adverse treatment on the basis of a protected status with regard to the terms and conditions of employment.

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n8. See 42 U.S.C. 2000e-2 (1991) ('race, color, religion, sex, or national origin'); N.Y. Exec. Law 291 (McKinney 1998) ('age, race, creed, color, national origin, sex or marital status'). \par\par

n9. See 42 U.S.C. 2000e-2 (stating that employers cannot discriminate against individuals in compensation, terms or conditions of employment). \par

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These statutory schemes create or defer to administrative agencies, which are charged with investigating and adjudicating discrimination charges. Usually, subsequent to the filing of the administrative charge, each statute also permits an aggrieved claimant to commence a civil action for damages and/or reinstatement. The state legislatures have not specifically defined discrimination, but the courts have developed two widely cited paradigms for marshaling proof of discrimination: disparate impact and disparate treatment. In a disparate treatment case, the plaintiff attempts to use direct and circumstantial

l evidence to show that he/she suffered an adverse employment action as a result of intentional discrimination. n13 In a disparate impact case, a plaintiff attempts to show that a facially neutral employment practice has a statistically significant adverse impact on a protected group of which he/she is a member. n14\par

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n10. \i 42 U.S.C. 2000e-5\i0 (1991) (empowering the Equal Employment Opportunity Commission to bring discrimination charges against employers). \par\par

n11. See id. 2000e-5(f). \par\par

n12. See \i International Brotherhood of Teamsters v. United States, 431 U.S. 324, 335 n.15 (1977).\i0 \par\par

n13. See id. \par\par

n14. See id.; see also \i 42 U.S.C. 2000e-2\i0 (k) (explaining how to establish disparate impact in employment practices); \i Diehl v. Xerox Corp., 933 F. Supp. 1157 (W.D.N.Y. 1996).\i0 \par

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III. Challenges to Employer Testing and Screening Programs\par

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For many years, employers have used various tests to obtain information about job applicants and employees. These tests have run the gamut from written tests to more invasive procedures such as polygraphs and drug tests. n15 Written tests often are used to predict whether a job applicant can successfully perform a job. These tests, however, have been subject to challenge on the ground that they disproportionately exclude groups protected under Title VII of the Civil Rights Act of 1964. n16 Other tests, such as polygraphs, are occasionally utilized by employers to verify truthfulness or to ferret out criminal activity. n17 However, the danger of misuse or false results has led to legislative efforts to curtail or eliminate the use of polygraphs in the workplace. n18 By the mid-1980's, drug testing was widely utilized in the public and private sectors. In response, public sector employees have successfully challenged mandatory drug testing on constitutional grounds, contending, in part, that such procedures invade their protected privacy interests. n19 Drug testing programs have also been challenged by private sector employees. n20\par

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n15. See \i Washington v. Davis, 426 U.S. 229 (1976);\i0 \i Griggs v. Duke Power Co., 401 U.S. 424 (1971).\i0 \par\par

n16. See \i Griggs, 401 U.S. at 436\i0 (finding that the Act prohibits discrimination based on standardized tests which are not a 'reasonable measure of job performance'). \par\par

n17. See Lisa Brunn, Comment, Privacy and the Employment Relationship, \i 25 Hous. L. Rev. 389, 406 (1988).\i0 \par\par

n18. See \i 29 U.S.C. 2001\i0 -2009 (1988). \par\par

n19. See \i Patchogue-Medford Congress of Teachers v. Board of Educ., 119 A.D. 2d 35\i0 (2d Dep't 1986) (finding that mandatory urine test for teachers, without basis for suspicion, is an unconstitutional search), aff'd, \i 510 N.E.2d 325 (1987);\i0 \i Jackson v. Gates, 975 F.2d 648 (9th Cir. 1992).\i0 \par\par

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n20. See *Doi v. Roe, Inc.*, 160 A.D.2d 255 (1st Dep't 1990) (ruling that plaintiff stated a case under Human Rights Law by arguing that metabolites found in urine specimen resulted from food consumption and not drug use and that employer's drug test failed to distinguish between the two).

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Thus far, we have seen judicial and legislative efforts to restrict testing or screening programs that unduly interfere with an employee's statutory or constitutional rights. In the context of drug testing and polygraphs, these restrictive efforts have been based largely on the danger of false positive results and the invasion of constitutionally protected privacy interests. In the context of testing cases the focus has been upon the adverse impact on specific disadvantaged groups.

Some of these same concerns are implicated in the area of genetic testing. Like urine and blood samples, a person's genetic information is of a private nature. Moreover, genetic testing may occasionally yield erroneous data and such data could be misused to create a disadvantaged underclass.

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n21. See Kyle G. French, *The Elderly and the Discriminatory Use of Genetic Information*, 5 Elder L.J. 147, 149 (quoting Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 Nw. U. L. Rev. 1037, 1047 (1993)).

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Nonetheless, current genetic testing can be traced to the 1970's, when there emerged a number of government-sponsored sickle cell screening programs. In response, a number of states passed laws prohibiting discrimination in employment on the basis of the sickle cell trait. n22 In 1990, New York enacted a law prohibiting discrimination based on the sickle cell trait, Tay-Sachs trait or Cooey's anemia trait, unless such condition prevented the employee from performing his or her job. n23 This statute makes plain that discrimination based on a genetic condition will not be tolerated unless the employee's ability to perform the job is impacted. n24

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n22. See Fla. Stat. Ann. 448.75 (1986); see also La. Rev. Stat Ann 23:352 (West 1997); N.C. Gen. Stat. 95-28.1 (1975).

n23. N.Y. Laws 1990, c. 900, 1 (codified at N.Y. Civ. Rights Law 48-a).

n24. The statute states that "unless it can be clearly shown that a person's unique genetic disorder would prevent such person from performing the particular job, no person who is otherwise qualified shall be denied equal opportunities because of the unique genetic disorders." Id.

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Despite these early legal restrictions involving testing for the sickle cell trait, there is no legislation at the national level that was specifically drafted with the issue of genetic discrimination in mind. As a result, in a state

lacking a comprehensive statute, an aggrieved individual must search existing anti-discrimination legislation for a potential remedy. \par\par

IV. Current Law Does Not Plainly Restrict the Use of Genetic Testing in Employment\par
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Anti-discrimination statutes such as the Rehabilitation Act of 1973²⁵ and the Americans With Disabilities Act (ADA)²⁶ are founded, in part, on the well-intentioned notion that employers should be required to go to considerable lengths to allow disabled persons to work productively.²⁷ Many, if not most, workers with diseases or debilitating conditions may still be able to perform the essential functions of the job, with or without reasonable accommodation.²⁸ Therefore, it is plain that an employer cannot use the fact of a diagnosed disease or condition as a basis for an adverse job action such as a demotion, termination or failure to hire, unless the employee is unable to perform the essential functions of the job.²⁹ Given this current law, it makes even less sense to base an adverse job action on a latent genetic condition which has absolutely no impact on job performance, but may lead to a disease in the future.\par

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n25. 42 U.S.C. 12101 (1994). \par\par
n26. 29 U.S.C. 701 (1988 & Supp. 1993). \par\par
n27. See *Borkowski v. Valley Central Sch. Dist.*, 63 F.3d 131, 144 (2d Cir. 1995) (Newman, C.J., concurring). \par\par
n28. See *Susie v. Apple Tree Preschool and Child Care Ctr., Inc.*, 866 F. Supp. 390, 395 (N.D. Iowa 1994). But see *Larkins v. CIBA Vision Corp.*, 858 F. Supp. 1572 (1994) (ruling that employer was not required to restructure job in order to reasonably accommodate employee). \par\par
n29. See, e.g., *Oswald v. Laroche Chemicals, Inc.*, 894 F. Supp. 988, 994 (E.D.La. 1995) (discussing whether physical functions are essential functions of the job). \par

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Nonetheless, a review of the provisions of the ADA makes it plain that there is no express prohibition on genetic testing.³⁰ The ADA does make illegal most pre-offer health and medical questions.³¹ However, once the conditional offer of employment is extended, but before the individual begins work, the employer may presumably test and obtain genetic information (an employer could perhaps even require genetic screening as a condition of employment).³²\par
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n30. See 42 U.S.C. 12112 (7). The ADA merely requires that employers administer employment tests in the most effective manner to ensure that the tests do not reflect impaired sensory, manual or speaking skills, unless those skills are factors the test purports to measure. \par\par
n31. See ADA Enforcement Guidance: Pre-Employment Disability-Related Questions and Medical Examinations, EEOC No. 915-002, (1995). \par\par
n32. See 42 U.S.C. 12112 (c)(3); 29 C.F.R. 1630.14 (detailing employer's ability to require post-offer medical exams); see also Kirke D. Weaver, Genetic Screening and the Right Not to Know, 13 Issues L. & Med. 243, 268-69 (1997) (noting that the regulations seem to allow for the implementation of

f a company wide genetic monitoring or screening program to improve employee health or safety.'22). \par

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The only colorable basis for an ADA claim in the context of a challenge to genetic testing would require a plaintiff to stretch the '5B*45\5D existing definition of '22disability.'22 n33 The ADA prohibits an employer from discriminating against a qualified individual because of that individual's disability. n34 There are three ways to meet the definition of disability under the ADA. To qualify, an employee must (1) exhibit a substantial impairment of a major life activity, (2) demonstrate a record of an impairment, or (3) be regarded as disabled. n35 A latent genetic condition that predisposes one to disease is not an impairment that currently limits a major life activity or a record of such an impairment. However, such an employee may arguably be '22regarded as disabled.'22 n36 In fact, in 1995 the EEOC issued enforcement guidance that an employer who takes adverse action against an individual on the basis of genetic information regards that individual as disabled under the ADA. n37 However, this guidance does not have the force of statutory law, nor is it binding upon a court. A person is regarded as disabled when he/she has an '22impairment that substantially limits one or more... major life activities '5Bor is\5D regarded as having such an impairment.'22 n38 Given this vague standard, it is not surprising that '22regarded as disabled'22 claims have not fared well in court. n

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n33. Catherine J. Lancot, Ad Hoc Decision Making and Per Se Prejudice: How Individualizing the Determination of Disability Undermines the ADA, \i 42 Vill L. Rev. 327, 342 (1997).\i0 \par\par

n34. See \i 42 U.S.C. 12112\i0 (a) (1994). \par\par

n35. See \i 42 U.S.C. 12102\i0 (2); see also \i Dees v. Austin Travis County Mental Health and Mental Retardation, 860 F. Supp 1186 (W. D. Tex. 1994).\i0 \par\par

n36. See Mark S. Dichter & Sarah E. Sutor, The New Genetic Age: Do Our Genes Make Us Disabled Individuals Under the Americans with Disabilities Act?, \i 42 Vill. L. Rev. 613, 622-26 (1997)\i0 (hypothesizing that a claim that a genetic condition constitutes a disability under the ADA would necessarily fall under the '22regarded as'22 prong). \par\par

n37. Equal Employment Opportunity Commission, Compliance Manual, 902.8, (1995). \par\par

n38. 29 C.F.R. 1630.2(g). \par\par

n39. See, e.g., \i Collings v. Longview Fibre Co., 63 F.3d 828 (9th Cir. 1995)\i0 (ruling that employees fired for drug use failed to establish it was pretext for employer's '22perception'22 that they had drug addiction disability) ; \i Wooten v. Farmland Foods, 58 F.3d 382 (8th Cir. 1995)\i0 (finding that employee failed to show that physician- ordered restrictions which eliminated any possible work led employer to regard employee as having substantially limiting impairment). But see \i Milton v. Bob Maddox Chrysler Plymouth, Inc., 868 F. Supp. 320 (S.D. Ga. 1994)\i0 (finding question of fact whether employee was regarded by colleagues as being impaired and whether the perception led to his dismissal). \par

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In addition to the ADA, Title VII may be a source of protection from discrimination based on a genetic condition under limited circumstances. n40 It could be argued that Title VII protects an employee from adverse job action when an employer engages in discrimination against a particular racial or ethnic group based on a genetic trait that is substantially related to such racial or ethnic group. n41 However, unless the link between the condition and the protected status is beyond any scientific debate such as in the case of the sickle cell trait, this does not appear to be a sound basis for attacking a program of genetic screening.\par

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n40. See Kristie A. Deyerle, Genetic Testing in the Workplace: Employer Dream, Employee Nightmare--Legislative Regulation in the United States and the Federal Republic of Germany, 18 Comp. Lab. L. J. 547, 565 (explaining the legal limitations that Title VII places on employers); see also Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 Hous. L. Rev. 23, 33 (explaining that since genetic traits include race, ethnicity and gender, a cause of action for discrimination can also be supported under Title VII). \par\par

n41. See Rothstein, *supra* note 40. The plaintiff, however, must still demonstrate that the employer's claimed purpose in its use of the genetic information was a pretext for discrimination against the protected class. See *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976) (holding that the mere fact that petitioner's disability benefits affected an entire class by denying coverage for pregnancy does not make for a violation of Title VII). \par

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V. New York Law Restricts the Collection and Use of Genetic Information in the Workplace\par

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Prompted in part by the inadequacy of federal law, the New York Legislature has followed the lead of other states, and passed legislation to restrict genetic testing. n42 This is accomplished statutorily in three ways. First, the New York statute adds "genetic predisposition or carrier status" to the list of other protected categories under the general Human Rights Law prohibition against discrimination by employers, employment agencies, labor organizations or licensing agencies. n43 Second, it adds "genetic condition" to the definition of disability. n44 The amendment also defines "genetic anomaly," "genetic predisposition," "carrier" and "genetic test." A "genetic anomaly" means any variation in an individual's DNA, which has been demonstrated to confer a genetically influenced disease or predisposition to a genetically influenced disease, or makes the individual a carrier. n45 A "genetic predisposition" means that one has a DNA anomaly that is closely linked to a particular disease. n46 A "carrier" is defined as one who does not have a genetic predisposition but who is at risk of passing a genetic predisposition to offspring. n47 A "genetic test" is a device that diagnoses a genetic anomaly. n48\par

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n42. See N.Y. Exec. Law 296 (McKinney 1998). \par\par

n43. See id. 296(1). \par\par
n44. See id. 292(21). \par\par
n45. See N.Y. Exec. Law, 292 (21-a). \par\par
n46. See id. 292(21-b). \par\par
n47. See id. 292(21-c). \par\par
n48. See N.Y. Exec. Law 292(21-d). \par
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The third substantive addition to New York Law is a new sub section dealing with the administration of genetic tests and the use of test results. n49 It provides that employers, employment agencies, labor organizations, or licensing agencies may not '22directly or indirectly solicit, require or administer a genetic test'22 as a condition of employment, membership or licensure. n50 Employers, employment agencies, labor organizations or licensing agencies are also prohibited from purchasing or otherwise acquiring such test results. n51\par
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n49. See N.Y. Exec. Law 296(19). \par\par
n50. N.Y. Exec. Law 296(19)(a)(1). \par\par
n51. See N.Y. Exec. Law 296(19)(a)(2). \par
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Under Section 296, an employer may offer genetic tests after hire. n52 They can be used under the new statute provided that an employee requests a genetic test and provides written informed consent and only for purposes of a Workers Compensation claim, pursuant to civil litigation, or '22to determine the employee's susceptibility to potentially carcinogenic, toxic or otherwise hazardous chemicals or substances found in the workplace environment....'22 n53 However, in any of these cases, the employer may not terminate or take other actions against the employee based on the genetic test results. n54\par
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n52. Id. 296(19)(c). \par\par
n53. See id. \par\par
n54. See id. \par
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Undoubtedly, the New York statute has a very broad impact. The New York State Human Rights Law defines an employer to exclude only those entities employing fewer than four persons. n55 Therefore, unlike Title VII and the ADA which require at least fifteen employees for coverage, n56 the New York statute applies to very small companies and local businesses as well as large regional and national businesses.\par
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n55. See N.Y. Exec. Law 292(5). \par\par
n56. \i 42 U.S.C. 2000e(i) (b); \i 42 U.S.C. 12111(i) (5)(A). \par
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The public policy that underlies the statute has been clearly set forth. The New York legislature has found that while genetic testing technology has improved, there is still a risk of incorrect results concerning those genetic predispositions that will result in actual disease or disability.⁵⁷ The legislature also seeks to prevent the creation of a genetic underclass branded by the employers as the result of genetic defects.⁵⁸ Finally, the New York legislature found that employers have no legitimate interest in requiring or requesting a genetic test or test result from an applicant, and should be prohibited from requiring or requesting such tests, except where the test is shown to be directly related to occupational health.⁵⁹ For example, occupational health is implicated when the employee applicant with a particular genetic anomaly might be at an increased risk of disease as a result of working at a particular site.⁶⁰

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⁵⁷. See N.Y. Exec. Law 292(21)(b) (defining the terms "genetic predisposition and genetic test"); see also 1996 N.Y. Laws ch. 204, Assembly Memorandum in Support (finding only a "limited possibility of predicting whether or when a particular genetic anomaly will result in disease....") "Hereinafter Assembly Memorandum".

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⁵⁸. See Assembly Memorandum, *supra* note 57.

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⁵⁹. See *id.*

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⁶⁰. See N.Y. Exec. Law 296(19)(b).

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There are significant legal issues raised by the interplay of existing federal anti-discrimination law generally and New York law relating to genetic information. Preliminarily, it should be noted that the ADA does not preempt a state law such as New York's that provides greater protection to individuals.⁶¹ By its terms, the ADA does not protect workers from post-employment requirements or requests to provide genetic information. As noted above, under the ADA, once a conditional offer of employment is extended, but before the individual begins work, the employer may obtain genetic information.⁶² As a result of the 1996 statute, an employer in New York may not request or require genetic information, or make genetic screening a condition of employment, unless the test is directly related to the occupational environment, such as where it discloses an increased risk of disease due to the genetic anomaly.⁶³ Therefore, the protection afforded potential subjects of genetic tests under New York law is greater than that afforded subjects of other medical tests in New York or other states under the ADA.

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⁶¹. See 42 U.S.C. 12201(i)(C).

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⁶². See *supra* notes 30-32 and accompanying text.

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⁶³. See N.Y. Exec. Law 296(19).

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Lest attempts be made to stretch the New York statute beyond its intended ap

plication, the protection provided under New York law in the context of genetic information, however, is limited to the concept of disease. The term "genetic predisposition" means the

presence of a variation in the composition of the genes of an individual which is scientifically or medically identifiable and which is determined to be associated with an increased statistical risk of being expressed as a physical or mental disease or disability in the individual but which has not resulted in any symptoms of such disease or disorder.

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n64. N.Y. Exec. Law 292(21-b) (emphasis added).

-----End Footnotes-----

Similarly, a genetic anomaly means any variation in a person's DNA that confers or is likely to confer a genetically influenced disease. As a result, the protection from discrimination for those with a genetic predisposition or anomaly would not extend to claims of discriminatory treatment based upon sexual preference. Homosexuality has not been viewed as a "disease" by the medical or psychiatric community. Therefore, it is not a "disease" or a predisposition to a disease protected under this statute.

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n65. See N.Y. Exec. Law 292(21-a).
n66. See 1996 N.Y. Laws, Ch. 204 4.

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The New York statute does not eliminate all genetic testing; it strikes a balance between the protection of employee rights and the need to obtain important medical information based on either the employee's consent or when the test is related directly to the occupational environment.

There is a distinction drawn between situations in which an employer may offer genetic tests and those in which a test can be required. As noted above, an employer may offer genetic tests after hire. They can be used under the new statute on the employee's request and with his or her consent, and then only for purposes of a Workers Compensation claim, civil litigation, or to assist in preventing employees from dangerous workplace conditions. Therefore, genetic tests may still be used to obtain information that may benefit the employer and protect the interests of the employee.

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n67. See N.Y. Exec. Law 296(19)(c).

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It is clear that genetic testing may be required by an employer in New York

only when the test is directly related to the occupational environment. This is a provision of the statute that is likely to produce confusion and litigation. The State Division of Human Rights has interpreted this provision to be subject to certain basic guidelines.⁶⁸ First, the employer must obtain and make readily available to its employees and to the State Division of Human Rights, generally accepted scientific information that establishes that the anomaly is directly related to the occupational environment. Such scientific information must clearly indicate the particular anomaly, the correlated disease, the degree of correlation between the anomaly and the disease, and the nature and the extent of the anomaly's connection to the hazardous chemical or substance in the workplace. Second, tests may only be given to provide information to the employer and to the applicant or employee. Third, the Division of Human Rights is of the opinion that the employer, or its agent, must also comply with the informed consent provision set forth in the state.⁶⁹ It should be noted, however, that informed consent is not expressly mandated by the statute in this context.⁷⁰

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⁶⁸. See Interoffice Memorandum of Lawrence Kunin, Esq., General Counsel to John Lind, Deputy Commissioner for Regional Affairs (Apr. 30, 1997) (on file with the author).

⁶⁹. See N.Y. Exec. Law 296(19)(d).

⁷⁰. Even though informed consent is not required in this context, a New York employer is well-advised to seek it. The State Division of Human Rights is authorized to enforce the provisions of the Human Rights Law. See N.Y. Exec. Law, 290, 295. Therefore, the interpretation of the statute by the Division may be afforded deference by a New York court.

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VI. Conclusion

New York has adopted a comprehensive statute that restricts the employer's access to an employee's genetic information. The statute establishes genetic predisposition to a disease or carrier status as a protected category, much like age, race, creed and national origin. It also adds genetic condition to New York's definition of a disability. The statute does not eliminate all genetic testing in the workplace, but it sets forth limited circumstances where it can occur upon request after hire upon the employee's consent, or where there is a demonstrated danger in the occupational environment. Given the inadequacies of legislation at the federal level, Congress should follow the lead of New York and other states, and enact comprehensive legislation to restrict the employer's access to genetic information. This could be done by an amendment to Title VII to add genetic predisposition or carrier status to the list of protected categories or by an amendment to the ADA expanding the definition of disability to expressly encompass a genetic condition.

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ARTICLE: The Class Action Suit As a Method of Patient Empowerment in the Managed Care Setting \par\par\pard

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SUMMARY: ... The American health care system has undergone tremendous transformation over the past few decades. The fee-for-service (FFS) health care system in which physicians enjoyed a great deal of autonomy has become a managed care system in which cost and utilization considerations play a larger role in physician decision making. ... Despite the differences, this Article will not distinguish among MCOs because neither the corporate structural differences nor the possible differences in incentives that flow from the structural distinctions are crucial to the analysis of the utility of the class action device in the managed care setting. ... \22\5BA physician\5D cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative medical decisions go sour.\22 ... At one time, MCOs even issued \22gag rules\22 prohibiting physicians from discussing with patients (1) treatments their plans do not cover; and/or (2) their economic arrangements with the organizations. ... Health care cases involving high-dollar individual damages, such as UR cases, do not lend themselves to class action treatment. ... At the very least, it would seem that classes of patients with similar or identical plans could proceed to a liability determination, leaving individual damages determinations for later proceedings or settlement. ... \par\par\pard

TEXT: \5B*7\5D \par\par

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I. INTRODUCTION\par

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The American health care system has undergone tremendous transformation over the past few decades. The fee-for-service (FFS) health care system in which physicians enjoyed a great deal of autonomy has become a managed care system in which cost and utilization considerations play a larger role in physician decision making. Although physicians and other health care professionals are still patient advocates, this role often results in a conflict between their own economic interests and their duties to their patients. \par\par

Rather than depending on self-sacrificing health care professionals to advocate for them, patients need to assert their own power in the managed care arena. One way to gain such power is to use the class action device in litigation aimed at improving medical care quality, cost and access. Class actions, in fact, are likely to proliferate as managed care organizations (MCOs) grow and affect more patients' \5B*8\5D lives. There are well-recognized dangers to using the class action device, but if used properly, it could prove a valuable

remedy for patients.\par

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n1. Others - such as physicians who wish to maintain individual or small-group practices without affiliation with managed care organizations (MCOs), or who are affiliated with such organizations but disagree with their philosophy or decisions - may similarly wish to assert more force in the health care industry.

The plight of the patient, however, is more acute. Physicians have strong groups, such as the American Medical Association (AMA), lobbying on their behalf. Other physician groups have also organized to oppose managed care practices. See Peter T. Kilborn, Doctors Organize to Fight Corporate Intrusion, N.Y. Times, July 1, 1997, at A12. In contrast, patients - with the exception of older Americans, who have the American Association of Retired Persons (AARP) advocating for them - generally do not have organizations with great lobbying power safeguarding their interests. Compare John Q. La Fond & Mary L. Durham, Cognitive Dissonance: Have Insanity Defense and Civil Commitment Reforms Made a Difference?, 39 Vill. L. Rev. 71, 76 (1994) (noting how courts have urged legislatures to enact laws that protect those groups who have traditionally lacked political power, such as prisoners, poor people, minorities and patients), with Bruce Alpert, Breaux Defends Medicare Changes: Gamble Taken on Tough Issue, New Orleans Times-Picayune, July 8, 1997, at A1, available in 1997 WL 4230751 (noting that the AARP is senior citizens' largest lobbying group for Medicare reform). This Article will not address the use of the class action device in health care litigation by those other than patients. \par

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This Article will explore the possible use of the class action device in health care litigation. It will examine the changes in the U.S. health care system in an effort to explain partially why patients need more power in the evolving managed care system. It also will examine the drawbacks of class actions and explain why, despite these drawbacks, class actions can better serve patient-plaintiffs in managed care litigation than other remedies. The Article will conclude that the class action can be a powerful tool for asserting patients' political power on certain health care issues. \par\par

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II. HEALTH CARE LITIGATION AS A REFLECTION OF THE CHANGING INDUSTRY\par

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Health care suits are not the types of cases one typically thinks of in class action terms. When asked to define a health care claim, most people think in terms of personal injury allegedly resulting from caregiver negligence. Such cases, which address quality of care, generally do not lend themselves to class action treatment. Arguably, they are not even the types of cases the drafters of Federal Rule of Civil Procedure 23 intended to qualify for class action treatment. n4 Rather than alleging millions of like claims, litigators of typical personal injury claims usually want to make them appear unique. In cases of severe physical injury, for example, an attorney may not want her client sharing the spotlight, and thus a portion of a large recovery, with other plaintiffs. In more mundane disputes, an attorney may not want a jury or court to consider how much imposition of liability will cost in the aggregate. Cases in which these considerations are paramount conflict with the major, overriding requirement of class actions-that the parties banding together as a class have enough in common that representation of all by a few does not offend the notion of due pro

cess. n5\par
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n2. Quality, cost and access comprise the 'three-legged stool' of health care policy. See Thomas W. Mayo, Foreword: Nonfinancial Barriers to Health Care, 32 Hous. L. Rev. 1187, 1187 (1996) (citing articles). Parties attacking some aspect of health care target either its quality, cost, access or some combination thereof. \par\par

n3. Fed. R. Civ. P. 23 (authorizing class actions in the federal courts and outlining procedures for their maintenance, conduct, notice, judgment, dismissal, compromise etc.). This Article solely addresses class actions in the federal court system. States have their own class action rules, many of which resemble the federal rule. See, e.g., Ariz. R. Civ. P. 23; Del. Ch. R. 23. But see Fleming James, Jr. et al., Civil Procedure 10.22, at 567 (4th ed. 1992) (discussing how attitudes of states toward class actions vary). \par\par

n4. The drafters of Rule 23 'had dominantly in mind vindication of the rights of groups of people who individually would be without effective strength to bring their opponents into court at all.' Amchem Prods., Inc. v. Windsor, 117 S. Ct. 2231, 2246 (1997) (quoting Benjamin Kaplan, Prefatory Note, The Class Action: A Symposium, 10 B.C. Ind. & Com. L. Rev. 497, 497 (1969)). 'The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights.' Id. (quoting Mace v. Van Ru Credit Corp., 109 F.3d 338, 344 (7th Cir. 1997)). Aggregating several small claims into a large class gives the class suit enough value to be worth a representative litigant's, and an attorney's, time and effort. See id. \par\par

n5. See id. at 2257. \par
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Nevertheless, class action claims are surfacing in a variety of health care cases, n6 in part because of changes in the health care industry. Despite the concerns noted 'above, class actions appear to be a natural response to industry changes, and this response can help patients assert their concerns with inequities in the system. Through class actions, patients can band together to better their position via impact litigation n7 addressing the health care system in which they find themselves. Although class actions have experienced pendulum swings in public and judicial opinion over the years, n8 they remain the classic method of empowering 'groups of people who individually would be without effective strength to bring their opponents into court at all.' n9 Power, after all, 'is typically more effective when it is articulated by a group.' n10 Class actions also offer private parties the opportunity to redress wrongs that affect the public. n11 Finally, if nothing else, class certification may help plaintiffs 'by so increasing defendants' potential liability and litigation costs that they decide to settle cases they otherwise might have litigated. n12\par
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n6. See cases cited infra notes 192, 212, 231. \par\par

n7. Impact litigation is 'litigation oriented toward the change of institutional norms or practices, rather than the resolution of individual problems.'

²² Lucie E. White, Mobilization on the Margins of the Lawsuit: Making Space for Clients to Speak, 16 N.Y.U. Rev. L. & Soc. Change 535, 535 n.1 (1989).

8. See Arthur R. Miller, Of Frankenstein Monsters and Shining Knights: Myth, Reality, and the Class Action Problem, 92 Harv. L. Rev. 664, 678 (1979). Currently, class actions are not in great favor. See Richard L. Marcus, They Can't Do That, Can They? Tort Reform Via Rule 23, 80 Cornell L. Rev. 858, 858 (1995). Recent concerns over their use in the securities and mass torts areas have sparked a flurry of law review articles and at least two Supreme Court cases, as well as misgivings about their impact on existing federal legislation. For thoughtful discussions on the advantages and disadvantages of mass tort and securities fraud class action suits, see John C. Coffee, Class Wars: The Dilemma of the Mass Tort Class Action, 95 Colum. L. Rev. 1343, 1353-55 (1995) (discussing developments and changes in mass tort class actions as well as proposals for reform); James D. Cox, Making Securities Fraud Class Actions Virtuous, 39 Ariz. L. Rev. 497, 499-508, 515-23 (1997) (discussing reasons for distrust of securities class actions and discussing the reform measures of the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (codified in scattered sections of 15 U.S.C.A (West 1997))). For recent Supreme Court cases discussing the status of class action settlements, see *Amchem Products, Inc. v. Windsor*, 117 S. Ct. 2231, 2252 (1997) (upholding class decertification and vacating district court injunction against individuals who failed timely to opt out of an asbestos class action settlement, because requirements for class certification of commonality of issues of fact and law and adequacy of representation were not met); *Matsushita Electric Industrial Co. v. Epstein*, 516 U.S. 367, 378, 386 (1996) (holding that state class action settlement judgment has a preclusive effect on pending litigation of an exclusive federal claim arising under the Securities Exchange Act of 1934, 15 U.S.C. 78a-78l (1994)).

Concerns about federal securities class action lawsuits stem partially from use of the so-called Delaware settlement. In a Delaware settlement, a corporation can settle all related state and federal claims in the context of a state court class action even though the federal claims, such as securities law claims, may have been the plaintiffs' only valid claims and could not have been litigated in state court. See, e.g., *Epstein v. MCA, Inc.*, 126 F.3d 1235, 1248-51 (9th Cir. 1997) (opinion on remand) (holding that state court judgment approving a Delaware settlement did not have preclusive effect in a related federal securities lawsuit, because a conflict of interest existed between class counsel in the state court action and plaintiff class of shareholders, thereby rendering representation of the class inadequate); Brief of C.L. Grimes as Amicus Curiae in Support of Respondents *1, *Matsushita* (No. 84-1809), available in 1995 WL 782814 (emphasizing that Delaware settlement is an egregious misuse of class action procedure that should be put to an end).

9. Kaplan, *supra* note 4, at 497; see also *Califano v. Yamaski*, 442 U.S. 682, 701 (1979) ('The class-action device saves the resources of both the courts and the parties by permitting an issue potentially affecting every class member to be litigated in an economical fashion'); *cf.* *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 809 (1985) (stating that in a class action of plaintiffs whose claims average about \$100, 'most of the plaintiffs would have no realistic day in court if a class action were not available').

10. Steven L. Winter, The Power Thing, 82 Va. L. Rev. 721, 739 (1996).

11. See John C. Coffee, Jr., Rescuing the Private Attorney General: Why the

Model of the Lawyer As Bounty Hunter Is Not Working, 42 Md. L. Rev. 215, 216 (1983); see also Associated Indus., Inc. v. Ickes, 134 F.2d 694, 704 (2d Cir.) (referring to private persons who vindicate the public interest as 'private Attorney Generals'), rev'd, 320 U.S. 707, 707 (1943) (vacating court of appeals' order and remanding to determine if the liabilities and obligations incurred under the Bituminous Coal Act, 15 U.S.C. 828 (1994) (repealed Sept. 6, 1996), survive the Act's expiration). \par\par

n12. See Coopers & Lybrand v. Livesay, 437 U.S. 463, 476 (1978) ('Certification of a large class may so increase the defendant's potential damages liability and litigation costs that he may find it economically prudent to settle and to abandon a meritorious defense.');

Castano v. American Tobacco Co., 84 F.3d 734, 746 (5th Cir. 1996).

For a general discussion of the intense pressure on defendants to settle class actions, see In re Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1298-99 (7th Cir. 1995).

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A number of factors may lead to an increase in health care class action suits. First, patients need to assert more authority over the particulars of their health care. The transformation of the industry has led patients to become wary consumers of health care services. n13 Unlike patients in prior eras, today's patients now may believe they need to protect themselves rather than relying on the system, physicians or other providers for protection. n14 Second, economics has become increasingly important in health care. Always a factor even in the FFS system, the profit motive today fosters cutbacks in care rather than over treatment. In the face of such financial considerations, patients - much like civil rights litigants - may believe they must safeguard hard-won rights such as the right to informed consent. n15 Finally, the law itself (mainly through the Employee Retirement Income Security Act of 1974 (ERISA) n16) - and the way health care professionals, employers, insurers and attorneys have responded to the law in structuring health care benefit plans - may contribute to a rise in the feasibility and incidence of health care class actions.

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n13. For examples of popular media advancing consumer awareness of managed care tactics, see sources cited *infra* note 56.

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n14. See Ellyn E. Spragins, Beware Your HMO, Newsweek, Oct. 23, 1995, at 54, 54 (reassuring that 'By'Dou can protect yourself and your family').

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n15. See Elizabeth Gleick, Picking a Health Plan: A How-To Guide, Time, Jan. 29, 1996, at 60, 61 (discussing impact of health maintenance organization (HMO) 'gag clauses' on patient care); Spragins, *supra* note 14, at 55-56 (same).

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n16. 29 U.S.C. 1001-1461 (1994).

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A. Patients As Consumers

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Consumerism serves as a valuable metaphor for examining patients' needs for power in the managed care market. Deterred by litigation costs outweighing their individual damages, especially when the latter are discounted for likelihood (o

r unlikelihood) of success, \22most consumers do not bother to seek individual justice.\22 n17 Patients increasingly realize that they must act like consumers in the health care arena. n18 Rather than being treated as valued individuals who can trust caregivers with whom they have personal relationships, patients now face warnings that the \5B*11\5D health care system is one in which the buyer must beware. n19 Consumers of credit and financial services looked to class actions in the past to assert themselves in the costly, bureaucratic and technical area of bank regulation. n20 Consumers today may do likewise in the costly, bureaucratic and technical world of health care.\par \par

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n17. Leon E. Trakman, *David Meets Goliath: Consumers Unite Against Big Business*, 25 Seton Hall L. Rev. 617, 617 (1994).\i0 Class actions have proven useful in remedying situations in which consumer victims are treated similarly, have comparable losses, share an interest in redressing those losses and seek to advance a public interest in deterring future conduct such as that which caused them injury. See \i id. at 618;\i0 see also Shauna I. Marshall, *Class Actions As Instruments of Change: Reflections on Davis v. City and County of San Francisco*, 29 U.S.F. L. Rev. 911, 912 (1995)\i0 (reflecting on how a class action with subclasses helped litigants and class counsel achieve the broad shared goal that united them despite individual differences). \par\par

n18. See, e.g., sources cited *infra* note 56 and accompanying text. \par\par

n19. See, e.g., sources cited *infra* note 56 and accompanying text. \par\par

n20. Consumers of financial services, for example, have achieved some measure of success in disputing as classes the actions of banks in imposing surcharges. Cf. Trakman, *supra* note 17, at 620-21 (although criticizing a class action settlement with Wells Fargo Bank ending a dispute over surcharges imposed for checks returned due to insufficient funds). Such consumers, and consumers challenging prejudgment and prehearing remedies, debt collection practices and credit reporting procedures, to name a few, see 4 Herbert Newberg & Alba Conte, *Newberg on Class Actions* 21.01, at 21-2 to -3 (3d ed. 1992), have taken advantage of the class action device to try to recompense their individually minor damages at low cost, with more force but less inconvenience and stress than if each had filed suit. See generally \i Durrett v. John Deere Co., 150 F.R.D. 555, 561 (N.D. Tex. 1993)\i0 (summarizing the case for the efficiency and benefits of a consumer class action); 4 Newberg & Conte, *supra*, 21.01, at 21-3 to -9 (same). \par

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I. The Health Care System Undergoes a Transformation\par \par

Until relatively recently, American medicine functioned mainly on a FFS basis. n21 Because the vast majority of American patients had insurance covering most if not all of such charges, n22 patients did not have to deal directly with the costs of their health care. n23 They did not even have to worry about the cost of insurance, because most people received such coverage as an employee benefit. n24 Insurance companies had no incentive to push doctors and hospitals to charge less because they could recoup their costs by raising premiums. n25 And although they watched health insurance costs rise, employers had little incentive

e to police those costs strictly because they could deduct employee benefits payments from their business income for federal tax purposes. n26 With no one really watching the books, physicians and hospitals provided more and more services because doing so increased their incomes. Costs skyrocketed.

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n21. See Alexander M. Capron, Containing Health Care Costs: Ethical and Legal Implications of Changes in the Methods of Paying Physicians, 36 Case W. Res. L. Rev. 708, 711 (1986) (the dominant method by which consumers pay for health services and by which physicians are compensated is the fee-for-service method). Fee-for-service (FFS) is intended to encompass systems in which compensation actually is based on services rendered as well as systems in which a provider is compensated for services in accordance with the usual or customary cost of or charge for those services. See generally Vernellia R. Randall, Managed Care, Utilization Review, and Financial Risk Shifting: Compensating Patients for Health Care Cost Containment Injuries, 17 Puget Sound L. Rev. 1, 14-15 (1993) (explaining the private insurers' FFS model and the government's cost or charge model of the mid-1980s). In this system, physicians generally maintain private practices (either individually or in groups), hold privileges at hospitals and receive fees based on the services they performed. See Capron, supra, at 712. Hospitals similarly charge patients for services provided.

n22. By 1986, public or private insurers made 70% of payments to providers. See Randall, supra note 21, at 14 (citing George J. Annas et al., American Health Law 131 (1990)).

n23. See id. at 15-16 (contending that individuals with health insurance lack incentives to economize).

n24. See Annas et al., supra note 22, at 131 (stating that a majority of Americans receive their health insurance as part of their employee benefits).

n25. Third-party payers, however, are now motivated by profit and are rigorously looking for ways to control the untamed beast. Randall, supra note 21, at 15.

n26. See I.R.C. 419 (1994); see also Capron, supra note 21, at 713-15 (stating that expenditures are inflated because physicians lack incentives to provide the most economical treatment); Randall, supra note 21, at 14-15 (noting that both FFS and cost-basis reimbursement created powerful incentives for all players in the health care system not to economize). See generally Elaine Lu, Recent Development, The Potential Effect of Managed Competition in Health Care on Provider Liability and Patient Autonomy, 30 Harv. J. on Legis. 519, 523-25 (1993).

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By 1993 medical care costs totaled about fourteen percent of the nation's gross national product. n27 Although the rise in health care costs has slowed, n28 some believe the slowdown may be only temporary. n29 In fact, both private and government health care costs continue to rise, even though the overall rate of increase has slowed. n30

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n27. See Physician Payment Review Comm'n, 1995 Annual Report to Congress 182 (1995) \5Bhereinafter PPRC 1995 Report\5D (citing Katharine R. Levit et al., National Health Spending Trends 1960-1993, Health Aff., Winter 1994, at 14, 15). Health care spending topped one trillion dollars for the first time in 1996. See Robert Pear, Spending on Health Grew Slowly in 1996, N.Y. Times, Jan. 13, 1998, at A14. \par\par

n28. See PPRC 1995 Report, supra note 27, at 182; Pear, supra note 27, at A14. \par\par

n29. See PPRC 1995 Report, supra note 27, at 182-83. \par\par

n30. See id. at 183. \par

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The slowdown in growth stems from major cost-containment efforts, some of which even pre-date the health care industry's cost crisis. Initially within certain industries, n31 and later in other sectors, n32 health care systems developed that, in effect, were self-contained. That is, new institutions arose that provided health care and served as the entities with which employers contracted to pay for the health care provided. n33\par

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n31. The Farmer's Union began its Cooperative Health Association in Oklahoma in 1929, see Randall, supra note 21, at 20, and the Western Clinic in Tacoma, Washington, contracted with lumber mills to provide medical care for their employees for a set monthly fee around the turn of the century. See William M. Mercer, Inc., Integrated Health Plans: Managed Care in the 90s 3 (1990). Some date the development of managed care even earlier. See, e.g., Barry R. Furrow, Managed Care Organizations and Patient Injury: Rethinking Liability, 31 Ga. L. Rev. 419, 427-28 (1997)\i0 (discussing how \22\5Bi\5Dn the 1800s businesses such as railroads, sugar plantations, and lumber companies wanted to attract immigrant labor and retain it, often in isolated locations ... \5Bof the\5D United States\22 and, in order to do so, \22pioneered capitated health care and organized delivery of services\22). \par\par

n32. In the 1930s, two physicians started a prepaid group health delivery plan in Los Angeles, the Ross-Loos Health Plan. It is \22the oldest HMO still in existence.\22 See Randall, supra note 21, at 20 & n.76; see also Paul Starr, The Social Transformation of American Medicine 301 (1982) (noting that by 1935 the Ross-Loos Clinic had enrolled more than 12,000 employees and their 25,000 dependents). Also, in the 1930s and 1940s, industrialist Henry Kaiser established prepaid medical plans for his employees in California and the Pacific Northwest. See William M. Mercer, Inc., supra note 31, at 3. After World War II, Kaiser Permanente Health Plan opened to public enrollment. See id.; see also Randall, supra note 21, at 21 n.79 (stating that by 1988, Kaiser Health Foundation Plan had become \22the largest prepaid plan in the U.S.\22). See generally Capitation, Integration, and Managed Care: Lessons from Early Experiments, 275 JAMA 957 (1996)\i0 (tracing the latest \22structural transition\22 of the health care industry toward managed care, from its roots to present efforts). \par

n33. The Health Maintenance Organization Act of 1973 defines an HMO as \22a public or private entity which ... provides basic and supplemental health services to its members,\22 \i 42 U.S.C. 300e\i0 (a) (1994), \22for a basic health services payment.\22 Id. 300e(b)(1); see also \i Anderson v. Humana, Inc., 24 F.3d 889, 890 (7th Cir. 1994)\i0 (stating that an HMO \22offers, for a fixed

d fee, as much medical care as the patient needs\22). \par
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Moreover, some health care providers had incentives to reduce their costs even if they were not benefits payers or institutionally affiliated with such entities. The federal government instituted one form of managed care in 1983, when it began calculating hospital reimbursements for care provided under the Medicare program based on patients' diagnosis-related-groups (DRGs).³⁴ In response to the use of DRGs to compute reimbursements, hospitals began to influence what previously had been considered medical decisions solely within the purview of physicians.³⁵ The DRG system's limited payments encouraged hospitals to ensure that staff and physicians (1) diagnosed patients as suffering from conditions falling within high-payment DRGs; (2) rendered fewer, if any, unnecessary services; and (3) discharged patients as quickly as possible.³⁶ These measures helped ensure that each patient's care would cost no more than his DRG payment.³⁷ Hospitals began to implement quality assurance programs in which personnel other than the patient's treating physicians ... evaluate, recommend, or require protocols for the care provided by those physicians,³⁸ thus limiting physicians' discretion in managing cases.\par

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³⁴. See *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1327 (5th Cir. 1992).\i0 \par\par

³⁵. See Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 Harv. L. Rev. 381, 395 (1994).\i0 Kenneth Abraham and Paul Weiler note that, as a result of diagnosis-related groups, and presumably of the corresponding changes in the private payment systems, 'the distinction between medical and economic concerns has become greatly blurred.' Id. \par\par

³⁶. See id. \par\par

³⁷. See id. \par\par

³⁸. *Id.* at 397.\i0 \par

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Such a reordering of incentives is also true of managed care, which represents a movement away from providing maximum, sometimes unnecessary, services toward minimizing authorized care in a way that, one hopes, does not reduce quality.³⁹ Many forms of public and private managed care, or integration of health care financing and delivery systems, have evolved.⁴⁰ Although they may do so in different ways, all forms of managed care attempt to contain costs by modifying the behavior of doctors.⁴¹ Ranging from health maintenance organizations (HMOs) to integrated delivery systems (IDSs) to preferred provider organizations, the choice of organizational form may either foster or impede ethical medical practice.⁴² Despite the differences, this Article will not distinguish among MCOs because neither the corporate structural differences nor the possible differences in incentives that flow from the structural distinctions are crucial to the analysis of the utility of the class action device in the managed care setting. Instead, the Article will refer globally to MCOs except in situations that require reference to a particular type of MCO.\par

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n39. See David Mechanic & Mark Schlesinger, The Impact of Managed Care on Patients' Trust in Medical Care and Their Physicians, 127 JAMA 1693, 1694 (1996); Larry J. Pittman, ERISA's Preemption Clause and the Health Care Industry: An Abdication of Judicial Law-Creating Authority, 46 Fla. L. Rev. 355, 361 (1994) (citing E. Haavi Morreim, Cost Containment and the Standard of Medical Care, 75 Cal. L. Rev. 1719, 1720 (1987)). \par\par

n40. Marsha Gold et al., Mathematica Policy Research, Inc., Arrangements Between Managed Care Plans and Physicians: Results from a 1994 Survey of Managed Care Plans app. A, at 3 (1995) (report submitted to the Physician Payment Review Commission, Washington, D.C.). \par\par

n41. Lu, supra note 26, at 528; see Barry R. Furrow, The Changing Role of the Law in Promoting Quality in Health Care: From Sanctioning Outlaws to Managing Outcomes, 26 Hous. L. Rev. 147, 171 (1989) (stating that "measuring the behavior of the providers is accomplished ... through implementation of clinical algorithms, outcome-based studies, application of quality control principles from industry, and large-scale analysis of practice patterns"). \par\par

n42. See Kate T. Christensen, Ethically Important Distinctions Among Managed Care Organizations, 23 J.L. Med. & Ethics 223, 226-27 (1995) (summarizing the structural features of MCOs that maximize the ethical treatment of patients). See generally Jack K. Kilcullen, Groping for the Reins: ERISA, HMO Malpractice, and Enterprise Liability, 22 Am. J.L. & Med. 7, 25-28 (1996) (discussing a range of organizational structures where the payer is the provider). \par\par

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In all managed care systems, the payer has more influence over medical (or what should be medical) decisions than in traditional FFS medicine. In some systems, physicians receive bonuses if, at year end, they have limited the number of special tests they have ordered or the number of patient referrals to specialists. n43 In others, the MCO withholds a percentage of a physician's income throughout the year. n44 The physician will receive this "withhold" if she minimizes the specialized types of care recommended or requested. n45 Additionally, many MCOs operate on a capitated basis. Under capitation, physicians and other health care providers n46 receive a set fee per month per patient plan participant. n47 This means the provider receives the same amount for seeing a patient twenty-five times as she receives for seeing that patient only once. n48 Finally, most managed care plans employ systems of concurrent or prospective utilization review (UR). In such systems, unlike retrospective review systems, managed care personnel review medical treatment decisions either before or during implementation. n49 The payer then decides whether it will pay for a recommended treatment based on the utilization reviewer's opinion of the necessity for or appropriateness of that treatment. n50 Thus, patients and physicians know somewhat in advance whether an MCO will pay for a recommended treatment. n51 Like the other cost-containment mechanisms just identified, this financial pressure could motivate physicians to limit care. \par\par

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n43. By structuring bonus systems in this manner, organizations shift the risk of financial loss from themselves to physicians or other providers. See Randall, supra note 21, at 6. See generally Jim M. Perdue & Stephen R. Baxley, Cutt

ing Costs - Cutting Care: Can Texas Managed Care Systems and HMOs Be Liable for the Medical Malpractice of Physicians?, 27 St. Mary's L.J. 23, 48-49 (1995) (describing how the actuarial risks are shifted to the provider).

n44. See, e.g., David J. Oakley & Eileen M. Kelley, HMO Liability for Malpractice of Member Physicians: The Case of IPA Model HMOs, 23 Tort & Ins. L.J. 624, 636 (1988) (noting that 20% is typically withheld from FFS payments to physicians).

n45. See id. at 636 & n.45 (outlining the guidelines for physician's withdrawal).

n46. For simplicity's sake, this Article will discuss the issues it raises with reference to physicians. Some of the concerns expressed or cases described, however, could similarly relate to or be alleged against other health care providers, such as nurses, nurse-practitioners, psychologists or technologists.

n47. See, e.g., Oakley & Kelley, supra note 44, at 635-36.

n48. See Randall, supra note 21, at 30.

n49. See Furrow, supra note 31, at 474.

n50. See id. at 482.

n51. See Maxwell J. Mehlman, The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?, 25 Conn. L. Rev. 349, 379-83 (1993) (noting that physicians sometimes provide medical services with the knowledge they will not be reimbursed; conversely, physicians may deny treatment if they suspect they might not be reimbursed).

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2. The Patient Becomes a Consumer

Patients thus have watched the traditionally personal physician-patient relationship transform into a sterile interaction in which care might be denied or might not be offered because of cost considerations. n52 Public and private sector cost-cutting initiatives have accelerated the transformation of health care from a purely professional undertaking to a business enterprise providing professional services. n53 Health care corporations devote increased attention to marketing. n54 Mergers of health care corporations result in huge, often for-profit rather than charitable, conglomerates that provide care. n55 Although some for-profit entities act responsibly and, conversely, not-for-profit status is no guarantee of responsible behavior, the providers resulting from such mergers are to patients a far cry from the Marcus Welbys of old. Consumers of health care services hear that the system today depends not on confidence, trust and personal relationships, but on caveat emptor:

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n52. Increasingly, even the qualifications of personnel in health care institutions reflect a more businesslike tenor. In the 1994-1995 school year, 13 medical schools offered combined doctor of medicine (M.D.) and master's of business administration (M.B.A.) degree programs. See Barbara Bazansky et al., Educational Programs in U.S. Medical Schools, 274 JAMA 716, 720 (1995); see also John Bernard Henry, The Effect of Changing Technology on Manpower in Pathology and Laboratory Medicine, 111 Archives Pathology & Laboratory Med. 662, 665-66 (1987) (predicting that the demand for pathologists will decrease as technolog

y improves and with the advent of a competitive, cost-conscious health care industry, but that there will be a \22growing national need\22 for those with a combination M.D./M.B.A. degree to face the changes); Gary L. Schechter, Maintaining Quality in a Discount Store Arena, 122 Archives Otolaryngology 90, 90-91 (1996) (describing the increasingly businesslike nature of the health care industry); cf. \i Florence Nightingale Nursing Serv., Inc. v. Blue Cross and Blue Shield, 832 F. Supp. 1456, 1460-61 (N.D. Ala. 1993)\i0 (criticizing a physician trained in \22cost containment\22 acting as chief claims evaluator for Blue Cross as lacking objectivity in her determination of a reasonable rate for medical services because she used her employer's low hourly rate for nursing services). \par\par

n53. Abraham & Weiler, supra note 35, at 396. \par\par
n54. Cf. George Anders, Health Against Wealth 63, 66 (1996) (noting that some HMOs have spent huge sums of money for purely aesthetic reasons rather than for providing health care). \par\par
n55. See Joanne B. Stern, The Benign History of a Scam: The HMO Experience (As Seen by a Health Lawyer), 1 DePaul J. Health Care 395, 404-05 (1997). \par

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Even though managed care has only recently taken hold in the bedrock of American medicine, it has already inspired a couple of popular sayings. One is that managed care is about managing costs, not care. The other is that the new health plans work really well - so long as you don't get sick. To these, consumer advocates add a third adage: people should approach health-care coverage as they would buying a car; shop around, read the fine print, and buyer beware. n56\par

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In this respect, patients are no different from countless American employees who have watched their industries become more businesslike. For example, some bemoan the demise of law as a profession and the rise of law firms that operate as businesses. n57 In the media, journalists watch marketing, advertising, graphic appeal and public opinion polls take precedence over news-gathering. n58 In business and industry themselves, thousands of current and former employees wonder what happened to company loyalty as their employers lay them off even though profits and stock prices soar. n59\par

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n56. Gleick, supra note 15, at 60; see also Spragins, supra note 14, at 54 (\22Some can be counted on in a pinch, but many delay or deny crucial care if you require expensive tests or procedures.\22). \par\par
n57. See, e.g., Martin Wald, Why a Law Firm Is Not a Business, Legal Intelligence, Nov. 27, 1995, at 3 (arguing that lawyers are no longer held in high regard because they do not recognize that their role is to prevent or help resolve disputes, not to run a business that is purely in the pursuit of profit; law firms operating as businesses have suffered from increased government regulation, and their lawyers from emotional and drug abuse problems, stress and long working hours). The Supreme Court's decision in \i Florida Bar v. Went For It, Inc., 515 U.S. 616 (1995)\i0 for example, prompted significant discussion about the purpose of the profession and the role of money-making in it. See Chasing

After Ethics: Does the Aggressive Pursuit of Business Contaminate the Profession of Lawyering? What Are the Limits in Pushing Legal Services upon the Needy but Grieving?, Recorder, Aug. 21, 1995, at 8, available in LEXIS, News Library, Arcnws File (transcript of a discussion on LEXIS Counsel Connect, an online service for lawyers).

n58. See Doug Underwood, When MBAs Rule the Newsroom 91 (1995).

n59. See N.R. Kleinfield, The Downsizing of America: In the Workplace Musical Chairs, N.Y. Times, Mar. 4, 1996, at A1 (printing a graph that depicts Chase Manhattan Corporation's assets increasing while its workforce shrank over the same time period); Steve Lohr, Downsizing: How It Feels to Be Fired, N.Y. Times, Mar. 17, 1996, at E5 (collecting and publishing readers' responses to the New York Times series, "The Downsizing of America"); Robert J. Samuelson, Are Workers Disposable?, Newsweek, Feb. 12, 1996, at 47, 47 (describing the fear of "the era of the disposable worker"); Allan Sloane, The Hit Men, Newsweek, Feb. 26, 1996, at 44, 45 (discussing the backlash generated by corporate layoffs and rising stock prices); Louis Uchitelle & N.R. Kleinfield, On the Battlefield of Business, Millions of Casualties, N.Y. Times, Mar. 3, 1996, at A1 (describing how the number of workers has fallen while graphically showing the increase in business revenues).

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With respect to health care coverage, patients in particular lack power. To the extent that employers provide health care benefits, that patients will ever wield consumer power in the eyes of health care corporations is questionable because their employers negotiate their health care coverage for them. In these cases, to exert consumer power over health care corporations, patients need to pressure their employers or to ask their union representatives to do so. Unions traditionally have taken on such a role, and they sometimes continue to do so. Generally, however, they have declined in power and influence throughout the American economy. Because patients have little negotiating power and little information regarding the quality of MCOs, it is difficult for them to group together to assert any coherent voice.

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n60. See Peter H. Schuck, Rethinking Informed Consent, 103 Yale L.J. 899, 931 (1994) (stating that "employers and other large groups can and sometimes do act as consumer proxies").

n61. Cf. Forsyth v. Humana, Inc., 827 F. Supp. 1498, 1501 (D. Nev. 1993) (employers and employees bringing class action suit against Humana under the Employee Retirement Income Security Act (ERISA), the Sherman Act and the Racketeer Influenced and Corrupt Organizations Act (RICO)).

n62. The recent United Parcel Service workers' strike marked the first time in nearly two decades that the public sided with a union. See Paul Magnusson et al., A Wake-Up Call: The Teamsters' Win Means That Workers Can No Longer Be Taken for Granted, Bus. Wk., Sept. 1, 1997, at 28, 28.

n63. See infra notes 79-83 and accompanying text.

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Moreover, patients are not accustomed to acting like consumers. In medicine, they could traditionally depend on their physicians to act in their best interests. "Cost is always a part of the clinical decision," because taki

ng it into account is good for both society and individual patient care. n65 The shift toward a 'buyer beware' system, however, requires a reversal of emphasis and attitude for patients. In one famous case, an MCO avoided liability for a death that allegedly resulted from its refusal to authorize the medical care prescribed by the treating physician. n66 Although it acknowledged that MCOs can sometimes be liable for injury resulting from their UR decisions, n67 the court would not permit physicians to shirk their traditional duty to advocate for their patients. n68 'BA physician' cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative 'B*17' medical decisions go sour.' n69 Physicians might not want to argue too strenuously for expensive patient care, however, with the party that pays them, calculates their withholds or bonuses, or credentials them for inclusion on an MCO's list of approved physicians - and patients must modify their behavior to account for these additional physician concerns. n70

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n64. Furrow, supra note 41, at 161. The AMA agrees with Furrow. During the health care reform debate, the AMA Council on Ethical and Judicial Affairs opined, 'Cost alone is not a reason for including or excluding treatment, but cost relative to effectiveness or benefit is highly relevant.' Council on Ethical and Judicial Affairs, American Med. Ass'n, Ethical Issues in Health Care System Reform: The Provision of Adequate Health Care, 172 JAMA 1056, 1059 (1994).

n65. Furrow, supra note 41, at 161-62.

n66. Wickline v. State, 239 Cal. Rptr. 810, 819-20 (Ct. App. 1986).

n67. See id.; see also infra text accompanying note 149 (noting that, in dicta, the Wickline court stated that an MCO may be liable for harm caused by defects in the design or implementation of cost-containment mechanisms).

n68. 'The physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care.' Wickline, 239 Cal. Rptr. at 819.

n69. Id.

n70. 'HMO managers often declare at national conferences that the physician can no longer be an advocate for the patient.' George J. Annas, Patients' Rights in Managed Care - Exit, Voice, and Choice, 337 New Eng. J. Med. 210, 213 (1997).

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This challenge to the physician-patient relationship benefits no one, because it requires physicians and other health care providers to work against the medical profession's goal of caring for patients. It also erodes patients' trust in the medical profession, which is unfortunate because the success of the health care system depends on trust. n71

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n71. See Susan J. Stayn, Note, Securing Access to Care in Health Maintenance Organizations: Toward a Uniform Model of Grievance and Appeal Procedures, 94 Colum. L. Rev. 1674, 1705 (1994); see also Mechanic & Schlesinger, supra

note 39, at 1693 (stating that financial arrangements between HMOs and physicians have adversely affected the degree of trust between patient and physician).

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The foundation of the patient-physician relationship is the trust that physicians are dedicated first and foremost to serving the needs of their patients. In the oath of Hippocrates, trust is a central element in almost all the ethical obligations of physicians It is this trust that enables patients to communicate private information and to place their health, and indeed their lives, in the hands of their physicians. Without trust, the success of the healing process would be seriously diminished. \par\par

No other party in the health care system has the kind of responsibility that physicians have to advocate for patients, and no other party is in a position to assume that kind of responsibility.... \par

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Council on Ethical and Judicial Affairs, American Med. Ass'n, Ethical Issues in Managed Care, 273 JAMA 330, 331 (1995) (footnote omitted). \par
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Increasing distrust of physicians and other health care professionals negatively affects the system in at least two ways. First, it focuses patients on the medical liability system as an avenue of relief. n72 Second, it reduces the effectiveness of treatment. Patients who trust their caregivers often report more favorable treatment outcomes. n73 This is especially true in a managed care system, because good managed care depends on patients' active involvement. Any system that seeks to minimize physician visits and emphasizes preventive care requires the cooperation and involvement of patients who are informed about their health care options and are able to exercise some decision-making power. n74\par

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n72. See PPRC 1995 Report, supra note 27, at 194, which states that: \par
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As the growth of managed care changes the incentives of physicians and hospitals, the role of the medical liability system in ensuring quality and preventing medical injuries assumes greater importance. In addition, as integrated systems grow, the issue of enterprise liability - where the organization, not the individual physician, is at risk - may become more important. \par

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For more on enterprise liability as it relates to class action suits, see infra Part III.A.1. \par\par

n73. See Geoffrey H. Gordon et al., Physician-Patient Communication in Managed Care, 163 W.J. Med. 527, 527 (1995) (stating that 'good physician-patient communication ... improves biologic and psychosocial health care outcomes and enhances patient satisfaction'); Mechanic & Schlesinger, supra note 39, at 1693. \par\par

n74. See Gordon et al., supra note 73, at 527 (stating that doctors should 'educate and coach patients in the management of common health problems' and should 'consider sharing decision-making responsibilities with the patient to help patients adjust to the new method of care in managed care plans')

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3. Managed Care Exacerbates the Need for Consumerism\par

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Unfortunately, managed care has not encouraged patients to become more empowered or knowledgeable. Rather, it has had the opposite effect on patients. Structural features of the system and the way the system has treated patients have combined to discourage rather than to empower them. \par\par

One reason the health care system has discouraged patient involvement stems from the way most health benefits are funded. First, most Americans have health care coverage of some sort,ⁿ⁷⁵ and that coverage obscures the actual cost of treatment.ⁿ⁷⁶ Second, most Americans receive such health care coverage through their employers.ⁿ⁷⁷ To the extent their employers entirely fund their coverage, employees remain ignorant of its cost.ⁿ⁷⁸ Employees whose employers do not entirely fund health care coverage are not exempt from this characterization; they still demonstrate the residual effects of this cost-ignorant mindset in their own attitudes toward health care. Although they pay a portion of their health care costs, and probably make ever-increasing copayments for each physician visit or prescription, they remain somewhat in the dark regarding the true dollar value of the care they receive.\par

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ⁿ⁷⁵. See Joel Weissman, Uncompensated Hospital Care: Will It Be There If We Need It?, *127 JAMA* 823, 823 (1996)\i0 (noting that in 1994, the proportion of the population that was uninsured was 17.3%). \par\par

ⁿ⁷⁶. See *id.* at 826.\i0 Cost shifting is the practice by most hospitals of charging higher prices to some health insurers to offset lower prices paid by others. Therefore, the actual cost of the treatment is not reflected in the insurance payment. See *id.*; see also Annas et al., *supra* note 22, at 131, 140 (noting that for those who receive insurance through employers, the impact of rising health care costs has been "partially disguised," and stating that cost-sharing arrangements, which are based on the theory that consumers will utilize more services if insulated from the "true costs" of care, may have contributed to obscuring the true cost of treatment). In 1994, the ratio of payments to costs for private payers was 124%. See Weissman, *supra* note 75, at 826.

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ⁿ⁷⁷. About 85% of Americans under age 65 have health insurance of some type. See Mark A. Rothstein, The Use of Genetic Information for Nonmedical Purposes, *9 J.L. & Health* 109, 113 (1995). Of the Americans under age 65 who have group insurance, 70% obtain it through employment. See *id.*; see also Bureau of the Census, U.S. Dep't of Commerce, Statistical Abstract of the United States 100 (1991) (reporting that, in 1988, 150.4 million Americans received health care coverage through employee benefits plans). \par\par

ⁿ⁷⁸. Patients and beneficiaries remain unaware of the value of their benefits because, although they are technically income, they need not be reported on tax returns. See I.R.C. 106 (1994). \par

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A second reason why patients have remained powerless - or at least have not gained power as consumers - is information flow. Although patients can compare plans' costs, for example by comparing monthly fees, deductibles, required cop

ayments or percentage of prescription costs paid, it is most difficult to judge a managed care system's quality. n79 In fact, there is great debate over how quality should be measured. n80 Despite state n81 and independent n82 efforts to require quality measure- \5B*19\5D ment, employers and patients thus lack quality-related information to use in differentiating between plans. n83 Cost, rather than quality, drives marketing of plans to employers and other large group purchasers. n84 This permits the survival of both good and bad MCOs - both those that give patients some power and those that proceed without input from or full disclosure to patients.\par

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n79. See Timothy Stoltzfus Jost, Oversight of the Quality of Medical Care: Regulation, Management, or the Market?, \i 37 Ariz. L. Rev. 825, 825-26 (1995).\i0 \par\par

n80. One may measure the quality of health care by analyzing an entity's structure, process or outcome. See \i id. at 826 n.7.\i0 Structure is used more often than outcome because it is easier to measure. See id. Outcome, although difficult to assess, is the most important variable. See id. \par\par

n81. See, e.g., Nev. Rev. Stat. 695G.010-.260 (1997); Act of May 29, 1997, ch. 97-159, 1997 Fla. Sess. Law Serv. 1827-35 (West) (to be codified in scattered sections of volumes 18D and 18E of the Florida Statutes); see also \i More States Join Nationwide Trend of Regulating Managed Care Networks, 66 U.S.L.W. 2026\i0 (July 8, 1997) (citing legislative efforts in Connecticut, Colorado, Florida, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, Ohio, Oregon and Texas). \par\par

n82. \22The preeminent \5Baccreditation\5D organization for managed care organizations has become the National Committee for Quality Assurance (NCQA). NCQA is an independent, nonprofit standard-setting organization that surveys and accredits managed care organizations.\22 Furrow, supra note 31, at 458. \par

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n83. See Jost, supra note 79, at 837 (suggesting that developments in information technology and the health care industry would allow for development of managed care report cards that would \22empower consumers (or other purchasers) to make choices among providers\22). \par\par

n84. See Furrow, supra note 31, at 426-27 (arguing that market competition would force MCOs to compete \22on the basis of both quality and cost,\22 but noting that, in practice, \22cost still drives the marketing of these organizations to employers and large groups\22). \par

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Finally, as previously noted, most MCOs operate under a gate-keeping system. n85 Although economically sound, this type of system can dampen some patients' inclinations to be proactive about their own medical care. Because primary care physicians or nurse-practitioners act as gatekeepers to more specialized services, patients who can easily self-diagnose recurring illnesses or conditions may be frustrated by the extra step required to obtain needed tests or specialist consultation. n86 They may, in fact, lose interest in their own care.\par

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n85. See id. at 444, 482-84 (discussing MCOs' use of primary care physicians

as gatekeepers who control costs). \par\par

n86. Similarly, patients \22frequently must obtain approval from the organi
zation to receive many specialty services and nonemergency procedures.\22 Marc
A. Rodwin, Consumer Protection and Managed Care: Issues, Reform Proposals, and
Trade-Offs, \i 32 Hous. L. Rev. 1319, 1331 (1996).\i0 \par
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Clearly, managed care would work better if patients were more involved. In
a system that requires reliance on impersonal alliances of physicians rather th
an on family doctors who are familiar with their patients, a patient who knows
about and understands his own medical needs can greatly assist caregivers. To t
he extent that MCOs try to reduce medical care costs by emphasizing preventive
care, a patient can assist her health care providers by knowing about and under
standing preventive and self-testing measures. Additionally, patients who are k
nowledgeable, active and empowered can better ensure that competition works as
it should in the managed care industry so the good organizations succeed and th
e bad ones fall by the wayside. Patients who feel cut out of the loop are unlik
ely to be so active. \par\par

Without a natural source of consumer power, patients must look to an extern
al source for assistance. The increasingly businesslike tenor of the health car
e industry has fostered a wariness among patients of their physicians. It thus
seems natural for patients to seek to define a class of others who are similarl
y situated - both to try to assert power and to gain strength through numbers.
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B. Patients As Civil Rights Activists\par

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In some ways, the shift toward cost containment in American medicine has force
d patients to depend on themselves to ensure respect for their rights. For exam
ple, one of the bedrock patient rights in the health care system is the right o
f informed consent. n87 It took years for this principle to become fundamental
in medical ethics and law. n88 The shift to managed care is wearing away such r
ights; it would be un- \5B*20\5D derstandable if patients felt a need to
defend them. Class actions are a classic way to preserve and enforce such hard-
won rights. n89\par

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n87. See Tom L. Beauchamp & James F. Childress, Principles of Biomedical Eth
ics 142 (4th ed. 1994). \par\par

n88. See Schuck, supra note 60, at 900. \par\par

n89. Rule 23 underwent major revision in 1966, just in time for lawyers repr
esenting the poor and civil rights lawyers to use it. See Mark C. Weber, Preclu
sion and Procedural Due Process in Rule 23(b)(2) Class Actions, 21 U. Mich. J.L
. Reform 347, 350-51 (1988). Lawyers representing those involved in the antiwar
and environmental movements similarly \22saw class actions as a useful means
to vindicate their clients' rights.\22 Id. at 351. These groups generally used
Rule 23, especially subdivision (b)(2), which provides for judgments binding a
ll class members, to assert that some government or private action contravened
a statute or the Constitution. See id. at 352. In this way, groups of people wh
o previously had been disenfranchised gained power. \par

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I. From Paternalism to Patient Autonomy\par
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At one time, the patient occupied a child-like role in the physician-patient relationship.ⁿ⁹⁰ This may have been due to the specific knowledge and training most physicians possessed.ⁿ⁹¹ It may have stemmed from the technical nature of physicians' expertise, encompassing, as it did and still does, scientific areas most patients find difficult to understand.ⁿ⁹² Perhaps one can attribute it to the mystical status physicians occupied in ancient times.ⁿ⁹³ Gender differences may also impact the relationship when patient and physician are of different genders.ⁿ⁹⁴ Whatever the cause, the medical profession generally once behaved paternalisticallyⁿ⁹⁵ toward patients.\par

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ⁿ⁹⁰. See Jay Katz, *The Silent World of Doctor and Patient* 100-01 (1984). \par
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ⁿ⁹¹. See Starr, *supra* note 32, at 142, 144. \par\par

ⁿ⁹². See *id.* \par\par

ⁿ⁹³. See Richard P. Suddick & Norman O. Harris, *Historical Perspectives of Oral Biology: A Series, I Critical Reviews Oral Biology & Med.* 135, 135 (1990).

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ⁿ⁹⁴. See, e.g., discussion *infra* note 95. \par\par

ⁿ⁹⁵. The use of the male modifier here is purposeful. Although women have always been an integral part of the health care profession, they initially were funneled into nursing, rather than medical school. See Teresa Amott & Julie Matthaei, *Race, Gender, and Work* 121 (1991). The result was an institutionalized 'sexual division of labor'²² between male physicians and female nurses until relatively recently. See *id.* at 121 & 369 n.94 (stating how, in the United States, midwives were replaced by males in the early 1900s). \par

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The paternalism manifested itself in, for example, physicians' decisions to operate on patients against their wishes or to treat patients without informing them of the risks attendant to treatment. In *Schloendorff v. Society of New York Hospital*, one of the most quoted decisions in American medical jurisprudence, the court considered a case in which two physicians allegedly removed a fibroid tumor from a patient without consent.ⁿ⁹⁶ Prior to surgery, the physicians had ascertained that the patient, a woman complaining of a stomach disorder, had a tumor.ⁿ⁹⁷ They could not, however, determine the type of tumor without an examination conducted while the patient was anesthetized.ⁿ⁹⁸ While she was anesthetized, the physicians did more than conduct an examination; they removed the tumor.ⁿ⁹⁹ The patient thereafter suffered from gangrene and other complications.ⁿ¹⁰⁰ She sued, claiming that she had consented to the examination but had specifically withheld consent to the operation.ⁿ¹⁰¹ \par

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ⁿ⁹⁶. 105 N.E. 92, 93 (N.Y. 1914),¹⁰ overruled by *Bing v. Thuring*, 143 N.E.2d 3, 8 (N.Y. 1957).¹⁰ \par\par

ⁿ⁹⁷. See *id.* \par\par

ⁿ⁹⁸. See *id.* \par\par

n99. See id. \par\par
n100. See id. \par\par
n101. See id. \par
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 \5B*21\5D Similarly, in *Canterbury v. Spence*, a nineteen-year-old man complaining of back pain underwent surgery to correct a suspected ruptured disc. n102 After the operation, the patient, due either to the operation or to a fall from his bed, became partially paralyzed and incontinent. n103 His neurosurgeon had informed his mother that the recommended operation was \22not any more \5Bserious\5D than any other operation.\22 n104 In fact, however, there was a risk of paralysis attendant to the operation about which neither the patient nor his mother knew before consenting to it. n105\par
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 n102. \i 464 F.2d 772, 776-77 (D.C. Cir. 1972).\i0 \par\par
 n103. See \i id. at 777.\i0 \par\par
 n104. Id. \par\par
 n105. See \i id. at 778.\i0 \par
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 The law devised a remedy for patients who find themselves in these situations - a remedy that was soon ensconced in medical ethics. n106 Both *Schloendorff* and *Canterbury* are famous for helping to establish patient autonomy and self-determination as concepts physicians are to honor. n107 In *Schloendorff*, the court admonished physicians that, \22Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages.\22 n108 In *Canterbury*, the court recognized a cause of action for the physicians' failure \22adequately to disclose the risks and alternatives of proposed treatment.\22 n109 It explained:\par
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 n106. It is a matter for debate whether law precedes ethics or ethics guides the law. In the area of informed consent, however, it seems that the law guided ethics. \22\5BP\5D paternalism really characterized the practice of medicine for the centuries up to approximately 1965.\22 Robyn Meinhardt & Kenneth W. L. andis, *Bioethics Update: The Changing Nature of the Doctor/Patient Relationship*, \i 16 Whittier L. Rev. 177, 183 (1995)\i0 (citing Mark Siegler, *The Progression of Medicine from Physician Paternalism to Patient Autonomy to Bureaucratic Parsimony*, 145 *Archives Internal Med.* 713 (1985)). The court decided *Schloendorff* in 1914, and scholars have targeted 1957, when \i *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170 (Cal. Dist. Ct. App. 1957),\i0 was decided, as the year in which \22a recognizable, relatively robust form\22 of informed consent emerged. Schuck, *supra* note 60, at 900 (citing Katz, *supra* note 90, at 60). \par\par

 n107. In some respects, the patients in *Schloendorff* and *Canterbury* were lucky. At least they found their way to court and were heard. Less fortunate patients, whose claims went unheard for various reasons, exercised no autonomy in medical settings. See, e.g., Vernellia R. Randall, *Slavery, Segregation and Racis*

m: Trusting the Health Care System Ain't Always Easy! An African American Perspective on Bioethics, 15 St. Louis U. Pub. L. Rev. 191 (1996) (discussing several examples of nonconsensual medical treatment of and experimentation on African Americans).

108. One exception, of course, is in an emergency. See id. Interestingly, the plaintiff did not prevail in Schloendorff because she had sued the hospital, not the physicians. See id. at 94. The court refused to hold the hospital responsible for the physicians' actions because it was not the physicians' employer. See id.

109. 464 F.2d 772, 779 (D.C. Cir. 1972); see also Cobbs v. Grant, 502 P.2d 1, 8 (Cal. 1972) (stating that a doctor's failure to disclose low probability risks to a patient before a treatment can be the basis for a cause of action).

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True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.

Combined, these principles form the bedrock of informed consent doctrine. They also surface in modern cases, in which at least one court has ruled that an MCO has a fiduciary duty to disclose its referral-discouraging financial incentives.

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110. Canterbury, 464 F.2d at 780 (footnotes omitted). The patient in Canterbury thus stated a cause of action because he claimed his physicians had not disclosed the risk of paralysis to him or his mother. See id. at 794.

111. See Paula Walter, The Doctrine of Informed Consent: To Inform or Not to Inform?, 71 St. John's L. Rev. 543, 547 (1997).

112. See Shea v. Esensten, 107 F.3d 625, 629 (8th Cir. 1997).

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2. Patient Autonomy Takes a Back Seat to Management of Care

The structure and incentives of managed care threaten, or at least raise questions regarding, quality of care. Few patients know the full range of facts material to medical decision making. Their realization of this state of affairs, coupled with increased UR and corporate denials of care, has caused patients to lose confidence in the MCO system as a whole. They need to feel as if they have enough power to protect themselves from losing any more important rights

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n113. See Contract Issues and Quality Standards of Managed Care: Hearing Before the Subcomm. on Health and Env't of the House Comm. on Commerce, 104th Cong. . 164-70 (1996) (statement of Dr. Raymond Scalettar, consultant to (and former Commissioner of) the Joint Commission on Accreditation of Healthcare Organizations); see also James Dao, New Pataki Bill Offers Protection to H.M.O. Clients, N.Y. Times, May 9, 1996, at A1 (describing proposals to regulate more tightly the managed care industry as 'responses to rising public concern about the quality of medical care given under some of the state's managed-care plans').

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n114. See Mechanic & Schlesinger, supra note 39, at 1694-95. \par

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Both under the law and as a matter of medical ethics, patients still nominally make informed decisions about their own medical care. It seems more likely now, however, that a patient will be unable to obtain desired treatment for economic reasons. n115 The courts tell physicians to advocate for their individual patients, n116 but the insurers paying the physicians' bills pressure them to advocate for patient populations instead. n117 Specifically, by giving them economic incentives to limit or eliminate tests or referrals that physicians formerly may have routinely authorized, MCOs urge physicians to put societal or plan-wide concerns ahead of individual patient needs. Prospective UR and physicians' economic incentives to limit treatment leave patients out of the decision-making picture in many instances. n118 At one time, MCOs 'B*23'5D even issued 'gag rules' prohibiting physicians from discussing with patients (1) treatments their plans do not cover; and/or (2) their economic arrangements with the organizations. n119\par

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n115. See, e.g., *Shea v. Esenstein*, 107 F.3d 625, 629 (8th Cir. 1997) (holding that financial incentives to discourage physicians from providing essential health care referrals must be disclosed to the patient and failure to do so breaches ERISA's fiduciary duties). Cf. John A. Most, Autonomy and Rights: Dignity and Right, 11 J. Contemp. Health L. & Pol'y 473, 474 (1995) (stating that 'autonomy, as it has become enshrined today, is going to be hard to live with in a time of scarcity'). \par\par

n116. See *Wickline v. State*, 239 Cal. Rptr. 810, 819 (Cal. 1987), which stated, in dicta, that \par

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the physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care. He cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative medical decisions go sour. \par\par

n117. See William M. Sage, 'Health Law 2000': The Legal System and the Changing Health Care Market, Health Aff., Fall 1996, at 9, 11. \par\par

n118. See, e.g., *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1332 (5th Cir. 1992) (stating that a prospective decision-making system influences a patient's options more than a retrospective system, because a patient knows

ws in advance that the plan will reject certain proposed treatments and thus will likely choose the treatment that the plan will cover). \par\par

n119. See generally Ruth Faden, Managed Care and Informed Consent, 7 Kennedy Inst. Ethics J. 377, 377-79 (1997) (reviewing the general forms of gag clauses, how the intolerance of the American public led to state and federal laws prohibiting gag clauses and the ill effect of gag clauses on informed consent due to a decrease in information and options provided to patients). \par\par

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In many states, MCOs need not reveal the presence of such economic incentives to refuse or limit recommendations for care. n120 Recent state and federal legislation, enacted only after public outcry, drastically restricted the ability of MCOs to use undisclosed financial incentives to limit care. n121 The need for such legislation in the first place, however, raises concerns about gutting the doctrine of informed consent. Moreover, the deletion of gag clauses does not mean that physicians believe they can disclose without adverse consequences. n122 Patients operate from limited medical knowledge and must trust their physicians to recommend the best treatment for them. In most cases, a patient cannot know when a physician has failed to mention a treatment option because it is exceedingly expensive and its use would risk reduction of the physician's year-end bonus. n123\par\par

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n120. The federal government and several states have passed regulations and statutes setting forth patients' rights in this regard. See Milt Freudenheim, Pioneering State for Managed Care Considers Change, N.Y. Times, July 14, 1997, at A1. The AMA Council on Ethical and Judicial Affairs says that "as part of the process of giving patients informed consent to treatment, physicians should disclose all available treatment alternatives, regardless of cost, including those potentially beneficial treatments that are not offered under the terms of the plan." Council on Ethical and Judicial Affairs, supra note 71, at 332. \par\par

n121. See, e.g., Ariz. Rev. Stat. Ann. 20-1076(A)(6) (West Supp. 1997) (requiring that a description of any incentives or penalties intended to encourage providers to withhold services or avoid referrals be provided to all enrollees); Ga. Code Ann. 33-21-13(c)(3)(H) (Supp. 1997) (requiring disclosure of any limited utilization incentive plans); Minn. Stat. 72A.20(33) (1995) (prohibiting financial incentives for providers that are "based solely on the number of services denied or referrals not authorized by the provider"); Medicare and Medicaid Programs; Requirements for Physician Incentive Plans in Prepaid Health Care Organizations, 61 Fed. Reg. 13,430, 13,448 (Mar. 27, 1996) (requiring organizations with physician incentive plans to disclose the following to any Medicare beneficiaries who request it: whether the physician incentive plan affects the use of referral services; the type of incentive arrangement; whether a top-loss protection is provided; and a summary of any survey results if the plan was required to conduct a survey). Various states and the AMA have attempted to abolish gag rules. See AMA and States Take Action Against Gag Rules, Healthcare Alert, Spring 1996, at 9, 9; Susan Brink & Nancy Shute, America's Top HMOs: Are HMOs the Right Prescription?, U.S. News & World Rep., Oct. 13, 1997, at 60, 63 (noting that state legislatures passed a record number of laws on managed care in 1997, including state laws banning gag clauses and requiring disclosure of financial incentives); Freudenheim, supra note 120, at A1 (documenting nati

onwide proposals for increased regulation of HMOs); see, e.g., California Leads Backlash to H.M.O.s, N.Y. Times, May 2, 1996, at B8 (describing two proposed initiatives in California seeking to ban gag clauses: the Patient Protection Act of 1996, backed by the California Nurses Association and Ralph Nader, and another led by Service Employees International Union).

n122. See Health, Educ., and Human Servs. Div., U.S. Gen. Accounting Office, Managed Care: Explicit Gag Clauses Not Found in HMO Contracts, But Physician Concerns Remain 2-3 (1997) (Rep. No. 97-175 to Congressional Requesters) (reporting that some physicians and health care lawyers believe that other clauses such as those that bar physicians from disparaging the plan, soliciting patients to join another health plan, or revealing confidential plan information provide more meaningful restrictions on the information physicians convey to their patients).

n123. This example slightly overstates the situation. Withholds and bonuses generally are calculated on the basis of a physician network's statistics rather than on the number of referrals or tests any one physician orders. See Deborah A. Stone, The Doctor as Businessman: The Changing Politics of a Cultural Icon, 22 J. Health Pol. Pol'y & L. 533, 547 (1997). This is not always the case, though. See *id.* (discussing a number of factors some plans use in determining withholds, such as the number of patients hospitalized, tests ordered, referrals to specialists and the amount of drugs prescribed). And even when it is the case, the specter of finances still influences decision making. See Furrow, *supra* note 41, at 148-49; Randall, *supra* note 21, at 34.

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'5B*24'5D Even laws requiring disclosure of financial incentives and in validating gag rules fail to rectify matters. The laws were hard-won; and it is not as if, once alerted to patients' concerns, insurers and MCOs voluntarily changed their practices. De jure change does not mean de facto change will follow.

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n124. After the seminal case of *Brown v. Board of Education*, 347 U.S. 483 (1954), for example, segregation continued throughout the South, and even in parts of the North. For subsequent cases finding segregation in schools, see, for example, *Alvarado v. El Paso Independent School District*, 593 F.2d 577 (5th Cir. 1979); *Dowell v. Board of Education of Oklahoma City Public Schools*, 307 F. Supp. 583 (W.D. Okla. 1970); *Booker v. Board of Education of City of Plainfield, Union County*, 212 A.2d 1 (N.J. 1965). In *Brown*, even a judicial pronouncement could not change social practices and make African-American citizens feel welcome in formerly all-white educational institutions. Legislation attempting to rectify matters in the health care industry similarly will not necessarily make patients feel they are receiving appropriate care simply because the laws are on the books.

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Suspicions about information levels combine with UR and the specter of the corporation overruling physicians' treatment decisions to paint for patients a bleak picture indeed. They know that, in a managed care setting, a doctor's allegiance is divided between her patient and the health plan that employs her. Patients who believe their physicians are health care brokers

likely believe they cannot rely on those physicians to advocate for them. As a result, these patients lose both their ability to participate in medical decision making and their confidence that someone else will have their best interests in mind when making decisions regarding their medical care. Not only are patients personally without power; they also have no one they trust looking out for their interests and exercising power to safeguard their rights. Thus, they may see the need to band together.

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n125. Lu, *supra* note 26, at 538; see also Edmund D. Pellegrino, *Ethics of Managed Care Plans*, 1668, 1668-69 (1994) (noting that under managed care, a physician's loyalties are ... divided among the needs of his or her patients, the needs of all patients served by the system, the plan's economic directives, and his or her own self-interest); Pittman, *supra* note 39, at 371 (noting that physicians will cut back on the information they give to the patient about the nature of the treatment required ... because of the disincentive to recommend standard treatment of which the utilization reviewer may not approve and thus not reimburse the physician for rendering such services).

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n126. See Perdue & Baxley, *supra* note 43, at 27 (using this term rather than labels that connote caregiving when referring to physicians).

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n127. See Alan A. Stone, *Law's Influence on Medicine and Medical Ethics*, 312 *New Eng. J. Med.* 309, 312 (1985), which states:

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It is one thing to entrust your life and health at times of crisis to a physician who is committed to the practical ethics that involves a quest for excellence and who may err on the side of doing too much. It is quite another to entrust your life and health at times of crisis to a physician whose diagnostic and therapeutic interventions are limited by new regulatory constraints or incentives of competitive efficiency that place the provider at economic risk.

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C. Patients As Victims of the System

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Closely related to the view of patients as civil rights activists, patients may believe they need to assert for themselves because they are otherwise unable to achieve justice, especially concerning quality of health care. Both federal and state laws erect barriers to redress patient injury in litigation. First, there is the ERISA vacuum. Americans who obtain health care coverage through employee benefit plans - that is, the majority of Americans - stand a good chance of learning that ERISA, the federal law governing employee welfare and pension plans, preempts any claim they might assert to compel payment for care. On the surface, this does not sound particularly terrible. In reality, however, ERISA claims often inadequately redress the types of injuries patients most often claim in the managed care system.

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n128. See Sage, *supra* note 117, at 12; see also Margaret G. Farrell, *ERISA Preemption and Regulation of Managed Health Care: The Case for Managed Federalism*

m, 23 Am. J.L. & Med. 251, 251-52 (1997) (discussing ERISA's "indeterminate provision for the preemption of state law"); Karen A. Jordan, Tort Liability for Managed Care: The Weakening of ERISA's Protective Shield, 25 J.L. Med. & Ethics 160, 161 (1997) (noting that ERISA's absence of substantive regulation of health plans "creates a regulatory vacuum that often fails to protect plan participants and beneficiaries").

129. See supra note 77.

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UR cases most starkly illustrate this situation. Cases such as *Corcoran v.*

United Healthcare, Inc. 130 and *Cannon v. Group Health Service of Oklahoma, Inc.* 131 have received much attention in academic literature.

132 Most saliently, *Corcoran* and *Cannon* involved deaths arguably caused by payers' refusals to authorize payment for physician-recommended treatment.

In *Corcoran*, a patient and her husband sued for the death of their fetus after their HMO refused to authorize twenty-four-hour-a-day nursing care during a difficult pregnancy.

133 In *Cannon*, the husband of a patient who died of leukemia sued after the patient's HMO delayed authorizing payment for an autologous bone marrow transplant.

134 Although these two cases are noteworthy, they are not unique.

135 Courts have ruled that because the entity performing UR is interpreting an ERISA plan, ERISA preempts any state-law claim a plaintiff tries to assert.

Then, paradoxically, they hold that ERISA does not provide a cause of action to redress this type of injury.

136 Thus, plaintiffs in such cases entirely lack a cause of action.

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130. 965 F.2d 1321 (5th Cir. 1992).

131. 77 F.3d 1270 (10th Cir.), cert. denied, 117 S. Ct. 66 (1996).

132. See, e.g., Jane D. Bailey, ERISA Preemption, 74 Denv. U. L. Rev. 473, 474, 483-84 (1997) (noting that *Cannon* reflects ERISA preemption of state-law even when preemption results in non-recovery for the plaintiff); Kilcullen, supra note 33, at 40 (citing *Corcoran* as an example of a case in which tort claims against HMOs arising out of negligent operation of quality assurance mechanisms may fail); Pittman, supra note 39, at 378-80 (criticizing the *Corcoran* court's reliance on broad U.S. Supreme Court language to extend ERISA's state law preemption to any theory of liability arising during a utilization reviewer's investigation); Randall, supra note 21, at 68 (discussing *Corcoran* with respect to the limitations imposed by ERISA on claims against third-party payers and utilization review organizations); Susan O. Scheutzw, A Framework for Analysis of ERISA Preemption in Suits Against Health Plans and a Call for Reform, 11 J.L. & Health 195, 210 (1996-1997) (contrasting *Cannon* where the plaintiff was denied any recovery due to ERISA preemption with another factually similar case where no ERISA preemption was found and the plaintiff recovered \$89 million); Craig M. Stephens, Note, ERISA: The Inevitable but Unexpected Hurdles of the Plaintiffs Welfare Benefit Plan, 20 Am. J. Trial Advoc. 151, 178-79 (1996) (citing *Cannon* as an example of a case in which a plaintiff was denied any remedy under the law due to ERISA preemption of his health plan).

130. 965 F.2d 1321 (5th Cir. 1992).

131. 77 F.3d 1270 (10th Cir.), cert. denied, 117 S. Ct. 66 (1996).

132. See, e.g., Jane D. Bailey, ERISA Preemption, 74 Denv. U. L. Rev. 473, 474, 483-84 (1997) (noting that *Cannon* reflects ERISA preemption of state-law even when preemption results in non-recovery for the plaintiff); Kilcullen, supra note 33, at 40 (citing *Corcoran* as an example of a case in which tort claims against HMOs arising out of negligent operation of quality assurance mechanisms may fail); Pittman, supra note 39, at 378-80 (criticizing the *Corcoran* court's reliance on broad U.S. Supreme Court language to extend ERISA's state law preemption to any theory of liability arising during a utilization reviewer's investigation); Randall, supra note 21, at 68 (discussing *Corcoran* with respect to the limitations imposed by ERISA on claims against third-party payers and utilization review organizations); Susan O. Scheutzw, A Framework for Analysis of ERISA Preemption in Suits Against Health Plans and a Call for Reform, 11 J.L. & Health 195, 210 (1996-1997) (contrasting *Cannon* where the plaintiff was denied any recovery due to ERISA preemption with another factually similar case where no ERISA preemption was found and the plaintiff recovered \$89 million); Craig M. Stephens, Note, ERISA: The Inevitable but Unexpected Hurdles of the Plaintiffs Welfare Benefit Plan, 20 Am. J. Trial Advoc. 151, 178-79 (1996) (citing *Cannon* as an example of a case in which a plaintiff was denied any remedy under the law due to ERISA preemption of his health plan).

133. See 965 F.2d at 1322-24.

134. See 77 F.3d at 1271-72.

135. See, e.g., *Tolton v. American Biodyne, Inc.*, 48 F.3d 937, 939, 942 (6th Cir. 1995) (bringing wrongful death action based on decedent being

2refused benefits pursuant to utilization review\22); \i Kuhl v. Lincoln Nat'l Health Plan, Inc., 999 F.2d 298, 300 (8th Cir. 1993)\i0 (wrongful death claim based on delayed preauthorization for surgery); cf. \i Settles v. Golden Rule Ins. Co., 927 F.2d 505, 507 (10th Cir. 1991)\i0 (wrongful death action alleging decedent's heart attack was caused by termination of his health insurance coverage). \par\par

n136. In *Corcoran*, the court admitted that its result meant that \22the Corcorans \5Bhad\5D no remedy, state or federal, for what may have been a serious mistake.\22 \i 965 F.2d at 1338.\i0 \par\par

Some courts, in cases not involving UR decisions, have displayed a willingness to rule that ERISA preemption is not so all encompassing, but it remains to be seen (a) whether those courts will reiterate such positions in cases involving UR; and (b) if so, whether other courts will follow them. In \i *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 356 (3d Cir. 1995),\i0 the U.S. Court of Appeals for the Third Circuit ruled that medical negligence cases had to be remanded to the state court from which they had been removed even though the medical care at issue had been provided pursuant to the terms of employee benefits plans. The court held that claims \22merely attack\5Bing\5D the quality of benefits ... received\22 are not claims for benefits under 1132. See *id.*; see also \i *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 649 (1995)\i0 (holding that state statute requiring hospitals to collect surcharges from patients whose commercial insurance coverage is purchased by employee health plans governed by ERISA and surcharges from HMOs insofar as their membership fees are paid by an ERISA plan did not \22relate to\22 employee benefits plans within meaning of ERISA's preemption provision and thus was not preempted); \i *Rice v. Panchal*, 65 F.3d 637, 641 (7th Cir. 1995)\i0 (\22Although the precise boundaries of 502(a)'s complete preemption are not clear, one prerequisite of complete preemption under 502(a) is a plaintiff eligible to bring a claim under that section.\22). See generally *Jordan*, *supra* note 128 (analyzing the methods by which courts are permitting state-law claims under ERISA). \par\par

Dukes and *Rice* presented their courts with \22straight,\22 that is, non-UR-related medical malpractice claims. See \i *Rice*, 65 F.3d at 638-39;\i0 \i *Dukes*, 57 F.3d at 360-61.\i0 Therefore, the holdings do not impact directly on the types of cases discussed in this Article. Moreover, the *Dukes* court explicitly left open the possibility that some quality-of-care issues might present ERISA questions, see \i *id.* at 358,\i0 and that health care providers might be able to establish their own malpractice standards through contract. See \i *id.* at 359.\i0 Each of these possibilities would, of course, leave additional gaps in remedy. See \i *id.* at 359 n.5.\i0 \par\par

n137. The Texas legislature has attempted to provide its citizens a statutory remedy for clinical injury caused by an MCO's failure to \22exercise ordinary care when making health treatment decisions.\22 Act of May 12, 1997, ch. 163, § 1, 1997 Tex. Sess. Law Serv. 318 (West) (to be codified at Tex. Civ. Prac. & Rem. Code Ann. 88.002(a)). A conglomeration of related insurance companies has challenged the law on preemption grounds. See *Compl. for Declaratory J. and Permanent Inj. P 1, Corporate Health Ins., Inc. v. Texas Dep't of Ins.*, No. H-97-2072, (S.D. Tex. filed June 16, 1997) (copy on file with author). \par

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As a result, health care providers and plans enjoy a \22zone of no liability\22 n138 in the law as it is now developing. Courts have interpreted ERISA's broad preemption provisions to foreclose resort to state-law remedies in cases

of injury caused by UR decisions. Yet ERISA's enforcement scheme, although described by the U.S. Supreme Court as 'comprehensive,'¹³⁹ falls far short of providing the complete relief that patients seek.

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n138. See Pittman, *supra* note 39, at 357. \par\par

n139. See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54 (1987).

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For example, patients may wish to allege claims based on fraud, negligent misrepresentation or failure to obtain informed consent¹⁴⁰ against their MCOs for treating professionals' failures to disclose certain aspects of arrangements with providers. If their benefits are provided through an employee benefits plan, however, such 'state-law claims will not succeed; they must proceed under ERISA.¹⁴¹ And under ERISA, damages are limited.¹⁴²

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n140. This list of possible state-law claims is illustrative rather than exhaustive. For a more complete list, see William A. Chittenden III, *Malpractice Liability and Managed Health Care: History and Prognosis*, 26 *Tort & Ins. L.J.* 451, 487, 489 (1991) (discussing a variety of direct and vicarious liability theories for malpractice, as well as 'breach of contract, negligent misrepresentation, intentional infliction of emotional distress, breach of an implied duty of good faith and fair dealing, tortious interference with the physician-patient relationship,'¹⁴¹ and 'fraud'¹⁴²), cited in Stayn, *supra* note 71, at 1706 n.218. \par\par

n141. See, e.g., *Anderson v. Humana, Inc.*, 24 F.3d 889, 891 (7th Cir. 1994) (holding that district court properly dismissed a state-law claim, alleging failure to disclose certain information about the incentive structure, because of federal ERISA preemption). \par\par

n142. Extracontractual damages are generally not available in ERISA lawsuits. See *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 272 n.6 (1993) (cataloging the various courts of appeals' decisions which analyzed the statutory language and legislative history of 502(a)(2)-(3) with respect to damages). \par

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Moreover, such gaps do not exist only in the quality-of-care area. To the extent that patients protest decisions to deny them access to certain types of treatment, ¹⁴³ a plan administrator's decision might be somewhat insulated from judicial review. In *Firestone Tire & Rubber Co. v. Bruch*, the Supreme Court ruled that an ERISA fiduciary's benefits determination is subject to *de novo* review unless the fiduciary has express discretion to construe the plan's terms, ¹⁴⁴ in which case the standard of review could be the more lenient arbitrary and capricious standard. ¹⁴⁵ Since *Bruch*, the exception has effectively swallowed the rule as plans simply revised their documents to accord their administrators the level of discretion necessary to invoke the more lenient standard of review. ¹⁴⁶ Even attempts to argue that the administrator made the decision in bad faith will likely be preempted, subjecting the claim only to remedies available under ERISA. ¹⁴⁷ The result is, if not another liability-free zone of activi

ty, certainly a limited-liability area in which MCOs can operate.\par
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n143. See, e.g., *Harris v. Blue Cross Blue Shield*, 995 F.2d 877, 878 (8th Cir. 1993)\i0 (plaintiff sought treatment for breast cancer); see also *infra* notes 236-38 and accompanying text (discussing the *Harris* case). \par\par

n144. *489 U.S. 101, 115 (1989)*.\i0 \par\par

n145. Cf. *id.* (stating that '22\5Bn\5Deither general principles of trust law nor a concern for impartial decisionmaking ... forecloses parties from agreeing upon a narrower standard of review\22). \par\par

n146. See Paul O'Neil, *Protecting ERISA Health Care Claimants: Practical Assessment of a Neglected Issue in Health Care Reform*, *55 Ohio St. L.J.* 723, 748 (1994).\i0 \par\par

n147. See, e.g., *Schachner v. Blue Cross & Blue Shield*, 77 F.3d 889, 897-98\i0 (6th Cir.), cert denied, *117 S. Ct. 173 (1996)*.\i0 \par
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Finally, even if ERISA does not preempt a patient's claim, it may be difficult to recover under state-law causes of action. State law indicating that MCOs may be liable for injury they cause through UR is in its infancy. n148 One option, for example, is to attempt to hold an HMO or an MCO liable for its own negligence in making UR decisions. To date, however, few courts have explicitly endorsed this theory of liability. In *Wickline v. State*, the California Court of Appeals endorsed in dicta the notion that '22\5Bt\5Dthird party payors of health care services can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost containment mechanisms.\22 n149 In *Wilson v. Blue Cross of Southern California*, the same court went further, actually imposing liability under the '5B*28\5D Wickline scenario. n150 Thus, third-party payers may be liable for injuries caused by negligent UR decisions, but imposition of such liability is rather recent and still relatively rare.\par

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n148. See *supra* notes 66-69 and accompanying text (discussing *Wickline v. State*, the 1986 case suggesting MCO liability for harm caused by UR procedures); *infra* note 149 and accompanying text (same). \par\par

n149. *239 Cal. Rptr. 810, 819 (Ct. App. 1986)*;\i0 see also *Lumley v. Board of Regents for the Univ. of Mich. and Univ. Health Servs. of the Univ. of Mich.*, 544 N.W.2d 692, 697 (Mich. Ct. App. 1996)\i0 (affirming state university hospital's vicarious liability for physician negligence); *Bush v. Dake*, No. 86-2576NM-2, slip op. (Mich. Cir. Ct. Apr. 27, 1989), discussed in *Pittman*, *supra* note 39, at 373-74; *supra* notes 66-69 (noting that the *Wickline* court also seemingly imposed a duty on the treating physician to advocate more forcefully for his patient). \par\par

n150. *271 Cal. Rptr. 876, 884-85 (Ct. App. 1990)*\i0 (holding that the HMO could be liable if the UR decision had been a substantial factor in the patient's death). In cases in which the patient is already ill, liability under *Wilson* may be difficult to establish. \par

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A similar option is to invoke 'enterprise liability,' or to attempt to hold an MCO liable for a physician's medical malpractice through an agency theory. ERISA may not preempt such a claim,¹⁵¹ and various theories of enterprise liability may provide avenues through which to sue conglomerate IDSs for the actions or omissions of their health care professionals.¹⁵² But courts still infrequently recognize such claims,¹⁵³ so these avenues, although promising, offer patients little comfort at present.

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¹⁵¹ The courts have split on this issue. See, e.g., *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482, 1495 (7th Cir. 1996) (holding that ERISA preemption applied in a claim involving vicarious liability claim for negligence of a provider physician and nurse); *Prudential Health Care Plan, Inc. v. Lewis*, No. 95-6255, 1996 WL 77018, at *2 (10th Cir. Feb. 21, 1996) (unpublished disposition) (citing ERISA and ruling that it does not preempt such claims); *Pacificare of Okla., Inc. v. Burrage*, 59 F.3d 151, 153 n.2 (10th Cir. 1995) (same); *Ricci v. Gooberman*, 840 F. Supp. 316, 317-18 (D.N.J. 1993) (holding that state claims stemming from vicarious liability theory are preempted by ERISA because the relationship between a provider and administrative plan relates to the plan). For similar reasoning, but concerning preemption for removal purposes rather than substantive preemption, see *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 361 (3d Cir. 1995) and *Prihoda v. Shpritz*, 914 F. Supp. 113, 117-18 (D. Md. 1996).

¹⁵² 'Enterprise liability' in this sense is merely a term for vicarious liability imposed on the basis of apparent authority or nondelegable duty. See *Jackson v. Powell*, 743 P.2d 1376, 1378-79 (Alaska 1987). But see Killcullen, *supra* note 33, at 47-50 (arguing that enterprise liability claims against health plans should be similar to products liability claims). See generally Diane M. Janulis & Alan D. Hornstein, *Damned If You Do, Damned If You Don't: Hospitals' Liability for Physicians' Malpractice*, 64 Neb. L. Rev. 689, 696-702 (1985) (discussing agency theories of liability against hospitals); William M. Sage et al., *Enterprise Liability for Medical Malpractice and Health Care Quality Improvement*, 20 Am. J.L. & Med. 1, 9-15 (1994) (discussing health plan accountability and improved quality as the benefits of enterprise liability); David D. Griner, Note, *Paying the Piper: Third-Party Payor Liability for Medical Treatment Decisions*, 25 Ga. L. Rev. 861 (1991) (discussing the justification for third-party payer liability).

¹⁵³ See, e.g., *Jackson*, 743 P.2d at 1385 (holding that hospital could not be held vicariously liable for negligence or malpractice of independent contractor/physician under enterprise liability). Recently courts have been more receptive to allowing plaintiffs to sue under an enterprise liability theory. See, e.g., *McEvoy v. Group Health Coop.*, 570 N.W.2d 397, 400 (Wis. 1997) (holding that the common law tort of bad faith does apply to HMOs making out-of-network benefit decisions); *Abraham & Weiler*, *supra* note 35, at 389 (stating that only the Supreme Court of Alaska has held that a hospital's legal responsibility for malpractice by its physicians is non-delegable and nonwaivable).

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Cases involving alleged misrepresentations in or omissions from health care plan documents pose their own problems of proof. In most states, plaintiffs must bear a heavier burden when attempting to prove common law fraud claims.¹⁵⁴

If they should try to enter the federal arena to prove a fraud claim under the Racketeer Influenced and Corrupt Organizations Act (RICO),¹⁵⁵ they will also encounter pleading and proof problems.¹⁵⁶ Further, MCOs could rebut claims that they disclosed insufficient facts in their plan documents by arguing that the standard of care applicable to disclosures in managed care is determined by examining the practices of MCOs themselves. Because they do not usually disclose certain facts, they can argue they are not liable for failing to disclose them in the instances on which the suits are based.¹⁵⁷ This argument resembles the reasoning that sometimes governs the standard of care in medical malpractice cases: physicians need only be as careful as most physicians are.¹⁵⁸ Although circular, at least one noted scholar has recognized the probable assertion, and possible success, of such an argument.¹⁵⁹

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¹⁵⁴ See, e.g., *Clark v. McDaniel*, 546 N.W.2d 590, 592 (Iowa 1996) (holding that fraudulent representation claim must be proven by clear and convincing evidence); *OMI Holdings v. Howell*, 918 P.2d 1274, 1299 (Kan. 1996) (holding that plaintiff must establish fraud by silence with clear and convincing evidence).

¹⁵⁵ *18 U.S.C. 1961* (1968) (1994).

¹⁵⁶ See, e.g., *Teti v. U.S. Healthcare, Inc.*, No. 88-9808, 1989 U.S. Dist. LEXIS 14041 at *4-5, *6-7 (E.D. Pa. Dec. 28, 1989) (unpublished opinion) (sustaining dismissal of plaintiffs' complaint that HMO's alleged concealment of the Compensation Referral Fund from purchasers of health care coverage constituted a pattern of fraudulent nondisclosure that violates RICO because plaintiffs' alleged injury arose from the HMO's alleged misrepresentations and not from any investment of funds by the HMO, and because plaintiffs failed to establish that an "innocent" or "passive" enterprise existed that was injured by the RICO "person").

¹⁵⁷ See Barry R. Furrow, *Litigation over Quality in Managed Care: Individual Malpractice/Negligence Claims in Arbitration and Litigation* (chart distributed at Annual Meeting, American Society of Law, Medicine & Ethics, Boston, Massachusetts, Sept. 29-30, 1995) (on file with author).

¹⁵⁸ See, e.g., *Hurlock v. Park Lane Med. Ctr., Inc.*, 709 S.W.2d 872, 883-84 (Mo. 1986) (holding that defendant-physician need not be judged by the standard of the plaintiff's expert, but merely the standard of the profession at large). See generally Mehlman, *supra* note 51, at 352 (discussing the medical malpractice standard of care as that of a reasonable physician under the circumstances); Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 Wis. L. Rev. 1193, 1213 (noting that physicians establishing their own standard of care is an anomaly in tort law).

¹⁵⁹ See Furrow, *supra* note 157.

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In sum, patient-plaintiff litigation today is an obstacle course. ERISA constitutes a substantial barrier in the path of most patient-plaintiffs. Patients seeking to assert state-law claims, assuming they make it passed the ERISA preemption hurdle, must overcome substantive legal difficulty to recover. Far more than simply losing their place in the decision making matrix, patients today can find little salvation in the law. Understandably, they may attempt to strengthen their arguments any way they can, including voicing them more loudly, as a

group. \par\par
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III. THE CLASS ACTION: PANACEA OR PITFALL?\par

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As discussed in the preceding sections, patient-plaintiffs have many reasons to assert themselves more forcefully. Today's legal and health care climates also have many attributes that facilitate the development of legal attacks along class lines. Already, in fact, in certain types of cases, patients have achieved favorable results by asserting power as a class. This section will examine these cases. It will also examine the drawbacks of the class action approach and identify other ways for patients to achieve and exercise power in the health care arena. It will nevertheless conclude that class action litigation is an appropriate tool for patients trying to gain power in the health care system. It will further advocate that patients use the class action device more frequently in certain situations. \par\par

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A. Classwide Empowerment Can Benefit Patients\par

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Perhaps paradoxically, the same legal doctrines that make it difficult for patients to recover individually can bolster patients' abilities to assert power through the class action device. Partially in response to ERISA decisions, insurers and employers providing health care coverage have altered the managed care industry to increase commonality among cases. n160 Thus, what previously were individual complaints about care now naturally appear as multiple manifestations of a single, more widespread complaint about a corporate practice affecting many patients. Such recharacterization of patients' claims fosters class action treatment.\par

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n160. Cf. Sage, supra note 117, at 12-13 (noting that the '22inevitable convergence'22 of the coverage and delivery of health care is affecting plaintiffs' rights and remedies in the legal system). \par

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1. The Ground Rules\par

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In a class action, a group of plaintiffs sues one or more defendants through one or more representative plaintiffs. n161 Although only the representative plaintiff or plaintiffs play an active role in the litigation, all members of the class either benefit from a favorable outcome or suffer the consequences of a negative one. n162 So that the process is fair, the federal procedural rule governing class actions imposes four basic requirements - numerosity, commonality, typicality and adequacy of representation - on any proposed class. n163 Plaintiffs' attorneys who seek to represent a class first must demonstrate that the class they define n164 meets these four requirements. n165\par

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n161. Alternatively, one or more plaintiffs might attempt to sue a group of defendants simply by naming one or more defendants and asking the court to certify a defendant class. See Fed. R. Civ. P. 23. But see *Henson v. East Lincoln*

n Twp., 814 F.2d 410, 412 (7th Cir. 1987)) (holding that the language of Rule 23 precludes defendant class actions). This Article focuses on cases in which plaintiffs seek to represent a class. \par\par

n162. See Fed. R. Civ. P. 23(c)(3) advisory committee's note, 1966 revision. \par\par

n163. See id. \par\par

n164. Properly defining the class, by describing a group of people who meet all the requirements of Rule 23 and who have suffered injury concrete enough to confer standing, is crucial. The definition can affect justiciability and standing issues in the case itself. See Manual for Complex Litigation, 30.1, at 212 (3d ed. 1995). Further, it determines who will be bound by any judgment that results. See id. 30.14, at 217 (noting that class definition is of 'critical importance'). Both defendants and plaintiff class representatives have cause for concern in this regard. Defendants may seek to define a class broadly in a case they are settling or one in which they are confident of winning to ensure that the settlement or decision will determine many potential plaintiffs' rights. Plaintiffs seeking to represent a class will want not only to ensure an accurate definition of those affected by the conduct at issue but also to prevent intervenors from claiming they should also be class representatives. See, e.g., Doe v. Guardian Life Ins. Co. of Am., No. 89 C 7955, 1992 U.S. Dist. LEXIS 3214, at *58-62 (N.D. Ill. Mar. 19, 1992) (holding that a class including all plan members might not be certified because of conflicts of interest among those plan members who have claims and those who do not). \par\par

n165. Satisfying these four requirements does not end the inquiry, for 'these are necessary but not sufficient conditions for a class action.' 2 Fed. R. Civ. P. 23 advisory committee's note, 1966 revision; see also In re A.H. Robins Co., Inc., 880 F.2d 709, 727-28 (4th Cir. 1989)) (holding that in addition to meeting all four requirements under Rule 23(a), an action must fall into one of three factual classifications of Rule 23(b) for certification as a class action). In addition to finding that a proposed class satisfies Rule 23(a), the court must also certify the class action as coming within one or more of the three categories set forth in Rule 23(b). These are the subsections of the rule that segregate cases according to their factual settings and the legal and practical implications of their decision. See Jack H. Friedenthal et al., Civil Procedure 16.2, at 725-37 (2d ed. 1993). \par

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The first requirement, numerosity, is often easily met in the types of cases in which attorneys seek class certification. There are no absolute numerical limits, n166 but the class defined must be 'so numerous that joinder of all members is impracticable.' n167 The number of class members, their geographic locations and whether they are easily identified may help determine the impracticability of joinder. n168\par

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n166. See General Telephone Co. of the Northwest, Inc. v. Equal Employment Opportunity Comm'n, 446 U.S. 318, 330 (1980).\par\par

n167. Fed. R. Civ. P. 23(a)(1). \par\par

n168. See Hum v. Dericks, 162 F.R.D. 628, 634 (D. Haw. 1995).\par

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To satisfy the second requirement, commonality, a case must present questions of law or fact common to the class.¹⁶⁹ With the exception of classes certified under Rule 23(b)(3),¹⁷⁰ there need not exist many common questions of law or fact to support class certification. The presence of a single common question may support certification of a class, at least for determination of that issue.¹⁷¹

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¹⁶⁹ Fed. R. Civ. P. 23(a)(2).

¹⁷⁰ A court certifying a class under Rule 23(b)(3) must find that common questions predominate and that the class action is a superior method of adjudicating the matters at hand.

¹⁷¹ See *Stirling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988) (stating that a class action lawsuit may be appropriate where a common question, such as defendant's liability, can be determined on a class-wide basis); *Diehl v. Twin Disc, Inc.*, 1995 U.S. Dist. LEXIS 7569, at *8 (N.D. Ill. May 30, 1995) (stating that a class action may proceed based on single common question); *Wadleigh v. Rhone-Poulenc Rorer, Inc.*, 157 F.R.D. 410, 416 (N.D. Ill. 1994) (stating that for a class action in negligence, what defendants knew or should have known would be a common question given that all defendants were privy to the same information); see also *In re General Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 817 (3d Cir. 1995) (finding that Rule 23(a) does not require that class members share every factual and legal predicate to meet the commonality and typicality standards).

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The typicality requirement,¹⁷² intended to measure the extent to which the representative party or parties will truly speak for the other members of the class, tends to merge with the question of commonality.¹⁷³ If there are common questions of law or fact, the claims of the representative parties tend to be typical, at least as to those questions.

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¹⁷² Fed. R. Civ. P. 23(a)(3). A claim is typical if it arises from the same event or practice giving rise to the other class members' claims, on the same legal basis. See *Retired Chicago Police Ass'n v. City of Chicago*, 7 F.3d 584, 596-97 (7th Cir. 1993).

¹⁷³ See *General Telephone Co. of the Southwest v. Falcon*, 457 U.S. 147, 157 n.13 (1982).

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Finally, the representative party or parties must convince the court that she or they will fairly and adequately protect the interests of the class.¹⁷⁴ Thus, representative parties must be part of the class and 'possess the same interest and suffer the same injury' as the class members.¹⁷⁵

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n174. Class certification issues are within the district court's discretion. See *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 100 (1981); *In re American Med. Sys., Inc.*, 75 F.3d 1069, 1083 (6th Cir. 1996); *In re Agent Orange Prod. Liab. Litig.*, 818 F.2d 145, 168 (2d Cir. 1987).

n175. Fed. R. Civ. P. 23(a)(4).

n176. *East Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977) (quoting *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 216 (1974)); see also *Weiss v. York Hosp.*, 745 F.2d 786, 831 (3d Cir. 1984) (upholding district court's finding of liability in favor of class, but not the individual doctor). Courts engage in two inquiries in determining whether named parties will adequately represent a class: first, they determine whether the named parties' interests conflict with those of the class; second, they ensure that class counsel is competent to pursue the case. See *Falcon*, 457 U.S. at 157 n.13. This second requirement also ensures that absent class members receive due process. Cf. *Hansberry v. Lee*, 311 U.S. 32, 45 (1940) (holding that petitioner was deprived of due process of law when trial court ordered petitioner bound to a judgment in an earlier litigation to which the petitioner was not a party).

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2. Fighting Fire with Fire

Patients in some cases can respond to their bleak legal positions by fighting fire with fire. They can capitalize on commonality stemming from the legal status of and the legal theories that could prevail against MCOs. The routinization of health care decision making that has accompanied the industry's increasing consolidation may help patients forge a bond among themselves to increase their own power.

For example, to the extent courts continue to hold that ERISA preempts health care claims, such preemption furthers the argument for class action treatment. One goal of ERISA is to ensure that plans and plan sponsors will be subject to a uniform body of benefits law.¹⁷⁷ To the extent ERISA governs, courts addressing health care claims need not concern themselves with the choice of law issues that often plague class action cases in which plaintiffs are citizens of several states.¹⁷⁸ The existence of national uniform standards for benefits plans, and their governance by a single statute (ERISA), make it more likely that class treatment of questions arising about them will be appropriate. ERISA nullifies arguments against class certification that resemble those raised in products liability cases (that the applicability of state-law defenses such as contributory negligence or assumption of risk differs from case to case, thus precluding classwide treatment of liability issues).¹⁷⁹

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n177. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142 (1990). The Court was discussing congressional intent that employee benefits plans not be subject to a different set of standards in each jurisdiction in which they operated. See *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677-78 (1995).

n178. See, e.g., *In re School Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (noting that when a class action involves the substantive law of many states, it increases the difficulty in resolving them). If ERISA preempts all

l or virtually all state-law claims that can be asserted, then there is no fear of the Delaware settlement criticized in the securities area. See supra note 8 (discussing generally Delaware settlements). This is because there is no state-law cause of action on which a state court could base jurisdiction over a lawsuit and thus over a settlement that involves '22exclusively federal'22 claims such as those existing in securities law. All claims would be governed by ERISA and could be litigated in either state or federal court. Conversely, if ERISA does not preempt all possible state-law causes of action, then the state-court remedies are more, not less, valuable to plaintiffs than their ERISA claims as ERISA is currently drafted and interpreted. See supra note 142 and accompanying text (discussing the unavailability of extracontractual damages under ERISA). Therefore, defendants could not settle more valuable federal claims in the context of suits involving both state claims and federal claims that states cannot adjudicate. \par\par

n179. See, e.g., \i In re General Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 817-18 (3d Cir. 1995)\i0 (admonishing the district court for failing to utilize subclassifications (e.g., statutory schemes or geographic residences) to resolve asserted differences among cases in a class action) (citing \i School Asbestos Litig., 789 F.2d at 1011).\i0 \par

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Similarly, to some extent enterprise liability n180 may encourage the filing of more class actions in the managed care setting. Imposing liability on a plan or institution rather than on a physician for malpractice n181 or for failure to disclose incentives to limit care n182 will force courts, parties and attorneys to focus more on the actions of the entity than on the actions of any individual caregiver. Correspondingly, more persons may be said to be victims of the activity in question, and class actions may arise more naturally. n183\par

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n180. '22Enterprise liability has been described as the tort law equivalent to Brown v. Board of Education.'22 Kilcullen, supra note 33, at 10. \par\par

n181. See, e.g., \i Schleier v. Kaiser Found. Health Plan, 876 F.2d 174, 177-78 (D.C. Cir. 1989);\i0 \i Boyd v. Albert Einstein Med. Ctr., 547 A.2d 1229, 1235 (Pa. Super. 1988).\i0 But see \i Raglin v. HMO Ill., Inc., 595 N.E.2d 153, 156-57 (Ill. App. Ct. 1992)\i0 (holding that HMO was not vicariously liable for negligence of its contracted doctors); \i Chase v. Independent Practice Ass'n, 583 N.E.2d 251, 253-55 (Mass. App. Ct. 1991)\i0 (holding that an independent practice association that contracted for an HMO's services was not vicariously liable for a doctor's negligence); \i Harrel v. Total Health Care, 781 S.W.2d 58, 60 (Mo. 1989)\i0 (applying a statute that formerly exempted health service corporations from liability of physician's malpractice). \par\par

n182. See Mechanic & Schlesinger, supra note 39, at 1694. \par\par
n183. In this sense, the advent of enterprise liability may resemble the initial approval of market share liability in certain products liability cases and the initial acceptance of fraud on the market theories in the securities area. In both of these instances changes in the substantive law paved the way for class certification. See, e.g., \i Blackie v. Barrack, 524 F.2d 891, 905-08 (9th Cir. 1975)\i0 (applying fraud on the market theory in a securities class action); \i Sindell v. Abbott Lab., 607 P.2d 924 (Cal. 1980)\i0 (adopting market share

are liability in diethylstilbestrol cases); *vi Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1078 (N.Y. 1989) *vi0* (same); cf. Miller, *supra* note 8, at 669-76 (arguing that the increase in class actions after 1966 was a function of change s made by Congress, the courts, society and the legal profession). \par

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Moreover, the very structure of the industry, and the way it has responded to the law's development, groups patients into identifiable classes. Patients i ncreasingly receive treatment from IDSs, in which health care delivery and all financial risk and benefit are concentrated in one corporate entity. n184 Recei pt of treatment in larger, integrated settings with a cost-containment focus fo sters conditions ripe for the emergence of class actions. Administrators make m ore decisions on a global basis, in accordance with guidelines that affect larg e groups of people in virtually the same way. n185 An MCO is concerned with bes t serving populations, not individuals, n186 so it seems logical for patients t o respond to perceived problems as a group, rather than as individuals. n187 Fi nally, the larger an entity is, the more likely it is to use form documents and standardized procedures. n188 Filing a class action permits focus on entity-wi de documents or practices rather than on the practice of one subsidiary or affi liate at a time. n189\par

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n184. In 1996, for example, Aetna Life & Casualty Co., a large health insure r, announced plans to purchase a large managed care provider, U.S. Healthcare, Inc. See Leslie Eaton, *Aetna to Buy U.S. Healthcare in Big Move to Managed Care*, N.Y. Times, Apr. 2, 1996, at A1. The merger would create '22the nation's sin gle biggest medical benefits company.'22 *Id.*; see also Milt Freudenheim, *Manag ed Care Empires in the Making*, N.Y. Times, April 2, 1996, at D1 (noting the tre nd of mergers between HMOs or insurance companies and traditional health plans) . News reports at that time indicated that about 58 million people were enrolle d in HMOs and 81 million more were enrolled in '22less tightly disciplined var ieties of managed health care.'22 Milt Freudenheim, *Health Care in the Era of Capitalism*, N.Y. Times, April 7, 1996, at E6 (citing American Association of He alth Plans statistics). \par\par

n185. See, e.g., Sage, *supra* note 117, at 17 (noting that as health care sys tems become more corporate-like, delivery practices become more uniform and les s patient-specific). \par\par

n186. See *id.* at 11. \par\par

n187. See *id.* at 17 (describing the procedural effect of large-scale managed care on the judicial system). \par\par

n188. Cf. Robert H. Jerry, II, *Understanding Insurance Law* 189 (2d ed. 1996) (discussing how standardization '22pervade\5Bs\5D modern commerce\22 and i s '22the rule with regard to insurance contracts,\22 but carries the risk tha t the '22superior\22 party will take advantage of the '22weaker, less inform ed party\22); Daniel T. Ostas & Frank P. Darr, *Redrafting U.C.C. Section 2-207 : An Economic Prescription for the Battle of the Forms*, *vi* 73 *Denv. U. L. Rev.* 403, 404 (1996) *vi0* (discussing how factors such as industrialization, mass-mar kets and the creation of large firms has lead to increased use of standardized forms). \par\par

n189. See Telephone Interview with D. Brian Hufford, Esq. (June 24, 1996) (o n file with author). \par

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\5B*34\5D Finally, employers and other groups providing health care coverage have responded to the ERISA preemption rulings by self-insuring. n190 In other words, a patient who receives health care coverage from an employer likely receives health care for which the employer itself pays, out of funds actuarially determined and segregated in its accounts. n191 The result is a practically pre-defined, natural class of patients and other beneficiaries of the health care provided by any one employer. Patients can and have begun to take advantage of this unity through the class action device.\par

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n190. The interaction of ERISA's three-tiered preemption provisions virtually ensures that state law will not govern claims relating to self-insured plans.

See \i 29 U.S.C. 1144\i0 (1994). \par\par

n191. See generally Employment Benefits Research Institute, Fundamentals of Employee Benefit Programs 37-38 (5th ed. 1997) (discussing how a self-insuring employer \22assumes the financial risk for the health plan\22 and funds a health plan both through segregated accounts and on a pay-as-you-go basis out of general funds). \par

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3. The Pursuit of Quality, Cost and Access\par

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Certain risk-shifting aspects of managed care have led some patients to express their concerns about quality of care through class action lawsuits. n192 Generally, these lawsuits have focused on the structure of MCOs. n193 All of the suits have roots in fraud, through allegations of common-law fraud, n194 violations of state consumer fraud statutes, n195 breach of fiduciary duty under ERISA n196 or civil RICO. n197\par

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n192. See, e.g., \i Anderson v. Humana, Inc., 24 F.3d 889, 891 (7th Cir. 1994)\i0 (rejecting a statutory claim alleging that class was misled into selecting an HMO by fraudulent information); \i Teti v. U.S. Healthcare, Inc., No. 88-9808, 1989 U.S. Dist. LEXIS 14041,\i0 at *3 (E.D. Pa. Dec. 28, 1989) (unpublished opinion) (dismissing fraudulent disclosure claim); \i Class Action Compl. P 8, Weiss v. CIGNA Healthcare, Inc., 972 F. Supp. 748 (S.D.N.Y. 1997)\i0 (No. 96 Civ. 1107 (SHS)) (class action alleging that important medical decisions concerning patients' treatment were not made by the patients' primary care physician, but by MCO \22bureaucrats\22 who are primarily motivated by cost reduction); \i Class Action Compl. P 7, Drolet v. Healthsource, Inc., 968 F. Supp. 757 (D.N.H. 1997)\i0 (No. 96-166-B) (copy on file with author) (alleging health plan's nondisclosure policies affected beneficiaries' ability to make informed medical decisions); Mot. for Class Certification and Request to Exceed Page Limit at 1-2, Lynch v. Intergroup Healthcare Corp., No. CV 94-15694 (Ariz. Super. Ct. filed June 27, 1995) (copy on file with author) (class action alleging that HMO \22intentionally failed to disclose a system of financial incentives given to contracting physician groups to encourage them to reduce the medical services\22 provided to HMO enrollees). \par\par

n193. See supra Part II.A.1 for a discussion of the use of financial incentives to limit care in managed care. Such incentives represent structural attempts to control health care costs, but the plaintiffs' concerns in bringing the cases described are with health care quality. \par\par

n194. See, e.g., \i Anderson, 24 F.3d at 891;\i0 Mot. for Class Certification at 9, Lynch (No. CV 94-15694). \par\par

n195. See, e.g., \i Anderson, 24 F.3d at 892;\i0 Mot. for Class Certification at 9, Lynch (No. CV 94-15694). \par\par

n196. See, e.g., Compl. P 3, Weiss (No. 96-1107); Compl. P 7, Drolet (No. 96-166-B). \par\par

n197. See, e.g., \i Class Action/Jury Trial Demanded at 1, Teti v. U.S. Healthcare, Inc., No. 88-9808, 1989 U.S. Dist. LEXIS 14041\i0 (E.D. Pa. Dec. 28, 1989) (copy on file with author). \par

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In some of these cases, attempts to exercise power through class pursuit of claims failed. In two of them, before considering class certification, the courts dismissed the federal claims and then declined to exercise jurisdiction over the remaining state-law claims. n198 In another, Lynch v. Intergroup Healthcare Corp., the court denied the plaintiffs' motion for class certification and the parties settled the case on an individual basis. n199 Two other cases, Weiss v. CIGNA Healthcare, Inc. and Drolet \5B*35\5D v. Healthsource, Inc., have proceeded, and they display some striking differences from the cases in which class certification failed. n200\par

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n198. See \i Anderson, 24 F.3d at 891-92;\i0 \i Teti, 1989 U.S. Dist. LEXIS 14041,\i0 at *2. \par\par

n199. See Electronic mail message from Ron Kilgard, plaintiffs' attorney (June 9, 1996) (on file with author). Specifically, the court refused to certify a class in part because \22the class representatives had to be current enrollees of \5Bthe defendant MCO\5D.\22 Id. Once the class representative in that case learned of the managed care incentive system, she disenrolled from the defendant MCO. See id. In the court's view, this meant that she would not present claims that were typical of those of the class. See Lynch, sub nom. Askins v. Intergroup Healthcare Corp., No. CV 94-15694, slip op. at 2 (Ariz. Super. Ct. Feb. 28, 1996). Moreover, the court stated that the representative would not fairly and adequately represent the interests of her class. See id. at 1. \par\par

n200. These cases differ both as to the types of claims asserted and as to the types of classes pled. See discussion supra Part III.A.1. \par

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In Lynch, plaintiffs alleged that the defendants, affiliated health care organizations and the owner of their predecessor corporation, misrepresented the type of care their HMO would provide. Specifically, the plaintiffs argued that although the defendants' marketing literature touted \22the highest quality medical care guided by their \5Bprimary care physician's\5D independent medical judgment,\22 n201 the physicians' medical judgment in fact was compromised by a series of financial incentives to limit care. n202 Plaintiffs, who were state employees, sought certification of a class comprised of all state employees e

nrolled in the defendants' HMO from 1992 until the time the suit was filed. n20
3 They sought compensatory damages, an injunction, treble damages under the sta
te RICO statute, n204 punitive damages and attorneys' fees. n205\par
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n201. First Am. Compl. P 14, Lynch (No. CV 94-15694). \par\par
n202. See id. PP 15-19. \par\par
n203. See id. PP 9-11; Mot. for Class Certification at 2, Lynch (No. CV 94-1
5694). \par\par
n204. Ariz. Rev. Stat. Ann. 13-2314 (West 1995). \par\par
n205. See First Am. Compl. PP 14-23, Lynch (No. CV 94-15694). \par
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The Weiss and Drolet cases, by contrast, were more focused. They alleged th
at the defendant managed care entities breached a fiduciary duty owed to benefi
ciaries by offering physicians financial incentives to limit care. n206 They pr
oposed classes of \22all participants and beneficiaries in employee welfare be
nefit plans through which health care benefits are provided by \5Bthe defendan
ts\5D.\22 n207 Furthermore, the plaintiffs asked only for injunctions prevent
ing the defendants from (1) implementing or enforcing undisclosed financial inc
entives to limit care, and (2) disseminating materials containing misrepresenta
tions or omissions. n208\par
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n206. See \i Class Action Compl. P 20, Weiss v. Cigna Healthcare, Inc., 972
F. Supp. 748 (S.D.N.Y. 1997) (No. 96 Civ. 1107);\i0 \i Class Action Compl. P 3
3, Drolet v. Healthsource, Inc., 968 F. Supp. 757 (D.N.H. 1997)\i0 (No. 96-166
-B). Section 502 of ERISA authorizes actions by beneficiaries for breach of fid
uciary duty. See \i 29 U.S.C. 1132\i0 (a)(2) (1994). Section 409 of ERISA more
completely describes the extent of fiduciary duties. See id. 1109; see also \i
Shea v. Esensten, 107 F.3d 625, 627 (8th Cir. 1997)\i0 (holding that plaintiff
's complaint stated a claim for breach of fiduciary duty under ERISA because th
e plan failed to disclose \22behind-the-scenes\22 incentives to reduce care).
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n207. Compl. P 18, Drolet (No. 96-166-B); see Class Action Compl. P 21, Weis
s (No. 96 Civ. 1107 (SHS)). See generally \i Weiss v. Cigna Healthcare, Inc., 9
72 F. Supp. 748 (S.D.N.Y. 1997)\i0 (failing to address class certification iss
ues, but dismissing claims alleging various breaches of fiduciary duty and allo
wing claim alleging breach of fiduciary duty for implementing an undisclosed ga
g-order policy); \i Drolet v. Healthsource, Inc., 968 F. Supp. 757, 759-62 (D.N
.H. 1997)\i0 (denying defendants' motion to dismiss predicated on the argument
that plaintiff failed sufficiently to allege an injury in fact; holding that d
efendant qualifies as a fiduciary; and remanding the case with instructions for
parties to submit a proposal to address class certification issues). \par\par

n208. See Compl. at 28, Weiss (No. 96 Civ. 1107 (SHS)); Compl. at 31-32, Dro
let (No. 96-166-B). Plaintiffs also requested \22restitution of the fair value
of the premiums they have paid \5Bto the defendants\5D for inadequate health
care benefits.\22 Compl. P 79, Weiss (No. 96 Civ. 1107 (SHS)); Compl. P 81, Dr
olet (No. 96-166-B). This claim for monetary relief seems to be the type of \2
2incidental relief\22 that can sometimes be accorded in a 23(b)(2) class actio

n. See, e.g., *vi Rice v. City of Philadelphia*, 66 F.R.D. 17, 20 (E.D. Pa. 1974)
 \i0 (holding that damages may be allowable under 23(b)(2) class action if they
 flow automatically from injunctive relief and are subject to ready calculation
 by uniform standards). \par

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\5B*36\5D Class actions addressing the cost of health care coverage are
 even more prevalent than those airing quality concerns. Unlike class actions c
 oncerning quality of care, which integrally involve MCOs by virtue of the finan
 cial incentives inherent in those organizations' procedures, these class action
 s often present claims that might have been raised as easily in a FFS environme
 nt as in a managed care setting. Indeed, cost-of-coverage claims generally aris
 e from FFS arrangements with defendants such as Blue Cross and Blue Shield corp
 orations. n209 Yet, as will be seen, their emergence is due to recent changes i
 n the health care industry, specifically to the increasing tendency of insurers
 and MCOs to designate certain hospitals or providers as \22preferred provider
 s.\22 n210\par

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n209. See, e.g., *vi Bridges v. Blue Cross and Blue Shield Ass'n*, 935 F. Supp
 . 37, 39 (D.D.C. 1996);\i0 \i McConocha v. Blue Cross and Blue Shield, 898 F.
 Supp. 545, 548 (N.D. Ohio 1995);\i0 \i Ambrose v. Blue Cross & Blue Shield, In
 c., 891 F. Supp. 1153, 1155 (E.D. Va. 1995);\i0 *aff'd*, \i 95 F.3d 41 (4th Cir.
 1996)\i0 (unpublished table decision). \par\par

n210. See Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Ef
 fectiveness Analysis in Health Care*, \i 72 Ind. L.J. 1015, 1017 n.7 (1997).\i0

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Cost-of-coverage class actions, or \22discount cases,\22 have been filed
 in great numbers and have met with mixed success. In the end, they appear to ha
 ve achieved their goals. In these cases, groups of plaintiffs covered by the sa
 me health care insurers n211 have claimed on a variety of grounds that their in
 surers profited at their expense. n212 Generally, the plaintiffs claimed they e
 ach had contracted to pay a deductible, then twenty percent of charges incurred
 over the deductible amount. n213 Each insurer generally had agreed to pay eigh
 ty percent of the post-deductible charges incurred until the insured reached hi
 s annual limit. n214 Insurers, however, negotiated discounts on providers' serv
 ices and did not notify their insureds. n215 Instead, they accepted from their
 insureds twenty percent of regularly charged rates, \5B*37\5D before disc
 ount. n216 The net result: insureds paid more - in some instances far more - th
 an twenty percent of the cost of their care.\par

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n211. In some of the cases, employers joined the class as plaintiffs. See, e
 .g., *vi Forsyth v. Humana, Inc.*, 827 F. Supp. 1498, 1505-09 (D. Nev. 1993)\i0
 (describing the two classes certified as a Premium Payor Class, consisting of \
 '22individual or entities paying all or a portion of the ... premiums\22 durin
 g a specified period, and a Co-Payor Class, consisting of \22employees who obt
 ained health insurance benefits\22 from the defendants). \par\par

n212. See, e.g., *Hoover v. Blue Cross and Blue Shield*, 855 F.2d 1538, 1540 (11th Cir. 1988); *Jhamb v. California Physicians Serv.*, No. C-93-2962, 1996 WL 61281, at *1 (N.D. Cal. Feb. 6, 1996); *Burris v. IASD Health Servs. Corp.*, No. 4-94-CV-10845, 1995 U.S. Dist. LEXIS 15913, at *3 (S.D. Iowa Oct. 2, 1995); *McConocha v. Blue Cross and Blue Shield*, 898 F. Supp. 545, 548 (N.D. Ohio 1995); *Ambrose v. Blue Cross & Blue Shield, Inc.*, 891 F. Supp. 1153, 1155 (E.D. Va. 1995), *aff'd*, 95 F.3d 41 (4th Cir. 1996) (unpublished table decision); *Misch v. Community Mut. Ins. Co.*, 896 F. Supp. 734, 737 (S.D. Ohio 1994); *Everson v. Blue Cross and Blue Shield*, 898 F. Supp. 532, 536 (N.D. Ohio 1994); *Forsyth v. Humana, Inc.*, 827 F. Supp. 1498, 1503 (D. Nev. 1993); *White v. Blue Cross & Blue Shield United, Inc.*, 95 CV 26, 1995 WL 465845, at *2 (Wis. Cir. Ct. July 12, 1995).

n213. See, e.g., *Hoover*, 855 F.2d at 1540; *Jhamb*, 1996 WL 61281, at *1; *Burris*, 1995 U.S. Dist. LEXIS 15913, at *2 (referring to a 20% deductible for nonselect providers only); *McConocha*, 898 F. Supp. at 547; *Ambrose*, 891 F. Supp. at 1155; *Misch*, 896 F. Supp. at 737; *Everson*, 898 F. Supp. at 537; *Forsyth*, 827 F. Supp. at 1501; *White*, 1995 WL 465845, at *1.

n214. See, e.g., *Ambrose*, 891 F. Supp. at 1155; *Misch*, 896 F. Supp. at 734; *Everson*, 898 F. Supp. at 537; *Forsyth*, 827 F. Supp. at 1501; *White*, 1995 WL 465845, at *1.

n215. See, e.g., *Hoover*, 855 F.2d at 1540; *Jhamb*, 1996 WL 61281, at *1; *Burris*, 1995 U.S. Dist. LEXIS 15913, at *3; *McConocha*, 898 F. Supp. at 547; *Ambrose*, 891 F. Supp. at 1155; *Misch*, 896 F. Supp. at 737; *Everson*, 898 F. Supp. at 537; *Forsyth*, 827 F. Supp. at 1501; *White*, 1995 WL 465845, at *1.

n216. See, e.g., *Hoover*, 855 F.2d at 1540; *Jhamb*, 1996 WL 61281, at *1; *McConocha*, 898 F. Supp. at 574; *Ambrose*, 891 F. Supp. at 1155; *Misch*, 896 F. Supp. at 737; *Everson*, 898 F. Supp. at 537; *Forsyth*, 827 F. Supp. at 1501; *White*, 1995 WL 465845, at *1.

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Plaintiff classes have pursued discount cases on various theories. Most often, they have alleged that the insurance companies that negotiated discounts without passing them on breached a fiduciary duty under ERISA n217 or failed to accord patients part of the benefits they were due (a share of the discount). n218 Some, though, either in addition to or instead of the ERISA claims, have alleged state-law claims such as fraud, n219 breach of a common-law fiduciary duty, n220 breach of contract n221 and violations of state statutes requiring disclosure in business dealings. n222 Others have alleged additional federal claims, most significantly violations of RICO n223 and attempted monopolization in violation of the Sherman Act. n224

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n217. See, e.g., *Hoover*, 855 F.2d at 1540; *Burris*, 1995 U.S. Dist. LEXIS 15913, at *4; *McConocha*, 898 F. Supp. at 550; *Misch*, 896 F. Supp. at 737; *Everson*, 898 F. Supp. at 535; *Forsyth*, 827 F. Supp. at 1503.

n218. See 29 U.S.C. 1132(a)(1)(B) (1994) (granting a plan participant the ability to bring a civil action to recover benefits due to him under the plan).

he terms of the plan\22); see, e.g., \i Hoover, 855 F.2d at 1541;\i0 \i McCon
ocha, 898 F. Supp. at 546;\i0 \i Everson, 898 F. Supp. at 535.\i0 \par\par

n219. See, e.g., \i Jhamb, 1996 WL 61281,\i0 at *1; \i White, 1995 WL 46584
5,\i0 at *1. \par\par

n220. See, e.g., \i White, 1995 WL 465845,\i0 at *3. \par\par

n221. See, e.g., \i Jhamb, 1996 WL 61281,\i0 at *1; \i White, 1995 WL 46584
5,\i0 at *1. \par\par

n222. See, e.g., \i Jhamb, 1996 WL 61281,\i0 at *1. \par\par

n223. See, e.g., \i Everson, 898 F. Supp. at 541;\i0 \i Ambrose v. Blue Cro
ss & Blue Shield, Inc., 891 F. Supp. 1153, 1159 (E.D. Va. 1995),\i0 aff'd, \i
95 F.3d 41 (4th Cir. 1996)\i0 (unpublished table decision); \i Forsyth v. Huma
na, Inc., 827 F. Supp. 1498, 1516 (D. Nev. 1993).\i0 \par\par

n224. See, e.g., \i Forsyth, 827 F. Supp. at 1509.\i0 The Sherman Act crimi
nalizes the monopolization or attempted monopolization of any trade or commerce
that affects interstate commerce. See \i 15 U.S.C. 2\i0 (1994). \par
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Courts addressing these cases either have granted class certification or ha
ve disposed of the cases before reaching the class certification issue. In one
representative case, the court quickly n225 certified a class consisting of\par

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n225. It took only five on-line pages to rule that class certification was a
ppropriate. See \i Misch v. Community Mut. Ins. Co., No. C-1-94-428, 1995 U.S.
Dist. LEXIS 5059,\i0 at *1 (S.D. Ohio Feb. 15, 1995). The text of the approved
class notice occupied three additional pages. See id. at *6-8. \par

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all persons who since June 24, 1979 have been participants in employer-sponsor
ed plans underwritten and/or administered by Defendant providing for shared pay
ments for medical and hospital charges and for which charges Defendant paid to
providers less than the percentage designated in such contracts because of Defe
ndant's agreements with such providers. n226\par

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Perhaps more important than the actual outcome of these cases was the eventual
result in the real world of insurance coverage. The filing of the class action
s, and the settlement of many of them for millions of dollars, made the news in
industry publications, n227 likely prompting many more settlements. Taking not
ice, state regulators \5B*38\5D began investigating such insurer practice
s, n228 and the federal Department of Labor launched similar investigations. n2
29 Evidence suggests that the insurance industry has acted to rectify the situa
tion by amending its documents to clarify that insurers may negotiate discounts
on services and whether they will pass those discounts on to insureds. n230\pa

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n226. Id. at *1. \par\par

n227. See, e.g., Colo. Blues to Pay \$3 Million to Settle Copayment Lawsuits, Managed Care Wk., Apr. 24, 1995, available in LEXIS, Market Library, lacnws File (describing how a \$3 million fund was created to settle class action lawsuit brought by those covered under the '22 preferred provider organization' program); Louisiana, Virginia Blues Battle Copayment Issue, Managed Care Wk., June 26, 1995, available in LEXIS, Market Library, lacnws File (describing how Blue Cross and Blue Shield of Louisiana settled a class action lawsuit by agreeing to refund as much as \$5.1 million in excess copayments, while Trigon Blue Cross and Blue Shield of Virginia entered into an agreement with Virginia's attorney general to refund \$23 million in excess copayments and to pay a \$5 million fine); Minnesota Blues Settles Inflated Copayment Lawsuit, Managed Care Wk., July 10, 1995, available in LEXIS, Market Library, lacnws File (describing a \$3.9 million settlement in Minnesota). \par\par

n228. See Kathryn A. Roe, *Whose Discounted Rate Is It?*, Legal Times, Mar. 4, 1996, at S31, S32; Angela Zimm, *State Launches Investigation into Health Insurer Practices*, Daily Rec., Sept. 28, 1995, at 1. \par\par

n229. See Roe, *supra* note 228, at S32. \par\par

n230. For example, the district court in *Everson v. Blue Cross and Blue Shield of Ohio*, 898 F. Supp. 532 (N.D. Ohio 1994), *dis*missed plaintiff Everson's ERISA and RICO claims regarding discounting practices because the contract at issue was unambiguous. See *id.* at 535, 538. The contract said in part: \par

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Some of the Plan's contracts with Providers allow discounts, allowances, incentives, adjustments and settlements. These amounts are for the sole benefit of the Plan and the Plan will retain any payments resulting therefrom. All claims submitted to the Plan will have copayment and deductible amounts calculated according to the Provider's charges for Covered Services without regard to the Plan's discounts, allowances or incentives. \par

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Id. at 537-38 (footnote omitted) (quoting Exhibit C, Group Contract 9.5). At the same time, however, the court permitted companion claims of plaintiffs who apparently had not received the same group contract to proceed. See *id.* at 538, 542, 545 (granting defendant's motion to dismiss as to plaintiff's RICO claim only). \par

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Finally, some plaintiffs have filed cases intended to ensure access to particular types of care for classes of patients. For example, a group of Medicare beneficiaries whose HMOs had denied them service filed a class action lawsuit in federal court in Arizona. n231 They alleged that the federal government had failed adequately to monitor and sanction HMOs serving Medicare patients. n232 In particular, they asserted claims under the Medicare statute and the due process clause of the U.S. Constitution, alleging that the federal Health Care Financing Administration (HCFA) had failed to oversee their HMOs properly. n233 They also charged that HCFA had failed to establish sufficiently speedy procedures for reviewing claim denials and had improperly shifted the burden of proof regarding entitlement to medical services from the HMOs to the patients. n234 The court certified two subclasses: one of Medicare beneficiaries who had unsuccessfully sought review or reconsideration on denial of service, and one of beneficiaries who did not receive adequate notice of their appeal rights, whether or not they ultimately obtained service. n235 \par

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n231. See \i Compl. at 1, *Grijalva v. Shalala*, 946 F. Supp. 747 (D. Ariz. 1996)\i0 (No. 93-711 TUC ACM) (on file with author). \par\par

n232. See id. at 17-18. \par\par

n233. See id. at 17-19. The plaintiffs alleged that their HMOs had denied them service and had failed to provide effective notice of, appeals from, or hearings regarding the denials. See id. \par\par

n234. See id. at 18-19. \par\par

n235. See Comp. at 17, *Grijalva* (No. 93-711 TUC ACM) (certifying a class of \i all persons, nationwide, who were enrolled in Medicare risk-based health maintenance organizations or competitive medical plans during the three years prior to this lawsuit,\i22 with subclasses) (copy on file with author). The plaintiffs prevailed on a significant portion of their case at summary judgment. See \i *Grijalva*, 946 F. Supp. at 750-51.\i0 \par

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\i5B*39\i5D At least one plaintiff has sought class certification in a lawsuit alleging that the plaintiffs' plan and insurance providers improperly refused to authorize high-dose chemotherapy with bone marrow transplantation or peripheral stem cell re-infusion as treatment for breast cancer. n236 Because of the life-threatening situations in which such claims arise, the plaintiff in this case, Patricia Harris, filed an individual motion for a preliminary injunction ordering treatment, which the district court granted. n237 Had class certification been granted, however, the outcome of the case could, on some issues at least, affect treatment choices for thousands of women. n238\par

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n236. See \i *Harris v. Blue Cross Blue Shield*, 995 F.2d 877, 878 (8th Cir. 1993).\i0 It is not apparent from this opinion that the case was filed as a class action, but Sheldon Weinhaus, counsel for the plaintiff, has confirmed that it was. See Telephone Interview with S. Sheldon Weinhaus, Esq. (June 25, 1996).

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n237. See \i *Harris*, 995 F.2d at 879.\i0 A similar case, \i *Henderson v. Bodine Aluminum, Inc.*, 70 F.3d 958 (8th Cir. 1995),\i0 filed by the same counsel, proceeded on an individual rather than a class action basis, in part because of the time factor. See Telephone Interview with Weinhaus, *supra* note 236. While Harris claimed an ERISA violation, see \i 995 F.2d at 878-79,\i0 the Henderson plaintiff claimed violations of the Americans with Disabilities Act (ADA), \i 42 U.S.C. 12101\i0 -12213 (1994); Title VII of the Civil Rights Act of 1964, \i 42 U.S.C. 2000e\i0 (claim available because the plan administrator/sponsor was her employer); and the Missouri Human Rights Act, Mo. Rev. Stat. ch. 213. See Compl. at 11, *Henderson v. Bodine Aluminum, Inc.*, No. 4:95CV01051CAS (E.D. Mo. filed June 13, 1995) (copy on file with author). \par\par

n238. For statistics on the number of women affected by breast cancer, see Denise S. Wolf, Who Should Pay for \i22Experimental\i22 Treatment? Breast Cancer Patients vs. Their Insurers, \i 44 Am. U. L. Rev. 2029, 2031 & n.6 (1995).\i0

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Cases such as Harris's seek to ensure for certain portions of the population access to treatment, or to payment for treatment, depending on how the issue is viewed. n239 Rather than allowing the legislative process to edge toward properly policing MCOs or permitting insurers to lag behind scientific advances, these plaintiffs have filed suits that could, if successful, benefit large classes of similarly situated individuals. n240\par

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n239. In these days of preauthorization of treatment and prospective and concurrent UR, a health care coverage dispute arises not so much over money as over access to the care in question. See \i Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1331 (5th Cir. 1992);\i0 see also Hines v. Sheehan, No. 94-\i P-H, 1995 U.S. Dist. LEXIS 11031,\i0 at *3 (D. Me. July 26, 1995) (class action challenging a Medicaid regulation restricting reimbursement for liquid dietary supplement for patients with acquired immune deficiency syndrome (AIDS)). \par

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n240. See, e.g., Doe v. Guardian Life Ins. Co. of Am., No. 89 C 7955, \i 1992 U.S. Dist. LEXIS 3214,\i0 at *1-3 (N.D. Ill. 1992) (alleging class-wide improper denial of payment for treatment of manic depressive disease). It is also possible to imagine a case involving, for example, patients who want their MCO to provide particular preventive services recommended by the medical profession.

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B. The Benefits of Class-wide Empowerment Outweigh Its Risks\par

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The class action has recently come under attack, for good reason: it is risky.

n241 As a method of empowerment, some say it fails miserably. n242 Against a common law tradition of individual justice, class actions seem administrative or bureaucratic, representing a loss of client control - not to mention decision making by broad brush rather than individual facts. n243 Over-aggressiveness on the part of attorneys on both \i5B*40\i5D sides has in some instances compromised the rights of individual class members. For example, some parties have attempted to bind large groups of persons, some of whom were unaware of their membership in the class, to privately operated administrative claims proceedings to adjudicate future claims. n244 Similarly, many accuse plaintiffs' attorneys of trading on the lucrative nature of class actions for their own personal gain. n245 This is especially true in class action settlements in which class members seeking damages receive only minimal sums or obtain no cash at all. n246 Any assertion that patients could gain power by using the class action device must acknowledge these potential drawbacks.\par

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n241. See David Rosenberg, Class Actions for Mass Torts: Doing Individual Justice by Collective Means, \i 62 Ind. L.J. 561, 564 (1987).\i0 \par\par

n242. See \i id. at 561.\i0 \par\par

n243. See \i id. at 561-62;\i0 see also Stephen C. Yeazell, Collective Litigation as Collective Action, \i 1989 U. Ill. L. Rev. 43\i0 (discussing both advantages and disadvantages of collective litigation, including class actions).

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n244. See, e.g., *Amchem Prods., Inc. v. Windsor*, 117 S. Ct. 2231, 2231 (1997) (discussing situations in which people are unknowingly brought into class action suits). \par\par

n245. See John C. Coffee, Jr., *Class Wars: The Dilemma of the Mass Tort Class Action*, 95 Colum. L. Rev. 1343, 1346 (1995); John C. Coffee, Jr., *The Corruption of the Class Action: The New Technology of Collusion*, 80 Cornell L. Rev. 851, 853 (1995) \Bhereinafter Coffee, *The Corruption of the Class Action*\5D; Coffee, *supra* note 11, at 229-30; Jonathan R. Macey & Geoffrey P. Miller, *The Plaintiffs' Attorney's Role in Class Action and Derivative Litigation: Economic Analysis and Recommendations for Reform*, 58 U. Chi. L. Rev. 1, 1 (1991).\i0 \par\par

n246. See Note, *In-Kind Class Action Settlements*, 109 Harv. L. Rev. 810, 811 (1996).\i0 For an anecdotal example, see Barry Meier, *Math of a Class-Action Suit: 'Winning' \$2.19 Costs \$91.33*, N.Y. Times, Nov. 21, 1995, at A1, which describes how 715,000 current and former mortgage holders brought a class action suit against Bank of Boston for keeping excessive amounts of its customers' money in escrow accounts. While the settlement amounted to \$40 million, the 300,000 current mortgage holders footed the \$8.5 million attorney bill. See *id.*\

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One risk with using the class action is that instead of fearing the power of a patient-plaintiff class, defendants may welcome it in certain cases. Given the strength of the law favoring defendants on certain issues, defendants may concede, or at least fail to fight strenuously, class certification because they expect to win on the merits. This may be especially true of ERISA cases or cases in which ERISA preemption can be argued. n247 Winning such a case against a class would leave a defendant in a much better position than winning against an individual. n248 Barring an unusual circumstance, the absent class members also will be bound by the judgment against the class. n249\par

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n247. See, e.g., *Hayden v. Blue Cross and Blue Shield*, 843 F. Supp. 1427, 1436, 1439 (M.D. Ala. 1994) (deciding a partial summary judgment against class action plaintiffs because of ERISA preemption). \par\par

n248. See John Leubsdorf, *Co-opting the Class Action*, 80 Cornell L. Rev. 1222, 1225 (1995) (stating that one benefit would be shielding defendants from further litigation). \par\par

n249. See Timothy Wilton, *The Class Action in Social Reform Litigation: In Whose Interest?*, 63 B.U. L. Rev. 597, 623 (1983).\i0 \par

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The specter of ERISA invites a second query regarding the advisability of using the class action device. By its very nature, litigation is contentious, and health care litigation is especially complex. Why add even more complexity by advocating time-consuming litigation n250 that maximizes the number of parties involved, creates much judicial work and offers many opportunities for various parties and counsel to argue about multiple layers of issues?\par

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n250. All litigation, of course, is time-consuming, but class actions may be especially so. See, for example, *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 159-61 (1974), where the class certification decision was litigated for eight years and suffered through three trips between the district court and the court of appeals before the Supreme Court ruled on a class notice issue. A majority of the Court warned that courts deciding certification issues should not examine the merits of the case until after certification is determined. See *id.* at 170.

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5B*41 This question can be answered by analogy. Class actions are undeniably appropriate in many cases involving civil rights and discrimination issues arising under federal civil rights statutes, the Americans with Disabilities Act (ADA) or the Age Discrimination in Employment Act. Like cases brought under these statutes, health care litigation can protect and secure the rights of a group of persons over whom some large entity has power. Civil rights cases can involve difficult issues, such as the presence of state action, the statistical development and interpretation of a disparate impact case and interpretation of vague statutory language such as "reasonable accommodation." The substantive complexity of these issues, however, does not provoke arguments that they should not receive class action treatment. Civil rights suits can be contentious, yet no one would say that the issues should not be litigated (assuming other attempts to resolve them have failed). Similarly, such thinking should not deter use of the class action in health care cases. If anything, there is an efficiency justification for requiring only one court to wrestle with the time-consuming and laborious process of making these decisions.

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n251. See, e.g., 42 U.S.C. 1983 (1994) (prohibiting individuals acting under color of state law from depriving anyone of equal protection or equal privileges and immunities); *id.* 1985 (preventing individuals from conspiring to deprive anyone of equal protection or equal privileges and immunities); *id.* 2000e-2 to -3 (guaranteeing equal employment opportunity).

n252. 42 U.S.C. 12101-12213 (1994).

n253. 29 U.S.C. 621-634 (1994). The same legal incentive structures, namely financial recovery for the class, and thus, the attorney, that explain the shortfall of class actions in general may also hinder the private law enforcement function of class action suits in the civil rights context. See, e.g., Coffee, *supra* note 11, at 235-36 (suggesting that entrepreneurial attorneys who predominate in the areas of private antitrust and securities class actions, shareholder derivative actions and mass tort and product liability cases, and who have been responsive to the incentive structure surrounding class actions are beginning to migrate into areas of civil rights, environmental and poverty law where "ideological" attorneys - or those motivated more by political goals than financial gain - have traditionally predominated). But see Noah D. Lebowitz, Comment, An Amendment to Rule 23: Encouraging Class Actions in Section 504 and ADA Employment Discrimination Cases, 30 U.S.F. L. Rev. 477, 478 (1996) (supporting use of class actions in ADA cases, but noting that courts have refused to certify classes in many employment-related cases).

n254. See, e.g., 42 U.S.C. 2000a(d) (1994) (listing the conditions on which discrimination or segregation by an establishment is supported by state

action); id. 2000e-2(k) (1994) (allocating burden of proof in disparate impact cases); id. 12112(b)(5)(A)-(B) (defining discrimination against a disabled but otherwise qualified employee or job applicant to include not accommodating '22 known physical or mental limitations,'22 unless making such accommodations '22 would impose an undue hardship on the operation of the business'22). \par

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A third risk of class action suits is that rather than being a tool of empowerment, they sometimes become simply a method of relegating a number of claims to privately devised administrative claims procedures. Courts recently have scrutinized class certification with particular care in mass torts cases involving both current and future monetary claims. n255 Although the drafters of Rule 23 expressed reservations '5B*42'5D about whether cases arising from '22 mass accidents'22 could be brought as class actions, n256 some courts have certified classes in suits alleging mass, long-term injury. n257 These certifications aroused critical commentary, n258 especially when the parties approached the courts for approval of a fait accompli - that is, when they filed simultaneously a complaint, a motion for class certification and a motion for settlement approval. n259 Consequently, courts are now decertifying classes that, through settlement, seek to legislate privately future claims-resolution procedures n260 and that involve plaintiffs with state-law claims from all fifty states. n261\p

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n255. See, e.g., *Castano v. American Tobacco Co.*, 84 F.3d 734, 752 (5th Cir. 1996)\i0 (decertifying a class of smokers because the collective wisdom of individual juries is necessary before the court will commit the fate of an entire industry or a class of millions to a single jury); *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 626, 635 (3d Cir. 1996)\i0 (decertifying class of people allegedly harmed by asbestos because class did not satisfy adequacy, typicality and predominance prerequisites for certification), *aff'd sub nom.*, *Amchem Prods., Inc. v. Windsor*, 117 S. Ct. 2231, 2252 (1997);\i0 \i In re American Med. Sys., Inc., 75 F.3d 1069, 1085 (6th Cir. 1996)\i0 (decertifying class action status to medical device product liability litigation because individual questions of law and fact predominated over common issues); *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1303-04 (7th Cir. 1995)\i0 (directing district court judge to decertify class of hemophiliacs because of the risk of entrusting potential multibillion dollar liability to a single jury). But see *Ahearn v. Fibreboard Corp.*, 162 F.R.D. 505, 530 (E.D. Tex. 1995)\i0 (approving asbestos settlement); Preliminary Approval for Big GM Settlement, N.Y. Times, July 5, 1996, at A15 (reporting that a Louisiana judge tentatively approved the same type of settlement rejected in *General Motors Corp. Pick-Up and Bloyed*). \par\p

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n256. See Fed. R. Civ. P. 23(b)(3) advisory committee's note, 1966 revision.

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n257. See, e.g., *In re A.H. Robins Co., Inc.*, 880 F.2d 709 (4th Cir. 1989)\i0 (injuries caused by a defective intrauterine device (Dalkon Shield)); *In re Agent Orange Prod. Liab. Litig.*, 818 F.2d 145 (2d Cir. 1987)\i0 (exposure of Vietnam veterans to dioxin in the herbicide Agent Orange). '22'5BT'5D these cases have generally involved the centrality of a single issue.'22 \i Georgine, 83 F.3d at 628.\i0 A.H. Robins concerned a joint tortfeasor issue; Agent Orange involved the military contractor defense. Compare *A.H. Robins*, 880 F.

2d at 741, with Agent Orange, 818 F.2d at 173. See Castano, 84 F.3d at 746 n.23, for citations to cases in which courts denied class certification for strict products liability claims. \par\par

n258. See, e.g., John C. Coffee, Jr., Rethinking the Class Action: A Policy Primer on Reform, 62 Ind. L.J. 625 (1987); see also Georgine, 83 F.3d at 618 n.2 (listing articles). In addition, volume 80, number four of the Cornell Law Review is an entire symposium issue devoted to mass torts class action settlements, settlement class actions and the Georgine case. \par\par

n259. These so-called 'settlement classes' usually establish private dispute resolution procedures whereby members of the class present their evidence of damages for adjudication in an administrative-type proceeding. See Georgine, 83 F.3d at 624-25; In re General Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 778 (3d Cir. 1995) 'Hereinafter GM Pick-Up'. Settlement classes can also arise in cases that were initially genuinely litigated; in these cases, 'settlement class is a device whereby the court postpones formal class certification until the parties have successfully concluded a settlement.' Georgine, 83 F.3d at 625 n.9. \par\par

n260. See, e.g., Georgine, 83 F.3d at 618 (decertifying a class exposed to asbestos and leaving 'legislative solutions to legislative channels' 2). \par\par

n261. See, e.g., Castano, 84 F.3d at 743. One of the court's primary reasons for decertifying the Castano class was its concern over variations among state-law claims at trial. See id.; see also In re Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1300 (7th Cir. 1995) (decertifying a class of hemophiliacs on the grounds that one six-person jury will have the power to decide the fate of an entire industry, making settlement much more likely whether or not the industry is really liable). \par

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These types of cases arise, some argue, because attorneys can profit tremendously from class actions. Class actions put great pressure on defendants to settle even cases they would not settle were only one or two plaintiffs involved.

n262 Settlements, like favorable verdicts, result in fees for attorneys. Necessary cooperation between attorneys who are mainly interested in their fees and defendants' counsel can raise concerns that the plaintiffs' attorneys bargained away the plaintiffs' rights in the name of a quick settlement. n263 This is not a great concern in a traditionally configured case, in which an attorney works closely with a sole client or a small number of clients. In those cases, clients can and often do express strong opinions about settlement proposals throughout the negotiation process. n264 In class actions, however, the named class representatives are often the only individuals with whom class counsel interact and consult. n265 Individual class members learn little, if anything, about the settlement negotiation process until the named parties ask the court to approve the settlement they have reached. n266 Thus, some fear that attorneys, rather than individuals, benefit most in certain types of class actions. n267 Even Congress n268 has displayed an 'inhospitality' to class actions. n269 \par

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n262. See Rhone-Poulenc Rorer, 51 F.3d at 1298-99. \par\par

n263. See, e.g., GM Pick-Up, 55 F.3d at 821 (citing John C. Coffee, J

r., Understanding Plaintiffs' Attorney: The Implications of Economic Theory for Private Enforcement of Law Through Class and Derivative Actions, 86 Colum. L. Rev. 669, 691 (1986), for the conclusion that the unique vulnerability of class actions to collusive settlements benefiting plaintiffs' attorneys rather than clients is the most persuasive reason why class actions produce unsatisfactory results and discussing the potential for financial incentives to prompt attorneys to urge settlements at low figures as an exchange for a high fee award).

n264. Cf. Mary Kay Kane, Of Carrots and Sticks: Evaluating the Role of the Class Action Lawyer, 66 Tex. L. Rev. 385, 389 (1987) (discussing how clients exercise little control over their attorneys in class action suits, and, therefore, class action attorneys make many substantive decisions normally reserved for clients).

n265. See *id.* at 394. The named representatives are selected and may be consulted ... However, the lawyer in the modern class action plays a more dominant role than the traditional adversarial model envisions.

n266. The court must issue notice of, hold a hearing on and approve all class action settlements. See Fed. R. Civ. P. 23(e). This is only one aspect of the way in which a court in a class action case acts as protector of the absentees' interests, in a sort of fiduciary capacity. *GM Pick-Up*, 55 F.3d at 784.

n267. See John C. Coffee, Jr., The Regulation of Entrepreneurial Litigation: Balancing Fairness and Efficiency in the Large Class Action, 54 U. Chi. L. Rev. 877, 883-84 (1987).

n268. See H.R. Conf. Rep. No. 104-369, at 31 (1995), reprinted in 1996 U.S.C.A.N. 730, 730 (indicating that private securities litigation and legislation is in part a response to manipulation by class action lawyers of the clients whom they purportedly represent).

n269. See *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 634 (3d Cir. 1996) (observing that the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737, 737, reflected congressional inhospitality toward class actions, but noting that such statutory reform may implicate due process concerns), *aff'd sub nom.*, *Amchem Prods., Inc. v. Windsor*, 117 S. Ct. 2231, 2252 (1997).

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- The role of the attorney in filing class actions cannot be ignored. It is no secret that the attorney actually controls a class action from inception to conclusion. n270 Class actions could perhaps arise more regularly in the health care setting simply because of the rise of the entrepreneurial attorney. n271 Fees for such cases can be lucrative even when the attorneys, although achieving nominal victories, do little to help the plaintiffs. n272 For these reasons, courts and commentators have begun decrying widespread use of the class action, especially in mass tort litigation. n273

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- n270. See Jean Wegman Burns, Decorative Figureheads: Eliminating Class Representation in Class Actions, 42 Hastings L.J. 165, 181 (1990); Howard M. Downs, Federal Class Actions: Diminished Protection for the Class and the Case for Reform, 73 Neb. L. Rev. 646, 650 (1994). For an example of one company's attempt to curtail the number of class actions filed against it by claimin

g that this was the case, see Robyn Meredith, Chrysler Lawsuit Takes Aim at Class Actions, N.Y. Times, Mar. 27, 1996, at A14. \par\par

n271. See Coffee, supra note 267, at 886. \par\par

n272. This is especially true in cases that settle, as most do. See Coffee, The Corruption of the Class Action, supra note 245, at 854. In consumer cases in which attorneys gained lucrative fees, plaintiff class members sometimes only received certificates for discounts on future purchases of the product in question. See, e.g., \i In re Domestic Air Transp. Antitrust Litig., 148 F.R.D. 297, 320 (N.D. Ga. 1993)\i0 (flight discount certificates); \i New York v. Nintendo of Am., Inc., 775 F. Supp. 676, 679 (S.D.N.Y. 1991)\i0 (five-dollar discount coupon); \i In re Cuisinart Food Processor Antitrust Litig., Nos. H 81-196, H 81-610, H 81-444, H 81-194, H 81-170, H 81-193, H 81-71, H 195, 1983 WL 153,\i0 at *4 (D. Conn. Oct. 24, 1983) (discount coupons with maximum cash value of \$100). Many criticize the current class action system because attorneys are rewarded with excessive fees, often greater than the plaintiffs' awards, from a 'common fund'. See, e.g., Francis E. McGovern, Resolving Mature Mass Tort Litigation, \i 69 B.U. L. Rev. 659, 689 (1989)\i0 (finding that in some mass tort cases, contingency fees range from 30 to 40%); see also \i In re Oracle Sec. Litig., 132 F.R.D. 538, 544 (N.D. Cal. 1990)\i0 (discussing how increasing the percentage of class counsel's share of the recovery could produce attorney windfalls that are unrelated to the quantity or quality of services provided). Cases primarily seeking injunctive relief, however, less often involve huge awards of attorneys' fees; in such cases, fees are usually awarded pursuant to statutes requiring payment of the fees and costs of the prevailing party. See generally Manual for Complex Litigation, supra note 164, 24.11-.13, at 186-93 (describing various fee payment procedures); Coffee, supra note 263, at 678 n.26 (explaining that a 'reasonable fee is based on a percentage of the funds bestowed on the class' (quoting \i Blum v. Stenson, 465 U.S. 886, 900 n.16 (1984))). \i0 \par\par

n273. See Coffee, supra note 263, at 670-71. \par

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Thus, the individual litigant gains at most a sense of voice rather than actual ability to effect change from participating in most class actions. Participating in impact litigation can sometimes lead to individual empowerment, but only outside the courtroom, in meetings or speak-outs at which litigants can express their chagrin in a safe environment. n274 Impact litigation can provide an issue around which class members can congregate to share stories and to become empowered through the telling and commiserating. Within the litigation setting, however, even representative named plaintiffs gain little personal power, for they make fewer decisions and are less involved in the class action itself than most realize. n275 Absent class members, to take concerns one step farther, only learn of their case when their class is certified and they receive a legal notice they may or may not understand. Then they generally hear nothing until the case is decided or settled. n276 When class certification and settlement approval occur in tandem, n277 receipt of the notice is tantamount to learning that you won the lottery - except that the prize may be rather small. n278 Thus, it is difficult to imagine that plaintiff class members, even those serving as class representatives, feel more powerful or believe they are equipped to be more actively involved in health care decision making after participating in a class action lawsuit. The sense of individual empowerment that could prompt patients to take charge of their own health care might not be achieved through this device.\par

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n274. See *White*, supra note 7, at 550-52 (detailing a speak-out of the Alliance of Disability Recipients). \par\par

n275. See *Burns*, supra note 270, at 165. \par\par

n276. See *id.* at 181. \par\par

n277. See *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 633-34 (3d Cir. 1996) (overruling trial court's determination that settlement proposal was fair enough to warrant class notice), *aff'd sub nom.*, *Amchem Products, Inc. v. Windsor*, 117 S. Ct. 2231, 2252 (1997); *Bloued v. General Motors Corp.*, 916 S.W.2d 919 (Tex. 1996) (detailing the problems with such situations).

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n278. See, e.g., *In re General Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 780 (3d Cir. 1995) (determining that each class member would receive a \$1000 certificate to use toward the purchase of a new General Motors vehicle to replace one with a defective gas tank); *Bloued*, 916 S.W.2d at 952 (same). \par

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Another type of empowerment, however, generally does result from use of the class action device: political power. This power, acquired by voicing concerns as a group, can have a positive effect on the health care system. In a way, achieving this type of power through the class action is analogous to using the political process. Some patients have gone the latter route, lobbying for and securing changes in the statutory law. n279 In other settings in which aggrieved parties have sought to flex some muscle, filing class action lawsuits has helped them do so. n280 \par

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n279. Cf. Robert Pear, U.S. Issues Rules for H.M.O.'s in an Effort to Protect Patients, *N.Y. Times*, Mar. 27, 1996, at B8 (discussing a recently enacted law restricting HMO's ability to offer financial incentives that are designed to induce doctors to limit services they provide to patients under Medicare and Medicaid). Inspired mainly by the UR cases, various actors have proposed legislative changes. Texas has attempted to eliminate the ERISA preemption hurdle altogether in certain cases. See *Tex. Ins. Code Ann.* 21.58A-6 to -6A (West Supp. 1998) (setting forth appeals process, including review by independent review organizations). The statute currently faces a court challenge. See *Corporate Health Ins., Inc. v. Texas Dep't of Ins.*, No. H-97-2072 (S.D. Tex. filed June 16, 1997) (copy on file with author) (arguing that this statute will be detrimental to Texans in managed care plans and is preempted by ERISA). On the federal level, the Corcoran court expressed a desire that Congress act. Cf. *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1334 (5th Cir. 1992) (discussing the difficulties created by Congress's broad drafting of ERISA). Some legislative proposals, which as of yet have not succeeded, would amend ERISA to provide plan beneficiaries additional remedies. See, e.g., *Employee Health Insurance Accountability Act of 1997*, S. 1136, 105th Cong. (1997) (providing that preemption rule shall not apply to certain state law actions in order to protect health insurance policy-holders). One commentator has called for what in effect would be an ERISA claim for bad-faith activity with regard to benefits. See O'Neil, supra note 146, at 780. Another has suggested that patients claiming injuries due to

UR decisions should follow an administrative procedure similar to that used to adjudicate workers' compensation disputes in most states. See Randall, *supra* note 21, at 73. Under such a system, patients would waive the right to recover for pain and suffering in exchange for a strict liability standard and, presumably, a quicker path to finality. See *id.* at 76-77. Yet another commentator has suggested alternative dispute resolution. See Stayn, *supra* note 71, at 1709 (calling for a uniform recourse system including both grievance and appeal mechanisms). Indeed, the health care plan proposed by the Clinton administration would have incorporated an alternative dispute resolution system. See The White House Domestic Policy Council, *The President's Health Security Plan* 189 (1993). These are a few of the ideas percolating through the legislative system. \par

n280. See David Pearl, *Legal Issues Arising Out of Medical Provisions for Ethnic Groups*, 4 *Health Matrix* 243, 257 (1994). Commenting on the British health care system, the Honorable David Pearl has opined that revising judicial review of health care decisions '22to enable class actions to be more readily available'22 would help various ethnic groups ensure that the system addresses their needs. See *id.* \par

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The filing of health care class actions has already achieved this end in one respect. The discount cases discussed above ultimately resulted in attracting the attention of government authorities n281 and in prompting at least one insurer to revise the documents explaining its practices. n282 No one can doubt that a substantial change in health care practice resulted from the furor surrounding those lawsuits. They are a prime example of successful impact litigation.\par

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n281. See discussion *supra* notes 228-29. \par\par

n282. Note the different group contracts described in Everson. See *supra* note 230 and accompanying text. Presumably Blue Cross and Blue Shield of Ohio will alter their insurance contracts to protect themselves from further discount lawsuits. See *Everson v. Blue Cross and Blue Shield*, 898 F. Supp. 532, 538-39 (N.D. Ohio 1994) (following the rule applied in several circuits and construing the ambiguous insurance contract in favor of the insured). \par

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The sense of political empowerment that could develop from pursuit of a class action is particularly useful in the health care setting because patients and attorneys are frustrated. The law is more unfavorable than helpful in many respects. n283 For individual patients, litigation may loom as a great inconvenience that ultimately offers only a small chance of monetary recovery on relatively small claims. n284 Studies conducted during the '22malpractice crisis'22 of the 1970s showed that even patients with medical injury likely caused by negligence tended to file suit only in small '5B*46'5D numbers. n285 For some attorneys, attempting to advance patients' rights may seem an exercise in futility. Although individual victories are sweet, they can seem irrelevant in the larger scheme of things, for, in health law, '22the post-hoc, fact-specific nature of court rulings limits their value as precedent and thereby may weaken their impact on various HMOs' actions and decision-making processes.'22 n286 Cla

ss actions offer both representative parties and attorneys a quintessential chance to make a difference.\par

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n283. For one account of the frustration, see generally Michael Jonathan Criefeld, Tilting at HMOs, Cal. Lawyer, Feb. 1997, at 48 (discussing the obstacles to successful plaintiff litigation under ERISA). \par\par

n284. For example, cases such as Weiss and Drolet appear to involve relatively small individual claims. See supra note 208 and accompanying text. \par\par

n285. See, e.g., Dep't of Health, Educ. and Welfare, Report of the Secretary's Commission on Medical Malpractice 12 (1973) (finding that fewer than one court trial was held for every 10 claims in 1970). \par\par

n286. Stayn, supra note 71, at 1708. \par

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In fact, use of the class action for this reason is especially appropriate in health care because aggrieved parties have few viable alternatives. n287 Among its benefits are its flexibility in fashioning remedies and its utility in highlighting problems. n288 The public spotlight, especially on successful suits, n289 can help recruit plaintiffs' lawyers to represent those seeking redress of injuries. n290 Finally, regulatory agencies have been spurred to litigate or to police more actively certain industries after private groups focused attention on problems. n291 Thus, patients may benefit even outside the courtroom by resorting to class action. n292\par

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n287. See Susan J. Hemp, The Right to Remedy: When Should an Abused Nursing Home Resident Sue?, 2 Elder L.J. 195, 219 (1994); see also Trakman, supra note 17, at 617 (discussing an individual plaintiff's limited options to sue large companies due to lack of resources). \par\par

n288. See Hemp, supra note 287, at 219. \par\par

n289. Class actions may be particularly inappropriate when they present immature claims or new, untested theories of liability. See *Castano v. American Tobacco Co.*, 84 F.3d 734, 752 (5th Cir. 1996).\i0 \par\par

n290. See Hemp, supra note 287, at 219. \par\par

n291. See *id.* \par\par

n292. See 1 Newberg & Conte, supra note 20, 5.21, at 5-25; Rodwin, supra note 86, at 1370-72. \par

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Finally, class certification is beneficial because the very nature of health care inhibits litigation. Despite concerns about managed care, the historically based tendency to trust one's caregiver remains strong. Some patients may not realize that caregivers and bill-payers are in many cases now the same entity. In a related vein, because they basically trust their caregivers, some patients may not realize that managed care structures or practices may be injuring them. Even if they realize it, they may choose to abide by the payer's decision rather than seek legal redress because they cannot afford the cost or delay of the litigation process. n293 Those who have enough money to litigate must still

ensure that they have complied with their plan's internal appeal procedures. n2
94 Finally, even if patients realize they have been injured and otherwise would
be willing to litigate, some are afraid of litigating against their \5B*47\5
D health care provider because they are concerned that their HMOs will retali
ate. n295 Hospitalized patients, or others who are receiving institutionalized
care, may be even more likely to fear retaliation because of their dependent st
atus. Group action can help alleviate this fear.\par

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n293. See Stayn, supra note 71, at 1708 n.229. Stayn proposes the developmen
t of a universal complaint and appeal procedure in HMOs. See id. at 1709. \par
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To some, it may seem anomalous to suggest a class action in an environment w
here delays can be injurious. Class actions do take a long time to litigate. Se
e discussion supra note 250. As will be explained, however, for all but the nam
ed plaintiff or plaintiffs, a class action can expeditiously resolve a legal is
sue. See infra notes 304-05 and accompanying text. \par\par

n294. ERISA requires each employee benefits plan to establish an internal ap
peals procedure through which a patient contesting a benefits determination ca
n challenge the plan administrator's decision. See \i 29 U.S.C. 1021\i0 -1022 (
1994). \par\par

n295. See Rodwin, supra note 86, at 1348 (noting patients' reluctance to com
plain both because they might jeopardize their relationships with their physici
ans and MCOs and because complaining \22might even subject the complainant to
reprisal\22). \par\par

Fear of retaliation may also discourage potential class members from express
ing interest in a lawsuit. See 1 Newberg & Conte, supra note 20, 3.06, at 3-35.
Many class members, however, can benefit from a favorable class action judgmen
t by merely standing quietly by, without expressing interest. In a class action
pursued under Federal Rule of Civil Procedure 23(b)(2), for example, all class
members are bound regardless of their opinion of the litigation; there is no o
pportunity to opt out. Thus, class members can benefit despite their fear. \par

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Class certification thus could be ideal for patient-plaintiffs for a number
of reasons. First, as noted, Rule 23 is intended to help provide judicial reme
dies for people whose injuries might otherwise go unredressed. n296 The rule th
us benefits those with little money, especially those with claims whose dollar
values do not exceed their probable litigation costs, those who might not be aw
are of their injuries and those who may resist or fear individual litigation. n
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n296. See supra notes 3-5 and accompanying text. \par\par
n297. See 1 Newberg & Conte, supra note 20, 5.02-.03, at 5-4 to -6, 5.07, at
5-12 to -13. Even critics of the class action, as it is currently structured,
admit that there are situations in which the class action device is used to adv
ance noble goals, providing great benefit to class members. See Leubsdorf, supr
a note 248, at 1223 (remarking that those who speak out against current manipul
ation of the class action by defendants \22are afraid that ... an institution

that lawyers and scholars have shaped to assist the relatively powerless will be turned against the powerless by the powerful²²); see also Coffee, *supra* note 263, at 679 (listing 'obvious advantages' of class actions).

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Most of the current uproar over class action practices has emerged from mass torts and securities law.²⁹⁸ Although similarities exist between those areas and health care litigation, there is no reason to believe dire consequences will result from health care class action certification. Like mass tort class actions, health care class actions involve many 'repeat players.'²⁹⁹ Many suits are related substantively because of the increasing standardization of forms, guidelines, practices and procedures that accompany the industry's aggregation.³⁰⁰ It seems unnecessarily expensive and time-consuming for the same companies to relitigate the same, or nearly the same, issues against the same group of plaintiffs' attorneys.³⁰¹ Like securities litigation, ERISA cases provide attorneys' fees for prevailing plaintiffs' counsel.³⁰²

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²⁹⁸ The Cornell symposium referred to earlier focused on settlement class actions in mass torts cases. The concerns about use of the class action to achieve a Delaware settlement and congressional action regarding class actions arose in the securities area. See discussion *supra* notes 178, 268-69.

²⁹⁹ Coffee, *supra* note 263, at 705.

³⁰⁰ See Jerry, *supra* note 188, at 129, 189; cf. Gary S. Belkin, The New Science of Medicine, 19 J. Health Pol. Pol'y & L. 801, 806-07 (1994) (discussing the increasing reverence among physicians for standardization associated with aggregation).

³⁰¹ The Weiss and Drolet cases, for example, have overlapping counsel. Compare *vi Weiss v. Cigna Healthcare, Inc.*, 972 F. Supp. 748, 750 (S.D.N.Y. 1997) (plaintiff represented by D. Brian Hufford), with *vi Drolet v. Healthsource, Inc.*, 968 F. Supp. 757, 757 (D.N.H. 1997) (same). Similarly, the attorney for the plaintiff in Harris later filed Henderson, an individual lawsuit based on substantially similar facts. See *supra* notes 236-37 and accompanying text.

³⁰² See 29 U.S.C. 1451 (1994) (providing for fee shifting for any prevailing party). Defendants pay prevailing plaintiffs' attorneys' fees as a separate matter rather than basing them on the size of the plaintiffs' award and thus potentially subtracting them from funds intended for the plaintiffs. See *id.*

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The dangers of entrepreneurial attorneys taking over to the detriment of class members need not develop, however. Health care cases involving high-dollar individual damages, such as UR cases, do not lend themselves to class action treatment. The ERISA cases that lend themselves to class actions tend to challenge entity structure and decision-making procedures as they affect cost, access and, to some extent, quality. They do not, however, result in recovery of extracontractual damages.³⁰³ There is less risk that the entrepreneurial attorney will abuse the device in health care cases than may exist, for example, in mass torts or securities cases.

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n303. See 29 U.S.C. 1132(a)(3) (1994); *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1338 (5th Cir. 1992) (holding that extracontractual damages of emotional distress and mental anguish sought by plaintiffs are not recoverable in an ERISA 502(3) action). \par

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Additionally, the class action can deliver relatively speedy justice. It seems counterintuitive to say that litigation can expeditiously resolve a legal issue. For the most part, litigation intrudes on the lives of those involved for longer than they might wish and causes great inconvenience to all parties. But class action litigation can be relatively painless for most class members, other than the named parties. Absent class members may not even encounter the coverage decision or structural issue in question in the litigation until after a decision is rendered. The class action certainly saves such absent class members time in resolving their cases. n304 Additionally, to the extent that class actions increase the pressure on defendants to settle, they resolve the problems raised in a fairly expeditious manner. n305 Many issues, whether decided or settled, are res judicata n306 before patient-plaintiffs even realize they have problems. \par

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n304. The named plaintiff or plaintiffs, however, must endure more delay in obtaining relief than in a normal case. See 1 Newberg & Conte, *supra* note 20, 5.24, at 5-27. \par\par

n305. See Bryant G. Garth, *Studying Civil Litigation Through the Class Action*, 62 Ind. L.J. 497, 501-02 (1987) (summarizing eight reasons why certification is important in settlement negotiations and further reporting the results of a study that revealed that almost 80% of certified class actions in the Northern District of California settled and that 67% of uncertified class actions were either dismissed or won by defendant through summary judgment). Like most litigation, usually class actions settle prior to trial. See *id.* at 501. n30 Certification greatly affects chances of settlement, which indicates that class members gain even more power through use of the class action device than through simple litigation. See *id.* at 502. When settlements accomplish few of the class' goals, however, it is apparent that settlement in the class action context is potentially more dangerous for class members than settlement in the usual litigation context because of the amount of control attorneys have. See Burns, *supra* note 270, at 182-83; Jonathan R. Macey & Geoffrey P. Miller, *The Plaintiffs' Attorney's Role in Class Actions and Derivative Litigation: Economic Analysis and Recommendations for Reform*, 58 U. Chi. L. Rev. 1, 3 (1991); Joan Steinman, *The Effects of Case Consolidation on the Procedural Rights of Litigants: What They Are, What They Might Be, Part II: Non-Jurisdictional Matters*, 42 UCLA L. Rev. 967, 978 (1995). This is especially true if the settlement occurred before the suit was ever filed. See *In re General Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 788 (3d Cir. 1995). \par\par

n306. Res judicata is the term traditionally used to describe two effects: (1) claim preclusion, which is a valid final adjudication of a claim that precludes a second action on that claim or any part of it; and (2) issue preclusion (or collateral estoppel), which is an issue of fact or law, actually litigated a

nd resolved by a valid final judgment that binds the parties in a subsequent action, whether on the same or a different claim. See *Baker v. General Motors Corp.*, 118 S. Ct. 657, 664 n.5 (1998) (citing Restatement (Second) of Judgments 17-19, 27 (1982)).

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Moreover, class actions can advance the public good by affording relief that reaches beyond the circumstances of the suit. In health care litigation, because many recipients of services may not fully comprehend the complexities of their coverage, their care or the incentives offered to physicians, the ability to achieve far-reaching change in a single suit is uniquely attractive. The increased sense of accomplishment may make some attorneys more willing than they otherwise would be to take on such enormously complex cases. Thus, health care class actions can help advance Rule 23's goal of achieving justice by encouraging suits that otherwise might not be brought in this important area.

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n307. When unclaimed funds remain after distribution from judgment or settlement amounts, for example, courts have approved distribution of the money to charity or to other good purposes. See 2 Newberg & Conte, *supra* note 20, 10.19, at 10-50; see also *Powell v. Georgia-Pacific Corp.*, 119 F.3d 703, 707 (8th Cir. 1997) (affirming, in a race discrimination case, deposit of residual settlement moneys in scholarship fund for African Americans); *Nelson v. Greater Gadsden Hous. Auth.*, 802 F.2d 405, 409 (11th Cir. 1986) (approving utilization of unclaimed funds to increase energy efficiency in a case involving utility allowances to tenants in public housing); cf. *New York v. Keds Corp.*, No. 93 CIV. 6708 (CSH), 1994 WL 97201, at *1 (S.D.N.Y. Mar. 21, 1994) (distributing \$5.7 million to charities after price-fixing case involving more than five million pairs of shoes with overcharges of \$1.00 and \$1.25 per pair); *United States v. Exxon Corp.*, 561 F. Supp. 816, 856 (D.D.C.) (establishing energy conservation trust in government escrow account to disburse damages paid by oil company that overcharged customers), *aff'd*, 773 F.2d 1240 (Temp. Emer. Ct. App. 1983).

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n308. See generally Sylvia A. Law, *A Right to Health Care That Cannot Be Taken Away: The Lessons of Twenty-Five Years of Health Care Advocacy*, 61 *Tenn. L. Rev.* 771, 777 (1994) (noting that lawyers must "think in systemic and social terms, not simply about the particular individual case" in order to provide an effective remedy for people seeking health care).

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To the extent plaintiffs seek injunctive relief the class action device may be unnecessary. All members of a losing class of plaintiffs will be bound by a single negative outcome and unable to seek relief again (even, perhaps, by using a different legal theory). This may be an acceptable trade-off in some cases. But in situations in which a positive outcome would require an MCO to redraft its documents or change its rules, one may wonder why an individual suit would not suffice to press the point. Such a positive outcome would affect all those involved, and there would be no concerns about a negative *res judicata* effect on many people.

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n309. See Fed. R. Civ. P. 23(c)(3) advisory committee's note, 1966 revision.

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One response is that filing the case as a class action still permits a more far-reaching recovery than would filing an individual lawsuit. In Weiss, for example, the purported plaintiff class sued CIGNA Healthcare, Inc. (CIGNA), which owns a number of subsidiaries including the one in New York in which the named plaintiff was enrolled. n310 That plaintiff seeks nationwide class certification of all CIGNA enrollees because, she alleges, CIGNA controls the named subsidiaries; produces the marketing materials and plan documents at issue, which presumably are all the same or substantially similar; establishes the policies for each entity; and makes UR decisions. n311 If the named plaintiff were to succeed in an individual lawsuit, she would force CIGNA to revise its documents and policies in New York, but it would be under no legal obligation to do so in any of the other states or districts in which it operates. Nor would CIGNA necessarily be forced to make nationwide changes as a practical matter; depending on how it perceives the effect of its disclosures on its enrollment and public image, it may wish to produce one set of documents and policies for New York and another set for other areas. Success as a CIGNA-wide class, however, would force CIGNA to revise all its documents and policies. n312\par

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n310. See *Class Action Compl. at Ex. A, Weiss v. Cigna Healthcare, Inc.*, 972 F. Supp. 748 (S.D.N.Y. 1997) (No. 96-1107 (SHS)) (naming New York subsidiary as a defendant in lawsuit). \par\par

n311. See *id.* passim. \par\par

n312. See *id.* at 28-29 (seeking injunctions against Cigna that would force revisions of the company's documents, policies and advertisements). \par

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\5B*50\5D Finally, the class action furthers ERISA's goals of ensuring redress of wrongs, and it may strengthen managed care as a whole. Far from being concerned only with uniformity, ERISA's purpose, in part, is to protect the interests of participants in employee benefit plans and their beneficiaries ... by providing for appropriate remedies, sanctions, and ready access to the Federal courts.'22 n313 Congress was concerned with the enforcement of strict fiduciary standards of care in the administration of mainly pension, but also employee benefit, plans when it passed the legislation in 1974. n314 Empowering beneficiaries of those plans, to the extent that it can be achieved through the class action, surely serves this purpose.\par

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n313. 29 U.S.C. 1001(b) (1994); see O'Neil, *supra* note 146, at 723 (stating that this purpose is clear in the Act and its legislative history'22).

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n314. See *Massachusetts Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 152-53 (1984) (Brennan, J., dissenting); see also Pittman, *supra* note 39, at 35

7-61 (stating that ERISA's primary purpose is to protect plan beneficiaries). \

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C. Patient-Plaintiff Class Actions - A Close-Up\par

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As indicated throughout the preceding section, some health care cases are more appropriate for class action treatment than others. In those others, use of the class action device can realize the worst fears of courts and commentators who believe they exploit, and sometimes even injure, innocent litigants. The remainder of this Article explores possible class actions regarding the three contentious areas of any health care system: cost, quality and access. \par\par

Cost concerns may not always involve situations that could give rise to litigation; but when they do, class action treatment seems particularly appropriate. Consumers shopping for the best value in health care coverage probably have few, if any, grounds on which to sue a plan that, in their opinion, offers a poor value. For example, a patient who watches her plan change from providing prescriptions for a flat ten-dollar charge per prescription to requiring that she pay fifty percent of the actual cost of each prescription, likely has no grounds for a lawsuit regarding the increase. These cost issues are matters of the marketplace, with consumers using their power to choose from among plan options offered by their employers as a way to combat perceived inequities or to send a message to the plans. Alternatively, in the employee benefit situation, where the employer negotiates with a health care organization, patients and beneficiaries may wish to voice such concerns to their employers, who then can negotiate with them in mind. \par\par

It is possible, however, to address some cost concerns in the litigation arena. Suits like the discount cases, n315 for example, lend themselves to resolution through class action litigation. Through such suits, patients who pay deductibles under their health care plans can assert claims including, but not limited to, breach of fiduciary duty under ERISA, fraud or violation of state disclosure statutes. n316 Most patients will have few damages, for they likely incurred relatively few medical expenses while covered under the insurance policy in question. Thus, they will have little incentive to bring suit individually. Patients should be informed, however, that they \5B*51\5D are not truly paying the percentage of treatment costs they believe they are paying. n317 The primary focus of such litigation, therefore, is likely to be injunctive relief. This again implies that class action treatment is appropriate, for it minimizes the danger that attorneys undertake the cases at issue solely for large contingency fees.\par

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n315. See discussion supra notes 211-30; see also *Stephenson v. Shalala*, 87 F.3d 350, 354 (9th Cir. 1996) (stating that plaintiff class protested the Medicare Act's lack of a cap on hospital outpatient charges). \par\par

n316. See discussion supra Part III.A.3. \par\par

n317. Insurers now seem to recognize this. Some have begun to explain it in their policies. See *Everson v. Blue Cross and Blue Shield*, 898 F. Supp. 532, 536-38 (N.D. Ohio 1994).\par

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Concerns about quality of care can be divided into those that merit class treatment and those in which individual patient involvement and empowerment is so important that asserting a class action would be counterproductive. The quality class actions described earlier, which focus on the financial incentives to limit care that inhere in the managed care system, represent the former category. n318 Cases alleging personal injury from decisions regarding patient care, in contrast, have thus far properly been filed as individual lawsuits. n319\par

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n318. See cases cited supra note 192. \par\par

n319. See, e.g., *Pacificare of Okla., Inc. v. Burrage*, 59 F.3d 151, 155 (10th Cir. 1995); *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1322-25 (5th Cir. 1992); *Wickline v. State*, 239 Cal. Rptr. 810, 812-17 (Cal. 1987).\i0 \par

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Such cases, involving clinical injury allegedly caused by UR n320 or garden-variety medical malpractice, n321 seem inappropriate for class action treatment even though they give rise to the most horrific stories about the effects of managed care on patients. Issues of causation, the patient's prior condition, and the effect of and reasoning behind the challenged action (refusal to honor a treating physician's recommendation in the UR cases and allegedly negligent care in the garden-variety medical malpractice cases) vary from case to case. Rather than presenting the opportunity for a common solution to a common problem through a single lawsuit, clinical injury cases generally present no common problem. Class treatment therefore should not be attempted, or if attempted, should generally be denied in such cases. n322\par

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n320. See cases and discussion supra notes 130-36. Similar claims arise in the Medicaid system, where they present state action issues. In *Catanzano v. Dowling*, 60 F.3d 113, 115 (2d Cir. 1995), *the plaintiff*, who was disabled, had been prescribed 24-hour-a-day home health care. After a hospitalization, however, a '22fiscal assessment'22 representative at the home health agency ruled that the plaintiff was only entitled to twelve hours of home health care per day. See *id.* The plaintiff challenged the action based on lack of notice and hearing. See *id.* \par\par

n321. See discussion supra note 136. \par\par

n322. Cf. *Hum v. Dericks*, 162 F.R.D. 628, 639-40 (D. Haw. 1995) *(considering lack of informed consent and issues of numerosity and predominance when denying class certification in clinical injury case)*. \par

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Moreover, in clinical injury cases, class action treatment may not inure to the patient-plaintiff's best advantage. Patients in these cases might have suffered horrific injury, even death. To the extent a case is worth a great deal of money, n323 a '5B*52'5D patient-plaintiff will probably recover more from a jury if no other injured party is competing for the spotlight or for a share

re of the reward. Moreover, these types of cases tend to involve sufficient potential recovery to justify individual litigation. Any lack of remedy stems from the need for legislative response, not from a dearth of patient-plaintiffs aware of their injuries, willing to risk litigation and interested in achieving justice whatever the cost. Similarly, in these cases, entrepreneurial attorneys might take a lawsuit simply to receive a percentage of the large potential recovery that may result. Rather than enabling these attorneys to negotiate a settlement compromising the rights of many plaintiffs, each of whom might have been able to recover a large sum, it is probably best to permit these cases to wind their way through the system individually.

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n323. See *Fox v. HealthNet*, No. 219692 (Cal. Super. Ct. 1993) resulting in a verdict for \$89.3 million in damages for the family of a patient who had died of breast cancer. See *Fox v. Health Net*, 29 *Trials Digest* 54, available in *West* 1993 WL 794305, at *1. The patient's HMO, HealthNet, had prospectively denied coverage of high-dose chemotherapy autologous bone marrow transplant (HDC-ABMT). See *Furrow*, *supra* note 31, at 447. Although she eventually received the treatment by paying for it herself, the patient nonetheless died, allegedly because of the delay in receiving treatment caused by the HMO's denial. See *id.* Thus, a decision regarding access to care arguably led to a quality problem, clinical injury and a large award for the decedent's family. See *id.* The case was later settled for five million dollars. See *id.*; Erick Eckhom, \$89 Million Awarded Family Who Sued H.M.O., *N.Y. Times*, Dec. 30, 1993, at A1; Larry Singer, Rationing: Can't Live With It, Can't Live Without It, *Chi. Daily L. Bull.*, Aug. 22, 1994, at 6, available in *Westlaw*, 8/22/94 CHIDLB 6. A UR decision could result in the same sort of expensive clinical injury, as, of course, could garden-variety malpractice cases.

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Clinical injury cases in fact may be the types of cases in which the power and notoriety that accompany the filing of a class action are least needed. Because these cases so vividly illustrate the plight of patients, they may result individually in systemic change through legislative responses. The headlines they generate attract great attention. n324 Thus, in addition to being unlikely to help patients feel individually empowered, class actions based on clinical injury are not even necessary to help patients achieve political power as health care consumers.

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n324. See, e.g., Deborah R. Hensler & Mark Amendment Peterson, Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis, *59 Brook. L. Rev.* 961, 1021 (1993) (discussing how mass media has played a key role in several mass torts by informing injured individuals of the existence and courses of litigation).

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On the other hand, quality-of-care cases challenging providers' failures to disclose economic incentives to physicians to limit care n325 are prime candidates for class action treatment. The failure to disclose referral-discouraging

provisions, bonuses or withholds in physician compensation contracts can constitute a breach of fiduciary duty under ERISA. n326 These cases arise directly from MCOs' attempts to control the costs of individual treatment in order to serve patient populations better. By bringing class action cases, then, patients give MCOs a taste of their own medicine: blanket decision making is inspiring group response.

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n325. See, e.g., *Teti v. U.S. Healthcare, Inc.*, No. 88-9808, 1989 U.S. Dist. LEXIS 14041, at *2-3 (E.D. Pa. Nov. 20, 1989); Mot. for Class Certification and Request to Exceed Page Limit at 7, *Lynch v. Intergroup Healthcare Corp.*, No. CV 94-15694 (Ariz. Super. Ct. filed June 27, 1995).

n326. See, e.g., *Shea v. Esenstein*, 107 F.3d 625, 628 (8th Cir. 1997) (finding breach of ERISA's fiduciary duty when an HMO's financial incentives to discourage a doctor from providing essential health care referrals were not disclosed).

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Disclosure cases also offer an opportunity to increase the amount of quality-related information available to employers and potential beneficiaries who are choosing health care plans. Requiring increased disclosures regarding financial incentives to limit care will enable beneficiaries to judge better the worth of each health care plan they may choose. Those plans that best safeguard patients' interests, as judged in part through this newly disclosed information, should prevail in the marketplace. The result will be a more effective and more trusted managed care system.

Moreover, disclosure cases appear to be strong both substantively and equitably. Even in states without statutes specifically addressing this issue, there is a strong argument that physicians, as part of their duty to disclose all relevant information to ensure truly informed consent, must disclose to patients the presence of financial incentives to limit care. n327 Thus, patients in managed care plans who have received care but have not realized their physicians' financial conflicts probably risk little by banding together as a class to attempt to rectify the situation.

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n327. See, e.g., *Shea*, 107 F.3d at 628-29. As discussed earlier, the AMA has stated that such disclosures are ethically required. See supra notes 120-21. Further, an MCO failing to make such disclosures in the context of providing Medicare and Medicaid care now would violate the federal regulations previously discussed. See supra notes 121-22. See generally Andrew Ruskin, *Capitation: The Legal Implications of Using Capitation to Affect Physician Decision-Making Processes*, 13 J. Contemp. Health L. & Pol'y 391, 400-06 (1997) (discussing the impact of capitation on physician decision making and legal theories for holding an MCO liable for physician misconduct).

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In these types of cases, many class members individually may not be able to identify how they have been harmed. As a class, however, each member clearly has received medical insurance of lesser value than that for which he contracted

. n328 Individually, absent clinical injury, any one patient will be unlikely to care enough to bring suit. Yet the situation should be rectified before clinical injury results. This is the classic class action situation.\par

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n328. These class members received medical insurance for care provided by physicians operating under conflicts of interest, which is likely to be priced lower than the medical insurance they thought they were getting - insurance covering care provided by physicians not operating under such conflicts. See Mot. for Class Certification at 9-10, 17-18, Lynch (No. CV 94-15694). \par

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Finally, there are cases that would seek to ensure access to health care, or at least a fair shot at access to health care, for some segment of the population. In this category, cases that involve attempts to gain approval of, and thus payment for, treatments that the payer considers experimental or investigational arguably could achieve political good if they were successful on a class-wide basis. They seem unlikely to gain class certification easily, however, and could lead to possible abuses by the entrepreneurial attorney. Class treatment thus seems inappropriate. On the other hand, it is relatively easy to conceptualize class actions alleging genetic discrimination or other concerns that are less related to each individual class member's condition. These types of access cases, which could, for example, rest on federal anti-discrimination law, may be well-suited for class action treatment. Similarly, class actions that focus on procedural issues regarding the provision and payment of medical care, such as *Grijalva v. Shalala*, n329 clearly are appropriate for class action treatment and can do a great deal to achieve reform.\par

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n329. No. 93-711 TUC ACM (D. Ariz. filed Nov. 15, 1993); see also *supra* note 231-35 and accompanying text (discussing the *Grijalva* case). \par

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The experimental or investigational treatment cases involve high costs, n330 often marginal outcomes and many patients. They vary in terms of stage of disease advancement, past medical history and current medical condition. They also, however, involve interpretation of insurance contracts, which are known to be highly standardized form contracts. n331 Thus, a class action on certain issues with subclasses encompassing patients with different types or stages of cancer and various categories of insurance policies may be possible. In one non-health-care case, *School Asbestos Litigation*, various manufacturers claimed that legal and factual differences among individual cases encompassed within an asbestos class action should preclude certification. n332 The court required the parties to reduce the various types of cases to a small number of patterns, and then certified subclasses within each pattern. n333 Similar treatment is possible in the experimental or investigational treatment cases.\par

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n330. See, e.g., *Henderson v. Bodine Aluminum, Inc.*, 70 F.3d 958, 960 (8th Cir. 1995).

h Cir. 1995)).¹⁰ This case involved a health plan's refusal to cover the '22e xperimental'22 treatment, HDC-ABMT, for breast cancer, costing substantially more than the standard chemotherapy. See *id.* The cost of HDC-ABMT can exceed \$100,000 per patient. See Wolf, *supra* note 238, at 2040. \par\par

n331. '22'5BC'5Dclaims arising out of form contracts are particularly appropriate for class action treatment.'22 \i Hoban v. USLife Credit Life Ins. Co., 163 F.R.D. 509, 513 (N.D. Ill. 1995)\i0 (certifying class, in part, because of court's view that class resolution of dispute over fraudulent practices with regard to second mortgage insurance policies would be '22more efficient than to allow a multitude of individual adjudications over a form insurance certificate'22); cf. \i Chicken Delight, Inc. v. Harris, 412 F.2d 830, 831 (9th Cir. 1969)\i0 (certifying class in regards to a challenge to provisions in a standard franchise agreement, but not to the alleged retail pricing issue). Insurance documents, and by extension the managed care documents used by the newer integrated corporations, are notoriously standardized. In cases involving comprehensive general liability policies, for example, courts and parties have referred to versions of each standardized revision of the form policy in shorthand. See, e.g., \i Chemical Leaman Tank Lines, Inc. v. Aetna Cas. & Sur. Co., 89 F.3d 976, 982 (3d Cir. 1996)\i0 (referring to general liability policies by reference to the particular type of exclusion clause it contained). \par\par

Sometimes insurers argue that common questions do not predominate because various employers differ in their understandings of the plan documents. In these cases, insurers attack commonality by saying each employer must testify about its understanding of the meaning of the insurance contract or health care coverage documents. See *Doe v. Guardian Life Ins. Co.*, No. 89 C 7955, \i 1992 U.S. Dist. LEXIS 3214,\i0 at *42-43, *46 (N.D. Ill. Mar. 19, 1992). Even if this is a valid argument, which may depend on the claims asserted and the governing law, it in no way diminishes the utility of the class action device to determine some issues, such as the meaning of the disputed provision. Cf. Fed. R. Civ. P. 23(c)(4)(A) (authorizing class certification for only certain issues). \par\par

n332. See \i In re School Asbestos Litig., 789 F.2d 996, 1009 (3d Cir. 1986) \i0 \par\par

n333. See \i *id.* at 1010.\i0 Plaintiffs' counsel had '22undertaken an extensive analysis of the variances in products liability among the jurisdictions'22 and had created four categories into which all applicable state legal rules could be placed. *Id.* Although skeptical, the appellate court did approve. See *id.*; see also *Diehl v. Twin Disc, Inc.*, No. 94-\i C50031, 1995 U.S. Dist. LEXIS 7569,\i0 at *8-9 (N.D. Ill. May 30, 1995) (holding, in ERISA case alleging unlawful modification of health insurance benefits, the fact that class members were covered under six separate insurance agreements was not a barrier to certification; '22this inquiry is not necessary to determine the question of liability, rather it is necessary to determine the amount of damages '5BT'5Dhe need to determine individual questions after the resolution of common questions does not preclude a finding of commonality.'22). \par

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Whether a court will certify subclasses in health care cases is, however, far from certain. Whether it should do so is even more debatable. In *School Asbestos Litigation*, the court was dealing with the asbestos crisis, which flooded federal and state courts over a period of years. n334 The crisis reached such epic proportions that in 1991, the Judicial Panel on Multidistrict Litigation reversed earlier decisions refusing multidistrict treatment n335 and required th

e consolidation of all asbestos personal injury cases in one court in the Eastern District of Pennsylvania. n336 In School Asbestos Litigation itself, which involved property damage rather than personal injuries, the court termed '22the asbestos scene'22 '22an unparalleled situation in American tort law.'22 n337 Whether subclassing in a similar fashion would pass muster in cases in an area in which the threat of litigation has not reached crisis proportions remains to be seen. This type of certification seems particularly questionable in experimental treatment cases, in which personal injury damages and incentives to sue on an individual basis are high.\par

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n334. See \i School Asbestos Litig., 879 F.2d at 1000.\i0 \par\par
n335. See \i In re Asbestos Prods. Liab. Litig. (No. VI), 771 F. Supp. 415, 417 & n.4 (J.P.M.L. 1991).\i0 \par\par
n336. See \i id. at 424.\i0 \par\par
n337. \i 789 F.2d at 1000;\i0 see also \i Amchem Prods., Inc. v. Windsor, 117 S. Ct. 2231, 2253 (1997)\i0 (Breyer, J., concurring and dissenting) (discussing the importance of settlement to asbestos litigation, overlooked by the majority, due to the number of workers exposed and the delays, inefficiency and inconsistent recoveries in the resulting lawsuits). \par

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'5B*55'5D Cases that seek access to health care for other categories of patients also may be alleged as class actions. A current example may be genetic discrimination. n338 Scientists have determined that a person's genetic makeup can indicate whether she is likely to develop diseases such as Alzheimer's, sickle cell anemia, breast cancer, colon cancer, Huntington's disease and cystic fibrosis. n339 Some patients undergo testing to determine whether they have the genes that could lead to development of these diseases. n340 Citing this information and claiming increased risk, insurers sometimes refuse to insure persons who have these predispositions. n341\par

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n338. Genetic discrimination is '22the denial of rights, privileges or opportunities on the basis of information obtained from genetically-based diagnostic and prognostic tests.'22 Larry Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, \i 117 Am. J.L. & Med. 109, 110 (1991).\i0 See generally National Human Genome Research Institute, Department of Health & Human Servs., Health Insurance in the Age of Genetics (July 1997) <<http://www.nhgri.nih.gov/NEWS/Insurance>> (discussing the expanding use of genetic information to deny health insurance coverage). \par\par

n339. See Office of Tech. Assessment, U.S. Congress, Genetic Monitoring and Screening in the Workplace 83-94 (1990); Gostin, supra note 338, at 110-11. \par\par
n340. Those with a genetic predisposition are, to varying degrees, either more likely or certain to develop a disease at some point. Most disease genes identified so far are '22single gene'22 diseases, in which the presence of a single mutated (or '22misspelled'22) gene can cause disease. See Reauthorization of the National Institutes of Health: Hearings Before the Senate Comm. on Labor and Human Resources, 104th Cong. 72 (1996) (statement of Francis S. Collins,

Richard D. Klausner and Kenneth Olden). Other diseases, such as certain cancers, diabetes and Alzheimer's disease, are much more complex and may involve the interactions of many genes as well as environmental factors. Id. \par

341. Researchers at Harvard Medical School have conducted a survey indicating that a fair amount of genetic discrimination occurs. See Susan Ince, Predictive Testing: A Bite of the Apple, Harv. Health Letter, June 1995, at 3, 4. See generally Karen H. Rothenberg, Genetic Information and Health Insurance: State Legislative Approaches, 23 J.L. Med & Ethics 312 (detailing state efforts to prohibit such genetic discrimination). Insurers or employers who self-insure have also been known to change the terms of benefits plans to limit coverage once they learn that an employee has a high-cost illness. See, e.g., McGann v. H&H Music Co., 946 F.2d 401, 404 (5th Cir. 1991) (noting that because employee welfare benefits are not vested, employer could reduce lifetime benefit for persons suffering from AIDS). For criticism of rulings such as McGann, see generally Carl A. Greci, Note, Use It and Lose It: The Employer's Absolute Right Under ERISA Section 510 to Engage in Post-Claim Modifications of Employee Welfare Benefit Plans, 68 Ind. L.J. 177 (1992). \par

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Patients with predispositions to disease may have claims under ERISA, in the form of claims that an MCO has breached its agreement to provide all necessary treatments, 342 the ADA, 343 or 42 U.S.C. 1983, 344 to name a few. 345 Obviously, these cases involve very high dollar values, because patients without health insurance may have to pay extremely high health care costs themselves. Similar to the experimental or investigational treatment cases, however, these cases will almost certainly involve many common issues, such as the interpretation of the ADA as applied to categories of plans. At the very least, it would seem that classes of patients with similar or identical plans could proceed to a liability determination, leaving individual damages determinations for later proceedings or settlement. 346 \par

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342. Such ERISA claims can be raised under ERISA section 514, see 29 U.S.C. 1144 (1994) (authorizing actions to recover benefits due), or ERISA section 510, see 29 U.S.C. 1140 (prohibiting discrimination in the provision or attainment of benefits). \par

343. 42 U.S.C. 12101-12212 (1994). The ADA contains a provision exempting underwriting, but says nothing specific about genetics. See Susan M. Wolf, Beyond Genetic Discrimination: Toward the Broader Harm of Geneticism, 23 J.L. Med. & Ethics 345, 352 n.14 (1995) (discussing the inadequacy of an antidiscrimination approach to genetics); see also Gostin, supra note 338, at 109 (noting that the ADA may not provide sufficient protection for employees and insureds from genetic discrimination). \par

344. Section 1983 cases, which must involve some state action, may allege deprivation of procedural due process, substantive due process or equal protection. See 42 U.S.C. 1983 (1994); Brett D. Babe, For Every Right There Is a Remedy: Civil Rights Litigation Pursuant to 42 U.S.C. 1983, 9 Me. B.J. 226, 226 (1994). Possible equal protection claims may arise from the fact that some genetic predictors are associated with particular races or ethnic groups. See Pearl, supra note 280, at 246 (noting that persons of African Caribbean descent are more likely to develop sickle cell anemia); cf. Wolf, supra note 343,

at 345 (likening genetic discrimination to racism and sexism). Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d (1994), also prohibits programs and activities that receive federal financial assistance, including hospitals, nursing homes, HMOs, and doctors, from discriminating on the basis of race, color, or national origin.²² Sidney Dean Watson, *Minority Access and Health Reform: A Civil Right to Health Care*, 22 J.L. Med. & Ethics 127, 130 (1994). Title VI, however, relies primarily on administrative enforcement, thus making its effectiveness dependent on the political will of the administration in power.²² Id. ¶¶

345. Compare *deMeurers v. HealthNet*, No. 239338, an arbitration decision in which the panel ruled that the HMO had intentionally interfered with doctor-patient relationship in denying coverage of HDC-ABMT and awarded the plaintiff more than one million dollars. See *HMO Interfered with Relationship of Doctor and Patient*, *Employee Benefit Plan Rev.*, Jan. 1996, at 55, available in LEXIS, *Business Library*, ABI File. The arbitration panel said that the HMO's conduct may be "a viable new tort" and constitutes "extreme and outrageous behavior exceeding all bounds usually tolerated in a civilized society." Id. (quoting the arbitration panel). For a general discussion of the *deMeurers* case, see *Contract Issues and Quality Standards for Managed Care: Hearings Before the Subcommittee on Health and Environment of the House Committee on Commerce*, 104th Cong. 146 (1996) (statement of Alan Charles deMeurers, husband of the late Christine Nesmith deMeurers, who died of breast cancer after having her treatment denied by her HMO); *Around the State: Briefs*, 7 *World Arb. & Mediation Rep.* 103, 103 (1996); Erik Larson, *The Soul of an HMO*, *Time*, Jan. 22, 1996, at 44, 44. ¶¶

Additionally, two other areas of concern come to mind, although neither necessarily relates specifically to health care coverage. When an employer is a plan administrator or self-insures, or when the genetic information causes an adverse employment decision, a plaintiff may have Title VII claims. See Kristie A. Deyerle, *Comment, Genetic Testing in the Workplace: Employer Dream, Employee Nightmare - Legislative Regulation in the United States and the Federal Republic of Germany*, 18 *Comp. Lab. L.J.* 547, 567 n.159 (1997) (noting that in a disparate impact case, the plaintiff only needs to prove that a "facially neutral policy has a disproportionate effect on a protected class"; the employer's intent is irrelevant); see also id. at 549-50 (discussing how no court in the United States has yet to adjudicate an alleged employment discrimination based on genetic makeup, but arguing that the potential for discrimination exists because "existing anti-discrimination legislation will not deter employers from using genetic technology to discriminate against workers based on their genetic constitutions"); Gostin, *supra* note 338, at 137-41 (discussing two examples of possible disparate impact cases based on genetic or gender discrimination); see, e.g., *Perkins v. Lake County Dep't of Utilities*, 860 F. Supp. 1262, 1276, 1280 (E.D. Ohio 1994) (denying defendant's motion for summary judgment in an employment discrimination claim alleging disparate treatment due to plaintiff's status as American Indian even though plaintiff was less than one-sixteenth Indian); Deyerle, *supra*, at 549 n.17 (discussing a class action lawsuit brought in federal district court in California in which plaintiff-employees of Lawrence Berkeley National Laboratory alleged that employer tested only African American employees for sickle cell anemia (a disease almost exclusively associated with that ethnic group) and that it tested for pregnancy and syphilis without employees' consent on blood and urine samples obtained during a mandatory medical examination). ¶¶

Another concern, which may arise either within or outside the employment context, is privacy. Privacy issues arise when insurers obtain genetic information without the insured's consent or when they require disclosure of genetic infor

mation in order to obtain insurance. See *Do v. Southeastern Pa. Transp. Auth.*, 886 F. Supp. 1186, 1187 (E.D. Pa. 1994) (employee sued employer for alleged invasion of privacy which occurred when employer was scanning medical records to check insurance payments), rev'd, 72 F.3d 1133, 1143 (3d Cir. 1995). A number of bills have been introduced to attempt to address such concerns.

See Sylvia Bennett, Congress Tackles a Full Agenda: Genetic Issues to FDA Reform, 88 J. Nat'l Cancer Inst. 402, 402-03 (1996) (listing and explaining the proposed Health Insurance Reform Act of 1996, S. 1028, 104th Cong.; the Genetic Privacy and Nondiscrimination Act of 1995, H.R. 2690, 104th Cong. (establishing limitations with respect to the disclosure and use of genetic information); and the Genetic Information Nondiscrimination in Health Insurance Act of 1995, H.R. 2748, 104th Cong.). The Health Insurance Reform Act of 1996 has been enacted and is now the Health Insurance Portability and Accountability Act of 1996, Pub.

L. No. 104-191, 110 Stat. 1936, which specifically prohibits group health insurance plans from using genetic information to establish rules for eligibility or continued eligibility. See *id.* at 1940, sec. 101(a), 701(b)(1)(B) (codified at 29 U.S.C.A. 1181(b)(1)(B) (West Supp. 1997)); *id.* at 1945, sec. 101(a), 702(a)(1)(F) (codified at 29 U.S.C.A. 1182(a)(1)(F)); *id.* at 1956, sec. 102(a), 2701(b)(1)(B) (codified at 29 U.S.C.A. 300gg(b)(1)(B)).

This is specifically authorized under Rule 23(c)(4)(A). See Manual for Complex Litigation, *supra* note 164, 30.17, at 222-23. But see *Do v. Guardian Life Ins. Co.*, No. 89 C 7955, 1992 U.S. Dist. LEXIS 3214, at *55-56, *62 (citing superiority concerns and refusing to certify 23(b)(3) class of persons alleging improper denial of payment for treatment of manic depressive disease as a "mental illness" within meaning of policies - but indicating it might consider 23(b)(1) or 23(b)(2) certification if the parties provide more information).

- - - - -End Footnotes- - - - -

Patients similarly may wish to challenge their managed care plans' decisions to limit the care they can receive as a matter of blanket policy. One such example could be a case challenging the composition of a plan's drug formulary. Patients who require a drug not on their plan's formulary may well lack access to that drug due to its cost. In special circumstances, most MCOs provide physicians waivers for drugs not on the formulary, but this may not always be the case. Moreover, the issue may not be an exemption for a special circumstance but rather an MCO's decision not to include a certain class of drugs on a formulary. Approved radiologic treatment may provide another example. Low-osmolar contrast media is a new type of dye used in radiographic studies. Use of this dye benefits patients who experience allergic reactions to an older dye; many patients find procedures more comfortable if the new dye is used. Yet an MCO may decide not to authorize use of the new dye because it is much more expensive than the older dye. Challenges to this type of decision - to exclude a drug from a formulary or to refuse payment for use of a new, superior contrast media - could allege breach of the terms of the plan under ERISA. Such challenges could involve not just the complaining patient but also all similarly situated patients.

- - - - -Footnotes- - - - -

A formulary is a list of drugs a plan can obtain at a discount from a manufacturer. See Furrow, *supra* note 31, at 448.

n348. A patient who needs a drug not listed on her plan's formulary may be able to obtain only its generic equivalent. See E. Haavi Morreim, *Diverse and Perverse Incentives of Managed Care: Bringing Patients into Alignment*, 11 Wid. L. Symp. J. 89, 98 n.27 (1996). Patients, however, sometimes react differently to the generic equivalents than to brand-name formulations. See *id.*

n349. See Furrow, *supra* note 31, at 449.

n350. See E. Haavi Morreim, *Moral Justice and Legal Justice in Managed Care: The Ascent of Contributive Medicine*, 23 J.L. Med. & Ethics 247, 247 (1995) (discussing how this radiation treatment is a superior, but far more costly, alternative).

n351. See D.M. Eddy, *Applying Cost-Effectiveness Analysis: The Inside Story*, 268 JAMA 2575, 2575 (1992).

n352. See Peter D. Jacobson & C.J. Rosenquist, *The Introduction of Low-Osmolar Contrast Agents in Radiology*, 260 JAMA 1586, 1587 (1988).

n353. See *id.* at 1586; see also Morreim, *supra* note 350, at 258 n.7 (listing examples of other treatments that are somewhat superior but vastly more costly).

n354. The availability of physician prescription waivers and of approvals for use of the newer dye for at-risk patients may negate liability for traditional malpractice. See Furrow, *supra* note 31, at 449. Liability might result from failure to disclose the more expensive option, or from failure to provide it despite plan language promising, for example, the most effective and up-to-date treatment. See, e.g., Morreim, *supra* note 348, at 100-01.

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Finally, allegations of delays in processing appeals or in initially determining coverage issues may also lead to class actions directed at policing access to health care. The Grijalva plaintiffs alleged a breakdown in the federal government's system of HMO oversight and review. n355 Because of the government action at issue, such cases involve constitutional claims. n356 Similar claims could arise from perceived delays in decision making funded or controlled by states. n357 These claims all have in common examinations of and challenges to a plan's or an entity's appeal structure. Nothing, or very little, is individualized in this structure, and each plaintiff has had to undergo the same procedure. Common questions supporting certification abound.

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n355. See *Grijalva v. Shalala*, 946 F. Supp. 747, 749-50 (D. Ariz. 1996).

n356. See *supra* notes 231-35. In *Grijalva*, the plaintiffs' allegations of lack of notice, appeal and hearing are examples of such constitutional due process claims. See *Grijalva*, 946 F. Supp. at 760.

n357. See *Catanzano v. Dowling*, 60 F.3d 113, 120 (2d Cir. 1995) (holding that home health care agencies' decisions constitute state action in case challenging system of decision making). Allegations of delay in decision making by the Health Insurance Plan of New York, for example, may provide fodder for such a lawsuit. Cf. Esther B. Fein & Elisabeth Rosenthal, *Delays by H.M.O. Leaving Patients Haunted by Bills*, N.Y. Times, Apr. 1, 1996, at A1. The General Accounting Office has recently expressed concern that California should more closely oversee Medicaid managed care. See Rodwin, *supra* note 86, at 1333 (similarly

noting that '22'5Ba'5D report by the Department of Health and Human Services (HHS) Inspector General indicates that serious problems exist with service access and enrollment procedures in Medicare HMOs'22). \par \par

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Clearly, class action litigation is not the appropriate tool for empowerment in all health care cases. Other methods of achieving power exist. But there are certainly categories of health care cases in which using the class action can help. Until now, the U.S. health care industry has relied on consumers' freedom to choose particular health plans to empower patients. n358 In reality, however, '22neither individual rights nor individual opportunity for exit and choices are sufficient to produce quality medical services. Organized consumer voice is also essential.'22 n359 Class actions can help organize, inform and amplify that voice.\par \par

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n358. See Law, supra note 308, at 793. \par\par
n359. Id.; see also Marc A. Rodwin, Consumer Protection and Managed Care: The Need for Organized Consumers, Health Aff., Fall 1996, at 110, 110, 116 (explaining that the disparity between the abilities of producers and consumers of medical services to protect their respective interests stems partly from the consumers' unorganized status and their lack of means to exert purchasing power or make their voice heard collectively). \par \par

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IV. CONCLUSION\par \par

Medicolegal developments have resulted in patients feeling victimized by corporatization. Managed care means that patients ostensibly have the right to self-autonomy, but in reality they learn only half the story and exercise little control over their health care. Patients thus need to find a way to reassert themselves in the managed care arena. They are unlikely to achieve individual empowerment from use of the class action, but if used properly and with care, this device can help restore balance in the system from a political empowerment perspective. \par\par

Therefore, despite its potential drawbacks, patients should make more use of the class action device as impact litigation in managed care. In certain instances, it can be a valuable instrument of redress, especially when other efforts (lobbying, pressuring employer-purchasers of health care benefits and engaging in alternative dispute resolution measures) fail. \par\par \pard

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LENGTH: 11624 words \par\par\pard

ARTICLE: Protecting Genetic Privacy by Permitting Employer Access Only to Job-Related Employee Medical Information: Analysis of a Unique Minnesota Law \par\par\pard

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SUMMARY: ... One of the most frequently expressed concerns about new scientific discoveries resulting from the Human Genome Project is the potential for genetic discrimination in insurance and employment. ... Undoubtedly, much of the concern about genetic discrimination in employment arises from the relationship between employment and group health insurance. ... Stated simply, legislators need to develop other criteria besides 'genetic' test results or information to determine whether an employer may gain access to or rely on an employee's medical information. The most promising approach to preventing genetic discrimination involves restricting employer access only to an employee's 'job-related' medical information. Thus, coupling a job-relatedness limitation on access to medical information with the general antidiscrimination provisions of disability discrimination laws is a more promising approach than using specific genetic discrimination laws. ... The permissible scope of an employee's medical examination is central to genetic privacy and confidentiality. ... That is, given the differences in how education and experience affect earnings in Minnesota and Ohio, how did that difference change after the enactment of the 1983 law prohibiting employers from obtaining non-job-related health information? The CPS data contains earnings figures for 23,389 observations in Minnesota and 58,982 in Ohio. ... Legislation restricting employer access to irrelevant medical information will be more effective than laws making the use of genetic information unlawful. ... \par\par\pard

TEXT: \5B*399\5D \par\par

I. INTRODUCTION\par

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One of the most frequently expressed concerns about new scientific discoveries resulting from the Human Genome Project is the potential for genetic discrimination in insurance and employment. The issue of discrimination in insurance, primarily health insurance, has justifiably received widespread attention in the scholarly literature. Among other research, there has been a special task force on insurance of the Joint Working Group on Ethical, Legal, and Social Implications of the Human Genome Project, n1 a special committee report of the National Action Plan on Breast Cancer, n2 a special report of the American Council of Life Insurance and the Health Insurance Association of America n3 and numerous reports and scholarly articles. n4\par

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n1. See NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, Genetic Information and Health Insurance: Report of the Task Force on Genetic Information and Insurance (visited Sept. 4, 1998) <<http://www.nhgri.nih.gov/About/NHGRI/Der/Elsi/itf.html>>; \par\par

n2. See Kathy L. Hudson et al., Genetic Discrimination and Health Insurance: An Urgent Need for Reform, 270 Science 391 (1995). \par\par

n3. See American Council of Life Insurance & Health Insurance Association of America, Report of the ACLI-HIAA Task Force on Genetic Testing (1991). \par\par

n4. See, e.g., Ray Moseley et al., The Ethical, Legal, and Social Implications of Predictive Genetic Testing for Health Insurance: Policy Analysis and Recommendations (The Human Genome Insurance Project Medical Humanities Program, University of Florida College of Medicine, 1993); Nancy E. Kass, The Implications of Genetic Testing for Health and Life Insurance, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 299 (Mark A. Rothstein ed., 1997); Thomas H. Murray, Genetics and the Moral Mission of Health Insurance, Hastings Center Rep., Nov.-Dec. 1992, at 12; Robert J. Pokorski, Genetic Information and Life Insurance, 376 Nature 13 (1995); Karen H. Rothenberg, Genetic Information and Health Insurance: State Legislative Approaches, 23 J.L. Med. & Ethics 312 (1995); Deborah A. Stone, The Implications of the Human Genome Project for Access to Health Insurance, in The Human Genome Project and the Future of Health 133 (Thomas H. Murray et al. eds., 1996). \par

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\5B*400\5D The ethical, legal and social implications of genetic discrimination in employment, although widely recognized as being very important, have received somewhat less attention than genetic discrimination in health insurance. n5 Undoubtedly, much of the concern about genetic discrimination in employment arises from the relationship between employment and group health insurance. n6 However, there are other problems. The disclosure of sensitive genetic information may result in invasions of privacy and breaches of confidentiality in obtaining the information and the loss of employment means denial of the opportunity to earn a livelihood for individuals determined to be at genetic risk. n7 As a result, many at-risk individuals forego genetic testing because they fear these consequences. n8\par

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n5. See, e.g., Council on Ethical and Judicial Affairs, American Medical Ass

ociation, Use of Genetic Testing by Employers, \i 266 JAMA 1827 (1991);\i0 Lor
i B. Andrews & Ami S. Jaeger, Confidentiality of Genetic Information in the Wor
kplace, \i 17 Am. J.L. & Med. 75 (1991);\i0 Lawrence O. Gostin, Genetic Discrimi
nation: The Use of Genetically Based Diagnostic and Prognostic Tests by Emplo
yers and Insurers, \i 17 Am. J.L. & Med. 109 (1991);\i0 Henry Greely, Health I
nsurance Employment Discrimination and the Genetics Revolution, in The Code of
Codes: Scientific and Social Issues in the Human Genome Project 264 (Daniel Kev
les & Leroy Hood eds., 1992); David Orentlicher, Genetic Screening by Employers
, \i 263 JAMA 1005 (1990).\i0 \par\par

n6. See, e.g., Mark A. Rothstein, Medical Screening and the Employee Health
Cost Crisis 195-217 (1989) (discussing the history of employers providing healt
h insurance coverage to employees) \5Bhereinafter Employee Health Cost Crisis\
'5D; Mark A. Rothstein, Genetic Testing: Employability, Insurability and Health
Reform, 17 J. Nat'l Cancer Inst. Monographs 87 (1995). \par\par

n7. See Michael Yesley, Protecting Genetic Difference, \i 13 Berkeley Tech.
L.J. 653, 658-59 (1998)\i0 (discussing denial of employment opportunities). \par\par

n8. See, e.g., Kimberly A. Quaid & Michael Morris, Reluctance to Undergo Pre
dictive Testing: The Case of Huntington Disease, 45 Am. J. Med. Genetics 41, 44
(1993). \par
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Recent legislative enactments at the state level have not resolved the probl
em and neither will current proposals in Congress. The current approach to the
issue of genetic discrimination in employment is to prohibit employers from con
ducting their own genetic tests, using the results of genetic tests or engaging
in genetic discrimination. n9 Nevertheless, proposed legislation will not, and
enacted genetic legislation does not, alter the current law under which employ
ers may require prospective employees to sign a release authorizing disclosure
of all of their medical records to the employers. Consequently, employers may r
outinely obtain genetic information from personal medical files and could poten
tially engage in surreptitious discrimination. Moreover, the fear of having to
disclose genetic information to employers discourages many at-risk individuals
from undergoing testing in the clinical setting.\par

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n9. See Yesley, supra note 7, at 655-69. \par
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This Article contemplates a different approach to the problem of employer ac
cess to and use of genetic information. Instead of advocating for another law p
rohibiting genetic discrimination in employment, arguably already prohibited by
the Americans with Disabilities Act (ADA), this Article analyzes a Minnesota s
tatute that prohibits employers from performing any tests or gaining access to
any medical information that is not job-related. The statute's approach avoids
the two main problems of current laws and proposals: (1) defining what is \22g
enetic\22 and (2) preventing employer access to medical records containing gen
etic information. \par\par

Since enactment in 1983, Minnesota is the only state with a statute that lim
its \5B*401\5D an employer's access to an employee's non-job-related medi
cal information. n10 This Article reviews the legislative history of the Minnes

ota law and attempts to determine what effects, if any, it has had. We conclude that although available data cannot accurately evaluate the Minnesota experience, its legislative approach still represents a better alternative to current proposals.

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n10. See Minnesota Human Rights Act, Minn. Stat. Ann. 363.01-.20 (West 1991 & Supp. 1998).

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II. GENETIC INFORMATION AND EMPLOYMENT \par\par

A. General Considerations\par

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It is important to understand why employers want to obtain diagnostic and predictive medical information about employees and prospective employees. Employers are concerned about their employees' fitness to work. Individuals who are unable to work because of physical or mental impairments cause an increase in absenteeism and turnover, higher accident and workers' compensation rates, decreased productivity and related problems. n11 Increasingly, many employers have determined that hiring and employing individuals who have medical problems or who are likely to develop them in the future could lead to substantially increased costs for employer-provided health benefits. n12 Thus, strong economic incentives may exist to refuse to hire or to terminate individuals who are deemed to be at an unacceptable risk of future illness. An important issue, however, is whether such employer actions would be lawful. The answer is somewhat complicated.

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n11. See Mark A. Rothstein, Medical Screening of Workers 191-201 (1984).

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n12. See Employee Health Cost Crisis, *supra* note 6, at 1-6.

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The employment-at-will rule, formulated in 1877 in the United States, is the starting point for analyzing employment law. n13 According to this rule, an employee working without a contract of definite duration is considered an employee 'at will.' The employer is free to hire or fire an employee 'at will' for any reason at any time and the employee is free to quit for any reason at any time. A series of federal and state laws, mostly enacted in the second half of this century, limit an employer's prerogative with regard to employment decisions. n14 Thus, an employer may refuse to hire or may discharge an employee for any reason, except race, color, religion, national origin, sex, age, disability, union membership or other statutorily or judicially proscribed reasons.

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n13. The rule originated in Horace G. Wood, A Treatise on the Law of Master and Servant (1877).

n14. See 2 Mark A. Rothstein et al., Employment Law 9.1, at 232 (1994).

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n15. See 1 Mark A. Rothstein et al., *Employment Law* 3.1, at 88, 109 (1994).

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B. State Law\par

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In the 1970s, as a response to irrational discrimination against heterozygous carriers of the sickle cell trait, state legislatures started enacting laws prohibiting genetic discrimination in employment. n16 The first type of law, such as those enacted in Florida, n17 Louisiana n18 and North Carolina, n19 establish a pattern of limited statutory prohibitions. New Jersey n20 and New York n21 also adopted laws based on this model of prohibiting discrimination against the unaffected carriers of recessive disorders. New Jersey's law, until amended and broadened significantly in 1996, prohibited discrimination against individuals with sickle cell, hemoglobin C, thalassemia, Tay-Sachs or cystic fibrosis traits. n22 New York's law, also amended and broadened in 1996, prohibited discrimination against individuals possessing sickle cell, Tay-Sachs or *-thalassemia traits. n23\par

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n16. See Rothstein, *supra* note 11, at 73-76. \par\par

n17. See Fla. Stat. Ann. 448.075 (West 1997) (enacted 1978). \par\par

n18. See La. Rev. Stat. Ann. 352 (West 1998) (enacted 1976). \par\par

n19. See N.C. Gen. Stat. 95-28.1 (1997) (enacted 1975). \par\par

n20. See N.J. Stat. Ann. 10:5-5(y)-(cc) (West 1993 & Supp. 1998) (enacted 1981). \par\par

n21. See N.Y. Civ. Rights Law 48, 48-a (McKinney 1992). \par\par

n22. See N.J. Stat. Ann. 10:5-5(y)-(cc). \par\par

n23. See N.Y. Civ. Rights Law 48 (McKinney 1992). The statute specifically prohibits discrimination against those who carry the sickle cell trait, Tay-sachs disease or carriers of Cooley's anemia. Id. Cooley's anemia is another term for *-thalassemia. See The Merck Manual 1173 (16th ed. 1992). \par

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In 1989, Oregon became the first state to enact a second type of genetic discrimination statute. n24 This law prohibits employers from requiring applicants or employees to undergo a genetic test, n25 although the term was undefined until subsequent amendments. n26 The state legislatures in Arizona, n27 California, n28 Connecticut, n29 Delaware, n30 Iowa, n31 New Hampshire, n32 New Mexico, n33 New York, n34 North Carolina, n35 Oklahoma, n36 Rhode Island, n37 Texas, n38 Vermont n39 and Wisconsin n40 enacted laws of this general type in their respective states. Most of the statutes prohibit employers from performing genetic tests on applicants or employees or conditioning employment on the results of a genetic test. The statutes generally define genetic test as a test analyzing human DNA. n41\par

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n24. See Or. Rev. Stat. 659.227 (1997). \par\par

n25. See id. 659.227(1), (3)(b). However, a job applicant or employee can co

nsent to a genetic test as provided by Oregon law, if the test is '22administe
red solely to determine a bona fide occupational qualification.'22 Id. 659.227

(6). \par\par

n26. See id. 659.700(6). A '22genetic test means a test for determining the
presence or absence of genetic characteristics in an individual, including tes
ts of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or prot
eins in order to diagnose a genetic characteristic.'22 Id. \par\par

n27. See Ariz. Rev. Stat. 41-1463(B)(3) (West 1992 & Supp. 1997) (enacted 19
97). \par\par

n28. See 1998 Cal. Legis. Serv. 99 (West). (including genetic characteristic
s as part of the definition of '22medical condition'22 referenced in Cal. Gov
't Code 12,926 (West 1998)). \par\par

n29. See 1998 Conn. Legis. Serv. 98-180 (West) (enacted 1998). \par\par

n30. See Del. Code Ann. tit. 18, 2317 (1998) (enacted 1998). \par\par

n31. See Iowa Code Ann. 729.6 (West 1993) (enacted 1992). \par\par

n32. See N.H. Rev. Stat. Ann. 141-H:3.I(b) (1997) (enacted 1995). \par\par

n33. See 1998 N.M. Adv. Legis. Serv. ch. 77 (enacted 1998). \par\par

n34. See N.Y. Exec. Law 296(1)(a) (Consol. 1998) (enacted 1996). \par\par

n35. See N.C. Gen. Stat. 95-28.1A (1997) (enacted 1997). \par\par

n36. See Okla. Stat. tit. 36, 3614.1 (1998) (enacted 1998). \par\par

n37. See R.I. Gen. Laws 28-6.7-1 (1995) (enacted 1992). \par\par

n38. See Tex. Lab. Code Ann. 21.401-.402 (West Supp. 1998) (enacted 1997).
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n39. See Vt. Stat. Ann. tit. 18, 9333(a) (1998) (enacted 1998). \par\par

n40. See Wis. Stat. Ann. 111.372 (West 1997) (enacted 1992). \par\par

n41. See, e.g., Iowa Code Ann. 729.6 (West 1993) (defining genetic testing a
s '22a test of person's genes, gene products, or chromosomes'22). \par

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In 1996, the New Jersey legislature enacted the third type of genetic discri
mination statute. n42 The law prohibits discrimination based on genetic test re
sults or the refusal to take a genetic test. n43 Additionally, it disallows \
'5B*403\5D discrimination based on genetic information. n44 New Jersey statu
tory law defines genetic information as '22information about genes, gene produ
cts or inherited characteristics that may derive from an individual or family m
ember.'22 n45 The New Jersey law is valuable because, unlike the other states'
laws, it prohibits discrimination based on a family's history of genetic disea
se. Its strength, however, is also its weakness. The law prohibits discriminati
on based on inherited characteristics derived from an individual. Because new d
iscoveries have identified associations between genes and common disorders, suc
h as cancer, heart disease, epilepsy, diabetes and hypertension, it is possible
that an employer could be prevented from considering an individual's history o
f such a disorder, which may be relevant to the ability to perform a job, becau
se it is '22genetic'22 information. In addition, the New Jersey law, like oth
er state laws, does not prohibit employers from gaining access to an individual
's complete medical history, which may contain genetic information. n46\par
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n42. See N.J. Stat. Ann. 10:5-12 (West 1998). \par\par

n43. See id. 10:5-12(a) (stating it shall be unlawful "for an employer, because of ... genetic information ... or because of the refusal to submit to a genetic test or make available the results of a genetic test to an employer, to refuse to hire or employ or to bar or to discharge or require to retire, unless justified by lawful considerations other than age, from employment such individual or to discriminate against such individual in compensation or in terms, conditions or privileges of employment").

n44. See id.

n45. See id. 10:5-5(oo).

n46. See id. 10:5-44 to :5-45 (West Supp. 1998). These statutes typically grant an employer access to an employee's medical records and genetic information through a signed employee authorization. See id.

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These state laws fail to effectively protect employees and, conversely, may even expose the public to unintended risks. n47 Stated simply, legislators need to develop other criteria besides "genetic" test results or information to determine whether an employer may gain access to or rely on an employee's medical information. The most promising approach to preventing genetic discrimination involves restricting employer access only to an employee's "job-related" medical information. Thus, coupling a job-relatedness limitation on access to medical information with the general antidiscrimination provisions of disability discrimination laws is a more promising approach than using specific genetic discrimination laws. n48 The proposal eliminates the need to stipulate what constitutes genetic information, a seemingly impossible task, and it restricts employer access to employee medical records that could contain the results of genetic tests and other sensitive, but non-job-related, medical information. It also avoids further stigmatizing genetic conditions by treating them differently from other medical conditions. n49

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n47. The broadest reading of the New Jersey law would prohibit employers from discriminating against individuals based on a history of a medical condition, such as epilepsy or diabetes, that may be influenced by genetic factors. In some situations, employing individuals with uncontrolled medical conditions creates a risk to the safety of the individual, coworkers or the public.

n48. See generally Mark A. Rothstein, Genetic Secrets: A Policy Framework, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 451, 475-79 (Mark A. Rothstein ed., 1997) (discussing the possibility of amending the Americans with Disabilities Act (ADA) to protect employees from discrimination based on genetic abnormalities and/or promulgating statutes, using the ADA as a model of proper construction, to control third-party access to employees' genetic information).

n49. By creating laws to address specific conditions, whatever they may be, an inference is created that they are somehow worse than similar conditions that have not been singled out. It is this negative inference that this approach seeks to avoid.

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C. The ADA

In general, the ADA and the disability discrimination laws enacted in virtually every state are quite similar. The main difference among them is that the ADA applies only to employers with fifteen or more employees whereas approximately half the state laws also cover employers with one to fourteen employees. The ADA operates as a minimum standard and does not preempt state laws that afford equal or greater protection than federal law.

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n50. 42 U.S.C. 12101-12213 (1994 & Supp. 1996).

n51. See 1 Rothstein et al., *supra* note 15, 3.39, at 323-30 (comparing state antidiscrimination laws with the ADA); 1 Rothstein et al., *Employment Law*, 3.38, at 67 (Supp. 1998).

n52. See 42 U.S.C. 12111(5)(A). However, there are a few exceptions to this general rule. See *id.* 12111(5)(B).

n53. See 1 Rothstein et al., *supra* note 15, 3.39, at 328.

n54. See 42 U.S.C. 12201(b) (''Nothing in this chapter shall be construed to invalidate or limit the remedies, rights, and procedures of any Federal law or law of any State or political subdivision of any State or jurisdiction that provides greater or equal protection for the rights of individuals with disabilities than are afforded by this chapter'').

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The ADA prohibits discrimination in any aspect of employment on the basis of a disability. To rely on the ADA for protection, an individual must come within at least one part of the three-part definition of an individual with a disability. With respect to an individual, the term ''disability'' means:

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n55. See *id.* 12112(a) (''No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment.'').

n56. See *id.* 12102(2).

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(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.

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n57. See *id.*

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Neither this nor any other provision of the ADA addresses whether discrimination against an individual because of an unexpressed genetic condition is unlawful under the statute. n58\par

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n58. See Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 Hous. L. Rev. 23, 39 (1992).\i0 \par

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In March 1995, in response to considerable urging, the Equal Employment Opportunity Commission (EEOC), the agency responsible for enforcing the ADA, issued an interpretation of the disability provision. n59 The EEOC opinion stated that when an employer discriminates against an individual because of his or her increased risk of developing a genetic disorder, the individual is 'regarded' as having a disability, and therefore the third prong of the definition of 'disability' applies to the individual. n60 No court has reviewed this interpretation. The EEOC interpretation extends coverage to individuals who are presymptomatic (e.g., those carrying an allele for a late-onset disorder) and those who are genetically predisposed to disease (e.g., cancer or other multifactorial disorder). n61 Under this interpretation, however, the ADA does not protect unaffected carriers of recessive and X-linked disorders from discrimination by employers concerned about possible future health care costs of dependents. This interpretation also does not address when an employer may 'B*405'D per form genetic tests or require employees to release medical records that could contain the results of genetic tests performed in the clinical setting.\par

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n59. See 2 EEOC Compl. Man. (CCH) P 6880, at 5303 (Mar. 14, 1995). \par\par

n60. See id. P 6888, at 5325. \par\par

n61. See id. at 5325-26. \par

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The ADA divides all medical examinations and inquiries into three stages: n62 preemployment, preplacement or 'employment entrance' and post-placement. At the preemployment stage, while the employer is assessing the applicant's qualifications, an employer or employer's agent may not legally conduct a medical examination or make any inquiries as to whether the applicant has a disability, or the nature or severity of the disability. n63 The only permissible inquiries at this time concern whether the individual can perform, with or without reasonable accommodation, essential job-related functions. n64 Thus, traditional preemployment medical examinations and medical questionnaires violate the ADA.\par

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n62. See 42 U.S.C. 12112(d). \par\par

n63. See id. 12112(d)(2)(A). \par\par

n64. See id. 12112(d)(3). \par

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The ADA permits employers to make offers of employment contingent on the successful completion of a medical examination. n65 The employer may require a conditional offeree to take a preplacement medical examination. n66 The ADA imposes three requirements on these exams. First, if an employer requires an employee in a certain job category to take a medical exam, then all entering employees in the same job category, regardless of disability, must take an examination. n67 Second, the employer must collect and maintain the information obtained at the examination, as well as all other employee medical information, on separate forms and store it in separate medical files. n68 The employer must treat the information in all medical records as confidential with only a few exceptions. n69 Although supervisors and managers may not have access to specific information regarding diagnoses, they may know of any necessary restrictions on the work or duties of the employee. If the disability requires emergency treatment, safety and first aid personnel may know any pertinent medical information. The employer must provide government officials investigating compliance with the ADA with relevant information on request. Finally, employers may not use medical criteria to screen out individuals with disabilities unless the medical criteria are job-related. n70\par

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n65. See id. \par\par

n66. See id. \par\par

n67. See id. \par\par

n68. See id. \par\par

n69. See id. 12112(d)(3)(B)(i)-(iii). \par\par

n70. See id. 12112(b)(6) ('The term 'discriminate' includes ... other selection criteria that screen out ... an individual with a disability ... unless the ... selection criteria, as used by the 'Employer', is shown to be job-related for the position in question and is consistent with business necessity.'; id. 12112(d)(4)(A) ('An employer shall not require a medical examination nor inquire of an employee as to the extent of his or her disability unless such examination or inquiry is shown to be job-related and consistent with business necessity.'). \par

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The ADA does not limit the scope of preplacement examinations. n71 An employer may require a comprehensive medical examination regardless of the job duties. Similarly, the employer may require the release of all of the individual's medical records as a valid condition of employment. n72 Nevertheless, it is unlawful to withdraw a conditional offer of employment for any medical reason except that 'the individual is unable, even with reasonable accommodation, to perform the essential functions of the job. n73 Medical examinations of current employees must be either voluntary or job-related and consistent with business necessity. n74\par

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n71. See id. 12112(d)(3)(B)-(C); *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1273 (9th Cir. 1998) (stating the 'ADA imposes no rest

restriction on the scope of entrance examinations; it only guarantees the confidentiality of the information gathered, and restricts the use to which an employer may put the information.\'

n72. See 42 U.S.C. 12112(d)(3)(A)-(C).
n73. See id. 12113(a).
n74. See id. 12112(b)(6), (d)(4)(A).

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The medical examination provisions of the ADA place conditional offerees in a precarious position. After extending an offer of employment, the employer may require the individual to submit to a medical examination. n75 There are no limits placed on the tests that may be conducted. n76 An individual undergoing the tests has no right to be told what tests are being conducted, what the results of the tests are or how the information generated by the test will be used in determining employability. n77 The employer also may insist that the individual release all of his or her medical records to the employer. n78 If the employer decides to withdraw the conditional offer of employment, the individual has no right to be told why, including whether medical considerations or business reasons caused the employer to withdraw the offer. n79 Although the ADA prohibits the withdrawal of a conditional offer for medical reasons unless they are job-related, the individual usually will not know the reason unless he or she files a complaint with the EEOC or obtains the information during the discovery phase of the lawsuit. These provisions facilitate surreptitious and unlawful discrimination. Furthermore, even if no overt discrimination occurs, such as withdrawing the job offer, an invasion of medical privacy through the unnecessary disclosure of sensitive information may occur. Additionally, the employer may discriminate in other ways, such as in job assignments and promotions.

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n75. See id. 12112(d)(3)(A)-(C).
n76. See EEOC Technical Assistance Manual on the Employment Provisions (Title I) of the ADA, at VI-2 (1992); 56 Fed. Reg. 35,726, 35,751 (1991) (interpreting 29 C.F.R. 1630.14(b) as permitting employers to condition employment offers on results of medical examinations, provided that all entering employees in the same job category are subjected to the same examination regardless of disability); Norman-Bloodsaw, 135 F.3d at 1273.
n77. See Mark A. Rothstein, Legal and Ethical Aspects of Medical Screening, 11 Occup. Med.: State of the Art Revs. 31, 37 (1996).
n78. See id. at 35. Under the ADA, a covered entity may require a medical examination after an offer of employment has been made. See 42 U.S.C. 12112(d)(3). As part of the medical examination, medical histories may be taken. See id. 12112(d)(4)(B).
n79. See Rothstein, supra note 77, at 37.

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During the congressional debates and drafting of the ADA, legislators attempted to restrict the scope of post-placement medical examinations. n80 However, the business community and its supporters argued that it would be too expensive for employers to determine which medical procedures and tests were job-related. Additionally, the industry argued that restrictions on the types of medical examinations employers could perform would undermine productivity by not permitting

ing the exclusion of medically unfit and potentially hazardous workers. n81 The employers' position prevailed, and Congress enacted the ADA without any restrictions on the scope of post-placement examinations, n82 in direct contrast to both 407(b)(5) prohibited pre-offer examinations n83 and limited preplacement examinations. n84

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n80. See 136 Cong. Rec. H2599 (daily ed. May 22, 1990); Chai R. Feldblum, Medical Examinations and Inquiries Under the Americans with Disabilities Act: A View from the Inside, 64 Temp. L. Rev. 521, 531-33, 537-38 (1991).

n81. Cf. Feldblum, *supra* note 80, at 535-38 (1991) (alluding generally to employer concerns that restrictions would be expensive and that further costs would arise from not permitting employers to screen those unable to perform essential job functions safely).

n82. See 42 U.S.C. 12112(d)(2)-(3) (1995) (the ADA specifically addresses only pre-offer and preplacement situations).

n83. See *id.* 12112(d)(2).

n84. See *id.* 12112(d)(3).

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The permissible scope of an employee's medical examination is central to genetic privacy and confidentiality. If individuals know that their future employers on whom they may depend for health insurance will have access to all of their medical records, including the results of genetic tests, they may refuse to undergo genetic testing in the clinical setting even if they are at-risk and would otherwise choose to have the testing. n85 Individuals also may be concerned that whenever they have blood drawn or another bodily specimen obtained, an unscrupulous employer could perform genetic testing without obtaining consent or informing the employee. As the costs of genetic tests decrease, these concerns become more realistic.

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n85. See Quaid & Morris, *supra* note 8, at 44.

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D. Other Laws

The 1998 case of *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* n86 raised the issue of surreptitious genetic testing. The blood and urine samples of certain employees, obtained during their preplacement medical examinations, were tested for pregnancy, syphilis and sickle cell trait without their express knowledge or consent. n87 Seven current and former employees of the research facility sued under the United States and California Constitutions, Title VII of the Civil Rights Act of 1964 and the ADA. n88 The district court found all claims were time-barred, and, in the alternative, that they failed on the merits. n89 In dismissing the ADA and federal privacy claims, the district court found the employees had notice that their employer might be performing these types of tests because the medical questionnaire included highly personal questions unrelated to employment and because the employees had consented to a comprehensive medical examination. n90 As such, any additional incremental intrusion caused by

y performing the testing was minimal. n91\par
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n86. \i 135 F.3d 1260 (9th Cir. 1998).\i0 \par\par
n87. See \i id. at 1265.\i0 \par\par
n88. See \i id. at 1264-66.\i0 \par\par
n89. See \i id. at 1266.\i0 \par\par
n90. See id. \par\par
n91. See id. \par
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The Court of Appeals for the Ninth Circuit reversed the dismissal and remanded the case for trial on the merits. n92 The court of appeals found that disputes of material fact existed as to whether the employees had reason to believe that the employer would perform these types of tests without their consent and whether performing such tests was inconsistent with sound medical practice. n93 As such, the district court erred in granting the defendants' motion for summary judgment. n94 In holding that the facts alleged raised a valid constitutional claim, the court stated that '22one can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.\'22 n95 The female employees raised a cognizable Title VII claim for sex discrimination because the employer conducted pregnancy testing of female employees. n96 Additionally, the '5B*408\5D black employees alleged a sufficient case of race discrimination under Title VII because the sickle cell trait testing was limited to black employees. n97 The court affirmed the dismissal of the ADA claims, however, because, under the ADA, preplacement medical examinations are of unlimited scope and need not be job-related. n98\par
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n92. See \i id. at 1261.\i0 \par\par
n93. See \i id. at 1267-68.\i0 \par\par
n94. See \i id. at 1275.\i0 \par\par
n95. See \i id. at 1269.\i0 \par\par
n96. See \i id. at 1272.\i0 \par\par
n97. See id. \par\par
n98. See \i id. at 1273-74.\i0 \par
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III. MINNESOTA HUMAN RIGHTS ACT (MHRA)\par
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Similar to virtually every other state, Minnesota has a state law prohibiting discrimination in employment on the basis of various criteria including disability. The MHRA, n99 as amended, is the only state or federal law to require that all medical examinations, including post-placement medical examinations, be strictly limited to measuring the individual's ability to perform job-related functions. n100 The MHRA provides that it is not an unfair employment practice for an employer\par
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n99. See Minn. Stat. Ann. 363.01-.20. (West 1991 & Supp. 1998). \par\par

n100. See id. 363.02(1)(9). \par

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to require or request a person to undergo physical examination, which may include medical history, for the purpose of determining the person's capability to perform available employment, provided: (a) that an offer of employment has been made on condition that the person meets the physical or mental requirements of the job ... \5Band\5D (b) that the examination tests only for essential job-related abilities n101\par

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n101. See id. 363.02(1)(9)(i)(a)-(b). \par

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The scope of this provision has not been litigated, but members of the Minnesota bar and officials at the Minnesota Department of Human Rights (MDHR) generally agree that the provision prevents employers from requiring \22blanket releases\22 of medical records in the possession of employees' personal physicians

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The impetus for this and other 1983 amendments to the MHRA was the Minnesota Council for the Handicapped. n102 Senator Allan Spear, Chairman of the Senate Judiciary Committee, sponsored the amendments and introduced them in the Senate on March 7, 1983, as Senate File 529; Representative Lee Greenfield did the same in the House on March 14, 1983, as House File 668. n103 Unlike other provisions, the part of the amendment package concerning employment medical examinations did not receive significant discussion in the hearings and was not subject to any revisions in the deliberative process.\par

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n102. Interview with Marsha Greenfield, Legislative Director for Minnesota State Senator Allan Spear (January 29, 1998). \par\par

n103. See State of Minnesota, Journal of the Senate: Seventy-Third Legislature 329 (1983); 1 State of Minnesota, Journal of the House of Representatives: 1982 Third Special Session and Index of the Legislature 597 (1983). \par

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The Senate Judiciary Committee's hearing on March 23, 1983, is instructive regarding the legislative intent behind the bill. n104 Senator Ron Sieloff questioned the wisdom of limiting medical examinations until after an offer of employment as well as limiting the scope of post-placement examinations to job-related matters. n105 Senator Spear replied, \22this language comes from federal regulations. It comes \5B*409\5D from section 504. n106 It's been around for a while. It's been used. It's proven workable.... I think we can live with it.\22 n107 There was no further debate on the issue of limiting medical examina

tions at this hearing or in later hearings.\par

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n104. Legislative hearings are not available in published text form, rather they are available on audio tape. There are five tapes from the Minnesota Senate and five tapes from the Minnesota House of Representatives on this particular legislation. \par\par

n105. See Minnesota Senate Judicial Civil Law Tape, Side B (Mar. 23, 1983). \par\par

n106. Undoubtedly, this is a reference to Section 504 of the Rehabilitation Act of 1973, which prohibits the federal government, government contractors and recipients of federal financial assistance from discriminatory employment practices. See Rehabilitation Act of 1973, Pub. L. No. 93-112, 504, 87 Stat. 355, 394. The entire amendment, not merely the medical examination provisions, were intended to incorporate into Minnesota law the provisions of the Rehabilitation Act. \par\par

n107. See Minnesota Senate Judicial Civil Law Tape, supra note 105. \par\par

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On May 16, the Minnesota Senate enacted Senate File 529 by a vote of 58-0. n108 The House previously passed House File 668 by a vote of 117-3. n109 Governor Rudy Perpich signed the legislation into law on June 6, 1983. n110\par

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n108. See State of Minnesota, Journal of the Senate, supra note 103, at 2750. \par\par

n109. See 1 State of Minnesota, Journal of the House of Representatives, supra note 103, at 3940. \par\par

n110. See State of Minnesota, Journal of the Senate, supra note 103, at 4451. \par

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It is always venturesome to draw inferences from a law's legislative history, especially when the basis for much of the inference is what was not said or done. Yet with regard to this legislation, it is difficult not to conclude that the Minnesota legislature enacted the law based on some misunderstandings. Senator Spear, the bill's sponsor, erred when he said at the hearing on March 23, 1983, that the provision was consistent with Section 504 of the Rehabilitation Act. Neither the Rehabilitation Act nor its implementing regulations, then or now, limit the scope of preplacement medical examinations. Similarly, while members of the Minnesota legislature and other interested parties suggested numerous clarifications and revisions of the language in other sections of the bill, there is virtual silence with regard to the most significant provision in the bill. \par\par

In 1983, the Minnesota legislature amended the MHRA to include a unique provision limiting the scope of employer-mandated medical examinations and inquiries; this is still a novel approach today. If the legislative history suggests that the effect of the law was not clear to the interested parties in 1983, would it become clear in the intervening years? \par\par

IV. MEASURING THE EFFECTS OF THE MHRA\par

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The enactment of the 1983 amendments to the MHRA provides an opportunity to measure whether limiting employer access to medical information results in any noticeable effects. We attempted to address this issue by reviewing five different types of data: (1) case filings with the MDHR; (2) interviews of Minnesota employment lawyers; (3) a questionnaire survey of Minnesota occupational physicians; (4) a questionnaire survey of Minnesota human resource managers; and (5) Minnesota economic data. \par\par

A. Case Filings\par

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The MHRA prohibits discrimination in employment on the basis of race, color, creed, religion, national origin, sex, marital status, status with regard to public assistance, disability, sexual orientation or age. n111 The first step in state discrimination cases is for an aggrieved individual to file a complaint with the MDHR. n112 Only the most recent five years of case filings are available for review. \5B*410\5D We reviewed every case filed with the MDHR from July 1, 1992 (fiscal year 1993), through June 30, 1996 (fiscal year 1997). We also reviewed additional cases filed in fiscal year 1998.\par

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n111. See Minn. Stat. Ann. 363.03(2) (West Supp. 1998). \par\par

n112. See id. 363.06. \par

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A total of 931 cases filed during these five fiscal years alleged disability discrimination. Of these filings, only four cases raised issues related to impermissible medical examinations or inquiries before the commencement of employment. The MDHR dismissed one case for failing to comply with the statute of limitations. n113 In another case, the MDHR held there was no probable cause to believe that a post-placement medical examination included questions that were not job-related and therefore dismissed the case. n114 In the two cases where the MDHR found probable cause to believe that unlawful medical inquiries were made, the cases settled. n115 No cases alleged that the employer required the individual to sign a release authorizing disclosure of all of his or her personal medical records. Nor are there any reported judicial decisions under the 1983 amendments. n116\par

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n113. See MDHR No. ER 19940952 (May 26, 1994). \par\par

n114. See MDHR No. 271222 (Mar. 21, 1997). \par\par

n115. See MDHR No. ER 19951085 (July 25, 1995); MDHR No. ER 19931523 (Aug. 30, 1993). \par\par

n116. \i Huisenga v. Opus Corp., 494 N.W.2d 469 (Minn. 1993),\i0 is the only case dealing with the relevant statutory provision. The Minnesota Supreme Court held that where an employer asked unlawful questions on the employment application regarding the physical condition and health of the applicant, extending beyond an inquiry into the applicant's ability to perform essential job functions, an applicant's false answers could not be used to deny that applicant's subsequent workers' compensation claim. See \i id. at 471-74.\i0 \par

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There are at least three ways of accounting for the extraordinarily low number of cases filed under the MHRA's provision limiting medical examinations and inquiries. First, employers may be in total compliance with the law and few individuals believe that their employers have violated their rights. Second, assuming that violations of the law have occurred, job applicants, employees and their lawyers may be unaware of the protections afforded by the law. Third, assuming violations have occurred and individuals knew their rights, they may have decided not to pursue their remedies under the Minnesota statute. Based on the results of the information obtained from employment lawyers, occupational physicians and human resource (HR) managers, it is apparent that employees and other relevant parties are unaware of the law's provisions. \par\par

B. Employment Lawyers\par

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The researchers interviewed a sample of employment lawyers to determine what effect, if any, the Minnesota law had on preplacement medical examinations and inquiries. n117 Although a few employment lawyers who specialize in disability discrimination law knew of the 1983 amendment to the MHRA, most did not. Even those lawyers familiar with the provision believed that it was generally not well known among the bar or the public and, as a result, it had little or no effect on the conduct of employers or employees.\par

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n117. Interviews with various employment lawyers, at the University of Minnesota School of Law and at a Continuing Legal Education Program on the ADA sponsored by the Minnesota Institute of Legal Education (Jan. 29, 1998). \par

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C. Occupational Physicians\par

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The survey team distributed a questionnaire about preplacement medical examinations to members of the North Central Occupational and Environmental \5B*411\5D Medical Association at a regular meeting. n118 The members were all practicing occupational physicians and their practices included independent practices, occupational medicine clinics and medical departments of large corporations. Their responses indicated a lack of familiarity with the provisions of the ADA and the MHRA as summarized in the following table.\par

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n118. The survey was administered by Mark A. Rothstein on January 29, 1998, in St. Paul, Minnesota. \par

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Question	Yes	No	Don't Know	Don't
Preplacement exams under the ADA must be job-related		13	6	0
Under the ADA, individuals can		5	13	1

be required to release all of their			
medical records			
Preplacement exams under the	9	5	5
MHRA must be job-related			
Under the MHRA, individuals can	2	8	9
be required to release all of their			
medical records			

Table 1: Minnesota Occupational Physicians' Perceptions about Relevant Laws.

N = 19. Note: Correct answers are in bold.

Table 1 is subject to varying interpretations. Most respondents did not know the requirements of the ADA and erroneously responded that the ADA requires job-related examinations but prevents access to medical records. On the other hand, respondents correctly answered that under the MHRA medical examinations must be job-related. Additionally, most responded correctly or "Don't know" to the question about release of medical records under the MHRA. As indicated by the number of "Don't know" answers, the respondents had more confidence in their knowledge of the requirements of the ADA than the MHRA. Ironically, the majority answered the ADA questions incorrectly and the MHRA questions correctly.

Although the number of respondents is small, it represents about one-fifth of the occupational medicine practitioners in Minnesota. The questionnaire did not ask respondents to indicate what medical information they obtained on their own employees nor when they request such information in their practices. In oral discussions with the respondents after completion of the questionnaires, most indicated that they obtained medical information of a non-job-related nature during preplacement examinations and that they obtained access to non-job-related information in the individual's medical records pursuant to a release. They did not realize that both of these activities are illegal under the MHRA.

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119. The 1996/1997 Membership Directory of the American College of Occupational and Environmental Medicine lists 113 members from Minnesota, excluding retired members. It is not known how many practice full time in occupational and environmental medicine.

120. Comments to this effect were made to the investigator, Mark A. Rothstein, during a discussion period after completion of the survey instrument.

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D. Human Resource Managers

The researchers gathered data from HR professionals in Minnesota at the state's annual conference of the Society of Human Resource Managers (SHRM). To allow for comparisons, the survey team collected parallel data at the Ohio SHRM group meeting during roughly the same time period. In both, the researchers gave the HR managers a hypothetical federal law with provisions that exactly matched the MHRA, although no reference to the Minnesota law was made to respondents in either state. Then the team asked the participants to indicate on the questionnaire whether "your state" currently had such a law

w and to assess on several dimensions the impact of such a law if it were enacted at the federal level. The researchers expected that if Minnesota respondents were familiar with their law and felt burdened by it, their answers would differ significantly from those of respondents in the control state Ohio. However, only Minnesota respondents who said their state had such a law were asked about its consequences.

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121. During the Society of Human Resource Managers (SHRM) conference held on September 22-23, 1997, in Duluth, Minnesota, questionnaires were placed in a sealed envelope in the packet of each registrant and labeled: "Please don't open this envelope until asked to do so." At an early plenary session, Betsy D. Gelb, a principal investigator, asked those present to open the envelope and complete the questionnaire immediately. The short time to complete the questionnaire minimized possible discussion of the issues and increases the probability that the registrants' answers are their own opinions.

122. Data from the Ohio SHRM conference, held on October 15-17, 1997, in Akron, Ohio, were collected by University of Houston researcher Andrea Stanaland, who followed a procedure similar to that used at the Minnesota SHRM conference.

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The Minnesota data from the HR professionals indicates a significant lack of familiarity with the provisions of the MHRA. When asked whether "your state currently had such a law, 47 of 88 respondents said "yes," while 41 said "no." Other responses, summarized in Table 2, are answers to questions concerning the hypothetical federal law. Only the 47 Minnesota HR managers who knew the law was valid were asked questions forecasting the consequences if it applied to all states, and 44 managers responded to such questions. Data from their responses are presented below. They were asked as a baseline, "Can your company currently obtain the medical information you need concerning prospective employees?" Twenty of the participants said "yes," 18 said "no," while the others said they did not know.

SEE TABLE IN ORIGINAL

Table 2: Minnesota Human Resource Managers' Perceptions about the MHRA.

As the research team predicted, no Ohio HR professional falsely believed that his or her state had a law similar to the one described. Data from all 32 Ohio respondents were therefore compared to data from the 44 knowledgeable Minnesota respondents. No statistically significant differences were indicated in the results. In other words, Minnesota HR professionals, who might have known what to expect from a hypothetical federal law identical to one that they were working under, provided responses that did not differ from the responses of Ohio HR professionals who knew they were not working under such a law.

These negative results could lead to either of two possible conclusions. First, the experience of the Minnesota HR professionals paralleled that of their Ohio counterparts because the MHRA had little effect. Or alternatively, the Minnesota respondents who "knew" they had such a law in fact were guessing that they did and had no actual experience with it to cause their responses to differ from those in Ohio who had no experience with the law. Although the bare d

ata suggest that either conclusion could be accepted, or even a combination of both, in light of the other Minnesota data discussed previously, it is likely t hat the former explanation is correct. \par\par

E. Economic Analysis\par \par

One of the key concerns resulting from the link of health insurance and employ ment is that employees may be unable or unwilling to change jobs because of he alth insurance-related reasons. n123 This factor is often called job lock. n124 Restrictions on labor mobility resulting from job lock are potentially costly to the economy. n125 Employees experiencing forms of job lock may not be well m atched to their current job because they decline job offers that would otherwis e be mutually advantageous. n126 In addition, such employees may be less conten t, which may affect their productivity or even willingness to invest in job ski lls. Thus, labor markets with greater job mobility restrictions may have lower average wages or poorer utilization of labor force skills because the employees are not matched to their best jobs.\par

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- \par\par n123. See Kanika Kapur, The Impact of Health on Job Mobility: A Measure of J ob Lock, \i 51 Ind. & Lab. Rel. Rev. 282, 282 (1998).\i0 \par\par

n124. See id. \par\par

n125. See Paul M. Schwartz, Privacy and the Economics of Personal Health Car e Information, \i 76 Tex. L. Rev. 1, 33 (1997)\i0 (finding job lock \i22introd uces significant distortions in the labor market\i22 which in turn adversely af fect the economy). \par\par

n126. Every year, Americans \i22turn down better jobs because they know if t hey take the better job, they will lose their health insurance.\i22 140 Cong. R ec. H28 (1994) (President Clinton's January 25, 1994 State of the Union Address), reprinted in 1994 U.S.C.C.A.N. D3, at D9. \par

\par -----End Footnotes-----

- \par\par In an economic sense, it is possible to regard all employee medical informat ion as job-related. n127 For one reason, it may be impossible to separate job-r elated health concerns from other health concerns because an employee's overall health affects his or her productivity. Even if it is possible to separate hea lth concerns into job-related and non-job-related categories, general employee health affects a firm because of the linkage between health care costs and the overall profitability of a firm. n128 Generally, a firm with higher health cost s than other firms will experience lower profits to the extent the firm pays at least some share of insurance premiums. Theoretically, this higher cost firm w ill not expand as quickly as similar firms with lower health costs because it i s not as profitable.\par

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- \par\par n127. See Schwartz, supra note 125, at 8. \par\par

n128. See id. at 26. \par

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- \par\par \i5B*414\i5D The link between profits and general health is one important motivation that inspires fair employment practice laws such as those under disc

ussion here. n129 If all employers are prohibited from obtaining personal health information, then all firms have an equal probability of bearing any particular health costs. As a result, there are no competitive changes in the marketplace. That is, no single firm is likely to be 'stuck' with unhealthy employees because employees are better able to sort themselves based on their employment characteristics and those of the jobs. Consequently firms in states like Minnesota, where job lock is not as prevalent, may have a competitive advantage over firms in other states. Thus, the local economy will benefit from labor mobility because employees are unconcerned with non-job-related health.

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n129. See id. \par
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To test whether the MHRA impacted the Minnesota job market, we compared the earnings of workers in Minnesota with earnings of similar workers in Ohio. We used the March Current Population Survey (CPS) data for our comparison over the years 1970 to 1996. n130 If the population were perfectly mobile, earnings of similar workers would be identical in the two states and the change in earnings due to various factors would also be identical. In fact, the earnings are not identical between states and the relationship between personal characteristics and earnings varies in Minnesota and Ohio as well. We view this as evidence that the two labor markets, while relatively similar, nonetheless represent different markets. Thus, the impact of the Minnesota personal health information law can be reasonably expected to be evident in Minnesota and not elsewhere.

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n130. The Current Population Survey is a monthly survey of about 50,000 households conducted by the Bureau of the Census for the Bureau of Labor Statistics. It should be noted that the federal Health Insurance Portability and Accountability Act, 42 U.S.C. 300gg-1 (1998), was enacted specifically to address the problem of job lock. See Health Insurance Portability and Accountability Act of 1996, H.R. Conf. Rep. No. E1502 (1996) (extension of remarks by Hon. Gary A. Franks). Because the law was enacted in 1996, it does not affect the economic analysis in this section. \par
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Our earnings comparison uses regression analysis n131 to compare individuals over time who vary by two key attributes determining earnings: education and experience. Our comparison utilizes what is called a 'difference in differences' approach. That is, given the differences in how education and experience affect earnings in Minnesota and Ohio, how did that difference change after the enactment of the 1983 law prohibiting employers from obtaining non-job-related health information? The CPS data contains earnings figures for 23,389 observations in Minnesota and 58,982 in Ohio. Our data cover annual earnings for the period 1970 through 1996. We split our sample into two approximately equally sized periods, from 1970 through 1983 and from 1984 through 1996. Our regression illustrates how the market return to education and experience has changed in the two different periods. We accomplish this by regression analysis where the natural log of earnings is specified to depend on, among other things, experience

and education. Because we used relatively few variables as statistical controls, the measured returns to experience and education include both direct and indirect effects on earnings. We then compare the returns to experience and education in the two markets for the two time periods. The natural log specification allows the return to experience and education to vary with total earnings. Further, we allow experience to have a nonlinear effect by adding a squared term to the regression. This element of the specification allows experience at some point to decrease earnings where the point is determined statistically within the regression.

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131. The regression procedure used was ordinary least squares. For more information on this procedure, see David S. Huang, *Regression and Economic Methods* 16, 33, 57, 127, 136 (1970).

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For comparison purposes, we studied an individual with average earnings in each state and examined how changes in experience and education affected earnings. During the early pre-1983 period, the average worker earned \$16,862 in Ohio and \$16,619 in Minnesota. During the late period, from 1984 to 1996, the average worker in Ohio earned \$20,771 and in Minnesota earned \$21,742. What is of interest here is whether the labor market worked more smoothly in Minnesota in one of the two time periods compared with the other, reflecting a change due to the health information law.

There are two methods by which we can examine returns to an additional year of experience due to the nonlinear specification for experience. One method is to examine the return at various degrees of experience, while the other is to determine when additional experience begins to decrease the earnings of a worker. The first year of experience in the early period is worth more in Minnesota than Ohio, \$394 compared with \$255. In the later period, the return to the first year falls to \$339 in Minnesota but falls by virtually the same percentage to \$207 in Ohio. For a worker with ten years of experience, the return in Ohio increases slightly compared with the amount in Minnesota, reflecting the slower rate at which the return to experience falls in Ohio in the later period. As a result, the age at which a worker's return to experience drops to zero rises much more slowly in Minnesota than Ohio. That is, during the early period, a Minnesota worker with 22.18 years of experience will have reached his or her peak earnings and earnings will begin to diminish after that time. This point is reached after only 20.18 years in Ohio. This age has been climbing, however, and averages 29.23 years in Minnesota for the later period, but it rose much faster in Ohio to 31.02 years. Thus, older workers, who might be expected to be most concerned with job lock due to medical insurance restrictions, improved their earnings by relatively more in Ohio compared with Minnesota in the time period after the Minnesota health information law was enacted.

An alternative, and equally important comparison, is in the returns to education. If workers are well matched to their jobs, the returns to education should be higher compared with a situation where workers are not well matched to their jobs. In the early period of our sample, one year of education is worth much more to workers in Ohio, \$671 per year, than it is to workers in Minnesota, \$268 per year. The returns to education have been growing rapidly, however, as illustrated by these data. In particular, the average returns to an additional year of education in Ohio rose 4.37 times to \$2,937. The gap between the two sta

tes has closed quite rapidly, however, as the return to education in Minnesota grew twice as fast to \$2,561 per year. Thus, the premium in Ohio for a year of education was formerly 250% times that in Minnesota, but has now fallen to only 15 percent.

The picture that emerges from these results is therefore rather muddled. Although the relative position of older workers has improved in Ohio relative to Minnesota, the return to education improved in Minnesota substantially more than in Ohio suggesting that in some ways the labor market in Minnesota has improved its utilization of more highly educated workers. The result that there is no clear picture, however, is consistent with the conclusion that the MHRA Amendments of 1983 have had virtually no impact on behavior. The effects suggested in this aggregate examination of the labor market would undoubtedly be the same in other economic analyses, such as productivity, workers' compensation claims and health care claims. Consequently, any economic changes in the Minnesota labor market in the period after 1983 do not appear to be driven by the amendment of MHRA in 1983.

Table 3: Labor Market Returns.

V. CONCLUSION

The research reported in this Article was designed to assess the effects, if any, of the 1983 amendment to the MHRA that permits employers to access only job-related employee medical information. The conclusion, however, is that there is little knowledge of the law among those individuals most intimately involved in employment-related medical information including occupational physicians, HR managers and employment lawyers. To a large extent, this finding limits the utility of the economic analysis and the comparison of the Minnesota HR managers with those in the control state of Ohio.

Although its effects are still uncertain, the 1983 amendment to the MHRA represents the most promising legislative approach for protecting the confidentiality of individual medical records and preventing employers from obtaining access to or basing employment decisions on such records. It is easier and more effective to protect the confidentiality of all medical records than attempting to identify, segregate and treat genetic information separately. Legislation restricting employer access to irrelevant medical information will be more effective than laws making the use of genetic information unlawful. Until meaningful medical privacy legislation is enacted, individuals will continue to be reluctant to undergo genetic testing in the clinical setting because they fear the possible uses of the information.

by the 105th Congress \par\par\pard
Jeremy A. Colby* \par\par\pard

* B.A., 1996, Niagara University; J.D. candidate, 1999, Boston University School of Law. The author thanks Alison Chen, Colin Kisor, Shana Lewinger, and Maureen Ormsby for their invaluable assistance in publishing this Note. Finally, this Note is dedicated to my parents, Diane and Barry, because their love and sacrifice have indelibly impacted my life. \par\par\pard

SUMMARY: ... The genetic age offers great potential, including a future where gene and germ-cell therapy may virtually eliminate genetic disease. ... Although genetic information will be used to develop revolutionary treatments, such as gene therapy and other molecular medicine, it will also bring genetic discrimination and heretofore unrealized invasions into the privacy of our genetic codes. ... Gene probes look for a base sequence associated with a disease or genetic predisposition. ... Concern about continued access to health insurance, and thus health care, is a major reason for many genetic discrimination bills. ... Genetic test results do not accurately indicate health risk because such testing fails to provide information about a person's 'actual state of health.'² ... Two federal laws that fill some of the legislative gaps left by state genetic discrimination laws include the Americans with Disabilities Act of 1990 (ADA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). ... Moreover, genetic discrimination bills introduced in both Congresses similarly define genetic information, genetic test, insurer and other terms necessary for effective prohibition of genetic discrimination. ... Many of the genetic discrimination bills introduced by the 104th Congress also prohibited employers from altering health benefits offered on the basis of genetic information.

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It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness ... it was the spring of hope, it was the winter of despair ... we were all going direct to Heaven, we were all going direct the other way. n1\par

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n1. Charles Dickens, A Tale of Two Cities 1 (Running Press 1986) (1859). This passage provides an apropos introduction into human genetics and the ramifications such knowledge will have. Although it is the genetic 'age of wisdom' because of potentially life-saving scientific discoveries, it is also the 'age of foolishness' because of our failure to safeguard ourselves from our own designs. Thus, 'the double helix reflects the hopes and fears of an age.'² Richard Saltus, Sounding the Alarm Like Splitting the Atom, Boston Globe Mag., May 26, 1996, at 14. \par

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- Charles Dickens \par
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I. INTRODUCTION\par
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The Human Genome Project (HGP) n2 provides information about the human genome that will forever alter society and the way we view ourselves. n3 The genetic age offers great potential, including a future where gene and germ-cell therapy

may virtually eliminate genetic disease. n4 However, genetic information may also result in a world characterized by genetic discrimination and genetic determinism. n5 Although genetic information will be used to develop revolutionary treatments, such as gene therapy and other molecular medicine, it will also bring genetic discrimination and heretofore unrealized invasions in to the privacy of our genetic codes. n6\par

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n2. See Human Genome Project, About the Human Genome Project (last modified Sept. 2, 1998) <<http://www.ornl.gov/TechResources/HumanGenome/home.htm>> (describing the Human Genome Project (HGP) as "an international 15-year effort formally begun in October 1990 to discover all the 60,000 to 80,000 human genes (the human genome) and make them accessible for further biological study"). \par\par

n3. See Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing on H.R. 2748 Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 9 (1996) (statement of Rep. Louise Slaughter) "hereinafter Slaughter Testimony" (stating that "our genes represent the most personal, private, and fundamental aspects of ourselves. They are inescapable; they cannot be concealed, disguised or avoided. They are the ultimate identification and definition of who we are Research efforts like the Human Genome Project are unlocking the secrets of our genes on an almost daily basis."). \par\par

n4. See Kathy L. Hudson et al., Genetic Discrimination and Health Insurance: An Urgent Need to Reform, 270 Science 391, 391 (1995); see also David Suzuki & Peter Knudtson, Genethics: The Clash Between the New Genetics and Human Values 165-66 (rev. ed. 1990) (predicting that gene therapy - the medical repair or replacement of defective genes in human living cells - will become a reality). \par\par

n5. The motion picture Gattaca provides an excellent glimpse into the future of genetic discrimination and subsequent genetic determinism - where people's lives are preordained by their genome. See Bob Kurson, Dabbling in DNA: 'Gattaca' Director Exploring Ethics, Chi. Sun-Times, Nov. 16, 1997, at 7, available in 1997 WL 6379554. Gattaca is "a journey into a world where humans are judged not by their characters but by their genes." Id. This journey describes a world where parents genetically engineer their children, selecting traits such as intelligence, attractiveness and near perfect health. See Kathi Wolfe, Genetic Engineering: Two Sides of the Coin, Las Vegas Rev.-J., Nov. 28, 1997, at 15B, available in 1997 WL 4558846. Vincent, the genetically inferior protagonist, is doomed to remain a second-class citizen because of poor vision and heart disease resulting from his natural conception. See Roger Ebert, Future Tense: 'Gattaca' Sees Flaws in a Perfect World, Chi. Sun-Times, Oct. 24, 1997, at 35, available in 1997 WL 6375250. The antagonist, Hugo, is Vincent's genetically engineered, and thus superior, brother. See id. In a society predicated on "prejudice with a scientific basis," genetically inferior Vincent is an "invalid" destined for menial jobs and low class status. See Rene Downing, 'Gattaca' Premise: Future's Not in Stars, but in Our Genes, Ariz. Daily Star, Nov. 20, 1997, at 1C, available in 1997 WL 7934923. Therefore, to avoid genetic stigmatization, Vincent undertakes an elaborate conspiracy to assume the identity of Jerome, a genetically superior "valid" left lame by a car accident. See id. Vincent pays Jerome for his skin cells, blood, urine, hair and other bodily products used for genetic identification through genetic testing. See id. Finally, against all odds, Vincent achieves his

is life-long dream of becoming an astronaut, a position reserved for the genetically superior because of the substantial investment involved. See *id.* Gattaca, whose title is comprised of the letters G, T, C, and A, which represent the four nitrogenous bases making up deoxyribonucleic acid (DNA), is a vision of a possible high-tech-militarized-corporate future with elements of Aldous Huxley's social-control dystopia, Brave New World. See *id.*

n6. See Hudson et al., *supra* note 4, at 391; see also Privacy, Confidentiality and Discrimination in Genetics, 1997: Hearing on H.R. 272 before the Task Force on Health Records and Genetic Privacy of the House Comm. on Commerce, 105th Cong. 10 (1997) (statement of Francis Collins, Director, National Center for Human Genome Research) (hereinafter Collins 1997 Testimony) (stating that "as knowledge grows about the genetic basis of diseases, so too does the potential for discrimination and stigmatization based on genetic information").

Genetic discrimination has been defined as "the denial of rights, privileges or opportunities on the basis of information obtained from genetically-based diagnostic and prognostic tests." Larry Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, 17 Am. J.L. & Med. 109, 110 (1991).

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Congress and the state legislatures have proposed and enacted legislation to prevent potential abuses of genetic information. n7 However, genetic discrimination legislation enacted thus far leaves several legislative loopholes permitting genetic discrimination. n9 Furthermore, many existing genetic discrimination laws leave unaddressed the issues of genetic privacy and autonomy. n10 Consequently, closing these gaps will require additional legislation.

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n7. See Hudson et al., *supra* note 4, at 392; see also Collins 1997 Testimony, *supra* note 6, at 19 (reporting that 19 states enacted laws restricting the use of genetic information in health insurance and that at least 31 states have introduced laws prohibiting genetic discrimination in insurance). For a discussion of state and federal legislation targeting abuse of genetic information, see *infra* Part VI.

n8. Genetic discrimination legislation is being used to refer to legislation protecting genetic privacy and prohibiting discrimination. See Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 9 (1996) (statement of Alan Goldhammer, Director of Technical Affairs, Biotechnology Industry Organization) (noting that Congress intends to prevent unauthorized use or dissemination of genetic information and use of such information to discriminate against individuals seeking health insurance).

n9. See Hudson et al., *supra* note 4, at 392 (stating that existing state genetic discrimination laws leave some people unprotected because the Employee Retirement Income Security Act of 1974 (ERISA) preempts state regulation of self-funded plans, and because many state laws focus narrowly on mandatory genetic testing rather than more broadly on the use of genetic information); see also *infra* notes 196-203 and accompanying text (discussing shortcomings of current state genetic discrimination legislation).

n10. See, e.g., Eric Mills Holmes, Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project, 85 Ky. L.J. 50

3, 647\i0 (1996-97). \par

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This Note focuses on genetic testing and discrimination legislation. Part II provides a brief description of the HGP and developments in genetic science. Parts III and IV respectively discuss arguments for and against legislation regulating the use of genetic information. Part V discusses the need for legislation to prevent abuse of genetic information, including a discussion of the various genetic discrimination bills proposed by the 105th Congress. Finally, Part VI concludes that legislation is necessary: to prohibit genetic discrimination by employers and health insurers; to protect individuals' genetic privacy from unauthorized disclosure of genetic information; to protect people from mandatory genetic testing; and to regulate the collection, use, storage and distribution of genetic information. Specifically, this Note argues that Congress should enact the Genetic Privacy and Nondiscrimination Act of 1997ⁿ¹¹ or the Genetic Confidentiality and Nondiscrimination Act of 1997.ⁿ¹² These bills should be reintroduced and enacted by a subsequent session of Congress because the 105th Congress failed to enact either bill.ⁿ¹³\par

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n11. H.R. 341, 105th Cong. (1997). \par\par

n12. S. 422, 105th Cong. (1997). \par\par

n13. Thus far, Congress has failed to enact either bill. Search of WESTLAW, Bill Tracking (Nov. 8, 1998). \par

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II. THE HGP AND ADVANCES IN GENOMIC RESEARCH FUEL CONCERN FOR GENETIC DISCRIMINATION\par

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The HGPⁿ¹⁴ is a federally funded project coordinated by the National Institutes of Health (NIH) and the U.S. Department of Energy.ⁿ¹⁵ Established in 1990, the HGP is scheduled to meet its goal of mapping the entire human genome by 2005.ⁿ¹⁶ Furthermore, the HGP produces genetic maps and the technology required to store^{\5B*446\5D} systematically the vast amounts of information contained in the human genome.ⁿ¹⁷ However, deoxyribonucleic acid (DNA) structural information revealed by the HGP^{\22}is only the beginning of biological interpretation,^{\22} as scientists must then determine what the^{\22\5Binstructions\5D} encoded in human DNA mean.^{\22} n18\par

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n14. The HGP is a collaboration among many independent international research institutions with the common goal of analyzing the human DNA structure and mapping and sequencing the estimated 100,000 human genes. See Holmes, *supra* note 10, at 517. The Human Genome Organization (HUGO), a private organization, coordinates genomic research conducted in the United Kingdom, Canada, France and Japan. See *id.* at 506 n.2. For discussion about the history of the HGP, see *id.* at 517 n.26. Further information about the HGP is available online at Human Genome Project Information (visited Nov. 18, 1998) <<http://www.ornl.gov/TechResources/HumanGenome/home.html>>. \par\par

n15. See Ari Patrinos & Daniel W. Drell, *Introducing the Human Genome Project*

t: Its Relevance, Triumphs and Challenges, Judges' J., Summer 1997, at 5, 6. The HGP will cost the federal government an estimated three billion dollars. See Holmes, *supra* note 10, at 518. This amounts to more than 20% of all biomedical research funding. See Catherine M. Valerio Barrad, Comment, Genetic Information and Property Theory, 87 Nw. U. L. Rev. 1037, 1042 n.19 (1993); see also Susan O'Hara, The Use of Genetic Testing in the Health Insurance Industry: The Creation of a Biologic Underclass, 22 Sw. U. L. Rev. 1211, 1215 (1993) (discussing the HGP's \$3 billion price tag).

n16. See Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 2 (1996) (statement of Francis Collins, Director, National Center for Human Genome Research) [hereinafter Collins 1996 Testimony]. However, some experts have predicted that the HGP may map 99% of the human genome with 99.9% accuracy by the year 2002. See Holmes, *supra* note 10, at 516; see also Patrinis & Drell, *supra* note 15, at 6. The human genome is defined as "all the information stored in a complete strand of human DNA ... including the three billion base pairs comprising roughly 100,000 genes." Holmes, *supra* note 10, at 521. The HGP's goal is to "develop efficient, cost-effective detailed genetic and physical maps of the human genome, determine the complete nucleotide sequence of human DNA, and create the new technology required to fulfill its purpose." *Id.*; see also Barrad, *supra* note 15, at 1042-43 (describing the HGP as a fifteen-year project with approximately five percent of the total three billion pairs of nucleotides identified in 1993).

n17. See Collins 1996 Testimony, *supra* note 16, at 1.

n18. See *id.* at 3.

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The human genome n19 is comprised of forty-six chromosomes n20 grouped into twenty-three pairs, n21 and is contained in "each somatic n22 human cell." n23 Chromosomes contain strands of DNA in the shape of a double helix. n24 These strands of DNA are called chromatin n25 and are "composed of four kinds of molecular sub-units called nucleotides." n26 Scientists estimate that the human genome contains three billion nucleotide base pairs, n27 and that these base pairs are divided into "between 50,000 and 100,000 genes." n28 Genes n29 chemically encode hereditary information by "determining the production of proteins which, in turn, determine the function of each cell and, ultimately an individual's traits." n30 Consequently, genes are responsible for a person's genotype, which represents the "actual genes carried by an individual (as distinct from phenotype, the physical characteristics into which genes are translated)." n31

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n19. See Holmes, *supra* note 10, at 520 (defining genome as "the totality of the genetic information that is stored in cells and passed from one generation to the next ... which determines how cells behave and how complex organ systems interact..."); see also Mahlon Hoagland & Bert Dodson, The Molecules of Life, Judges' J., Summer 1997, at 11, 11 (suggesting that if DNA is compared with language, then "there are four ... letters (nucleotides, or base pairs) arranged in paragraphs of 1,000 to 2,000 letters (genes), thence books of a million letters each (chromosomes), thence a library (genome). Our human library contains 46 books." See generally A Genetic Glossary for Judges, Judges' J., Summer 1997, at 65, 65 [hereinafter Judges' Glossary] (defining key

terms used in genetics). \par\par

n20. See Judges' Glossary, supra note 19, at 65 (defining chromosomes as '2structures found in the nucleus of a cell that contain the genes. Chromosomes come in pairs, and a normal human cell contains forty-six chromosomes, twenty-two pairs of autosomes, and two sex chromosomes.'22). Human chromosomes range in size from 50 to 250 million nucleotide base pairs. See Richard A. Bornstein, Genetic Discrimination, Insurability and Legislation: A Closing of the Legal Loopholes, 4 J.L. & Pol'y 551, 556 (1996). \par\par

n21. See Holmes, supra note 10, at 521. \par\par

n22. For a good discussion of the difference between somatic and zygotic cells, see Barrad, supra note 15, at 1042 n.20. \par\par

n23. See id. at 1042. \par\par

n24. The double helix model of DNA was first proposed in 1953 by James Watson, Rosalind Franklin and Francis Crick. See Holmes, supra note 10, at 519. Watson's 1961 discovery of DNA's genetic code subsequently led to the recognition that '22DNA's linear arrangement of paired bases in triplets provides the blueprint for protein synthesis.'22 See id. at 519-20. The double helix model of DNA '22looks much like a ladder that has been twisted.'22 See id. at 521. The '22rungs of the ladder'22 are the base pairs formed from the '22bonding of the four chemical '5Bnucleotide'5D bases.'22 See id. \par\par

n25. See Suzuki & Knudtson, supra note 4, at 31. \par\par

n26. See id. at 32. Furthermore, '22each nucleotide contains a sugar, a phosphate, and one of four kinds of nitrogen containing bases: adenine (A), guanine (G), cytosine (C), and thymine (T).'22 Id. The genetic code utilizes these four nucleotides as the chemical instructions for hereditary information. See Holmes, supra note 10, at 521. Nucleotides are complementary, so that pairs are either A-T or C-G base pairs. See id. Moreover, DNA sequences, or ordering of the nucleotides, are composed of three nucleotide units called codons. See id. Sixty-four codons comprise the entire genetic code responsible for making twenty different amino acids, which are the basic building blocks of living organisms. See id. Actually, only 61 codons are responsible for instructing the production of 20 amino acids, and the three remaining codons are '22regulatory'22 or '22stop'22 signals. See Hoagland & Dodson, supra note 19, at 13; see also Suzuki & Knudtson, supra note 4, at 43 tbl. 2.1 (listing the codons in the genetic code and resultant amino acids). Furthermore, '22variations in the linear ordering of the '5Bnucleotide'5D bases make up different genetic sequences.'22 Bornstein, supra note 20, at 556. Consequently, the '22body '22reads' these '5Bnucleotide'5D base pairs in groups of three '5Bi.e. codons'5D, and since every sequential triple identifies a specific amino acid, the body will string together amino acids to form the protein or other bodily chemical dictated by that particular sequence of triple base pairs.'22 Barrad, supra note 15, at 1042

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n27. See Suzuki & Knudtson, supra note 4, at 305; see also Judges' Glossary, supra note 19, at 65 (defining base pairs as '22two complementary, nitrogen rich molecules held together by weak chemical bonds. Two strands of DNA are held together in the shape of a double helix by the bonds between their base pairs.'22). Furthermore, each letter in each base pair '22is the chemical complement of the letter opposite it.... '5BAnd the nucleotide bases'5D, held together by weak bonds, can separate, have new chains laid down along them, and so be perfectly reproduced.'22 Hoagland & Dodson, supra note 19, at 11. \par\par

n28. See T.H. Cushing, Should There be Genetic Testing in Insurance Risk Classification?, 60 Def. Couns. J. 249, 250 (1993). However, despite the existence of approximately three billion base pairs in the human genome, '22most of the DNA in our chromosomes is not genes. We don't know what the function of the ex

cess DNA is.''' See Hoagland & Dodson, supra note 19, at 11; see also Denise K. Casey, What Can the New Gene Tests Tell Us?, Judges' J., Summer 1997, at 14, 15 (noting that genes ''are interspersed among millions of bases of DNA that do not code for proteins (noncoding DNA) and whose functions are largely unknown. In fact, genes constitute only a tiny fraction of the human genome, a mere 3 percent.'').

n29. See Judges' Glossary, supra note 19, at 65 (defining genes as ''units of inheritance; a working subunit of DNA ... with each gene containing the code for a specific product, typically a protein ...').

n30. Holmes, supra note 10, at 519. For a good description of the interaction between genes and proteins, see Hoagland & Dodson, supra note 19, at 11-13 (noting that ''proteins are workers, machinery; they do life's jobs. Genes are information molecules; they carry life's ideas. This relationship between genes and proteins is recursive: the two are locked together in a single, interdependent system.'')(emphasis in the original).

n31. See Judges' Glossary, supra note 19, at 66; see also Suzuki & Knudtson, supra note 4, at 344-46 (defining genotype and phenotype, respectively).

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Genomic research primarily focuses on mapping the human genome, or ''the process of assigning genes to specific chromosomes.''

n32 Genetic mapping determines where genetic loci are relative to each other ''on the basis of how often they are inherited together.''

n33 As of October 1998, maps to all forty-six human chromosomes have been drawn.

n34 Nonetheless, despite the rapid sequencing of the human genome, ''fewer than one percent of the more than three billion base pairs comprising the human genome have been sequenced.''

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n32. O'Hara, supra note 15, at 1213.

n33. Id. A genetic locus is an identifiable area or ''marker'' on a chromosome indicating that a specific trait will be expressed by the gene. See id.

n34. See Holmes, supra note 10, at 522-23. Detailed genetic maps of the 46 human chromosomes can be found at A Gene Map of the Human Genome (visited Nov. 18, 1998) <<http://www.ncbi.nlm.nih.gov/genemap98>>.

n35. Holmes, supra note 10, at 523.

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HGP research constantly leads to ''the discovery of particularized genes responsible for certain diseases.''

n36 These diseases have ''a molecular mechanism of pathology at the gene and protein levels''

n37 and are caused by genetic mutation.

n38 Although ''some hereditary diseases can be explained by a single gene, or ''monogenic,''

n39 defect the majority of genetic diseases are multifactorial, ''or are'' caused by the interaction of environmental factors and numerous abnormal genes ... on different chromosomes.

n40 Gene mapping associates diseases with genes.

n41 Consequently, ''high quality ''genetic'' maps have dramatically sped up the discovery of disease genes,''

n42 and hasten the day when such knowledge will be used systematically to eliminate genetic disease.

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n36. O'Hara, supra note 15, at 1213. Genomic research suggests that specific genes or groups of genes predispose individuals to some forms of cancer, emphysema, juvenile diabetes, Alzheimer's disease, ... heart disease and mental illness. Id. Moreover, genes have been identified that are associated with breast cancer, cystic fibrosis, and skin cancer Slaughter Testimony, supra note 3, at 7. Daily updates regarding genetic discoveries may be found on the Internet at The Institute for Genomic Research (visited Nov. 18, 1998) <<http://www.tigr.org>>. \par\par

n37. See Holmes, supra note 10, at 522. More than 5,000 diseases currently affect over half of the population of the United States. See Bornstein, supra note 20, at 557. \par\par

n38. See Judges' Glossary, supra note 19, at 66 (defining mutation as "a change in the number, arrangement, or molecular sequence of a gene"). Most genetic mutations are inconsequential. For example, changes in an amino acid here and there in proteins whose key function is unaffected. Hoagland & Dodson, supra note 19, at 13. Yet, some genetic mutations are detrimental because they alter an amino acid at a vulnerable location in a protein. Id.; see also Casey, supra note 28, at 16 (discussing the role genetic mutation plays in disease pathology). \par\par

n39. Monogenic disorders are relatively rare, comprising only three percent of all diseases. See Casey, supra note 28, at 16 (discussing monogenic disorders, including sickle cell anemia, cystic fibrosis (CF), Huntingtons disease (HD) and Tay-Sachs disease). \par\par

n40. Holmes, supra note 10, at 522. See Bornstein, supra note 20, at 557-59; see also O'Hara, supra note 15, at 1219 (stating that the manifestation of genetic disease also depends upon specific genes acting in concert with other genes because neighboring genes have various effects upon one another ... creating yet another variable in the manifestation of disease). \par\par

n41. See Collins 1996 Testimony, supra note 16, at 28 (stating that "As a result of the Human Genome Project, new disease genes are discovered almost weekly. Once a disease gene is identified, it is often only a matter of months before a diagnostic test can be made available."). \par\par

n42. Casey, supra note 28, at 17. \par\par

n43. See Roberta M. Berry, The Human Genome Project and the End of Insurance, 7 U. Fla. J.L. & Pub. Pol'y 205, 206-07 (1996). \par

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Although the HGP's immediate goal is to describe the human genome in molecular detail, its longer term goal and more profound impact will be to reveal critical mechanisms of human biology and supply the medical context within which investigations on the molecular pathology of human diseases can most efficiently take place. n44 Consequently, gene mapping technology will lead to a future medicine in which prevention will be firmly rooted in mechanistic knowledge and potential interventions can be more targeted and effective. n45 Thus, mapping the human genome is only the HGP's penultimate goal. n46 The ability to take information about the human genome and to develop viable gene therapies for most, if not all disease, is the ultimate goal of the HGP. n47 Although gene therapy technology itself still faces many obstacles before it can become a practical approach for treating disease, n48 DNA testing has

tened the day when gene therapy - the medical replacement or repair of defective genes in living human cells - will become a reality.\22 n49\par

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n44. Patrinos & Drell, *supra* note 15, at 6. \par\par

n45. *Id.* In other words, medical diagnostics will vastly improve \22by monitoring human DNA variability and correlating it with patients' therapeutic responsiveness, \5Bcreating\5D new methods for treating or curing diseases.\22 Jim Graves, *Should Evolution be Guided by Genetic Control?: University Lecture Wrestles with Ethics of Tomorrow's Biomedicine*, B.U. Bridge, Oct. 24, 1997, at 3. \par\par

n46. The HGP's penultimate goal, by definition, must be realized before the ultimate goal. In other words, \22once the human genome has been deciphered, medical researchers intend to use the information to cure genetically-based diseases by designing interventions to prevent the manifestation of these diseases.\22 Holmes, *supra* note 10, at 518. \par\par

n47. The ultimate goal of the HGP has been described as \22an attempt to erase the uncertainty of humankind regarding genetic illness.\22 O'Hara, *supra* note 15, at 1214; see also Casey, *supra* note 28, at 19 (stating that gene therapy \22holds great potential for treating or even curing genetic and acquired diseases, using normal genes to replace or supplement a defective gene or bolster immunity to disease\22). Over 150 clinical gene therapy trials were in progress as of summer 1997, mostly involving different kinds of cancers. See *id.*; see also Patrinos & Drell, *supra* note 15, at 6-7 (discussing the future of medical applications of genomic research). \par\par

n48. Casey, *supra* note 28, at 82; see also Leslie Sowers, *The Basics on Genes*, *Houst. Chron.*, Aug. 17, 1997, at 1, available in \i 1997 WL 13056793\i0 (stating that a \22genetic cure for a disease will take much more knowledge and experimentation\22 because scientists need to learn \22how to send a correct version of the instructions into the body on a cellular level and get the corrected version to keep reproducing itself\22). \par\par

n49. Suzuki & Knudtson, *supra* note 4, at 166 (emphasis in the original); see also Barrad, *supra* note 15, at 1043 (noting that \22identifying the genetic cause of disease could suggest new methods of treatment, aid early identification, or lead to eradication of the syndrome through gene therapy\22). \par\par

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\5B*449\5D Genetic testing bridges the gap between contemporary disease gene mapping and the future development of gene therapies, because once disease genes or their approximate chromosomal regions are identified, academic and commercial laboratories will develop gene tests to detect the mutations associated with a disease. n50 After accurate genetic tests are developed, \22commercial efforts will shift away from diagnostics and toward developing a new generation of therapeutics based on genes.\22 n51 Gene testing involves an analysis of bodily tissue or fluid, usually blood, for any genetic abnormalities. n52 Genetic technicians take extracted DNA and map the individual's base sequence in order to compare it with known sequences on HGP-created gene maps to determine whether the individual's DNA contains any differences in the base sequence. n53 There are two types of gene tests: n54 gene probes n55 and genetic marker or linkage tests. n56 Gene probes look for a base sequence associated with a disease or genetic predisposition. n57 Linkage tests involve analysis of chromosome segments containing a gene suspected to cause a disease. n58 Moreover, linkage te

sts require testing several generations of a family with a history of genetic disease to determine whether inheritance of the DNA segment correlates with inheritance of the disease. n59 Although direct gene probes are easier to perform and more accurate than linkage tests, the probes are available for fewer diseases because of their research intensive nature. n60 The price of genetic tests vary between several hundred and several thousand dollars, depending on the sizes of the genes and the number of mutations tested. n61 Genomic discoveries and improved methods for developing genetic tests decrease the cost of such tests. n62 Thus, reducing the cost of genetic testing will soon make widespread genetic testing feasible. n63 Consequently, the likelihood of universal genetic testing raises many ethical issues regarding such testing. n64\par

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n50. See Casey, supra note 28, at 17-19; see also Berry, supra note 43, at 206-07 (stating that with the knowledge gained from the HGP, diagnostic tests for genetic defects will soon be widely available, and cures for diseases caused by these genetic defects will follow).

n51. Casey, supra note 28, at 19.

n52. See Holmes, supra note 10, at 524; Cushing, supra note 28, at 250. Gene testing is defined as an examination of a sample of blood or other body fluid or tissue for biochemical, chromosomal, or genetic markers that indicate the presence or absence of genetic disease. Judges' Glossary, supra note 19, at 66; see also Casey, supra note 28, at 18-19 (discussing gene tests for HD, CF, Alzheimer's disease and breast cancer). For a table listing diseases for which gene tests were available as of 1996 in New York State approved clinical laboratories, see Casey, supra note 28, at 15.

n53. See Cushing, supra note 28, at 250-51. Genetic technicians accomplish genetic screening by testing the DNA in blood cells to determine the presence of certain genetic markers associated with various genetic diseases. Naomi Obinata, Comment, Genetic Screening and Insurance: Too Valuable an Underwriting Tool to be Banned from the System, 8 Santa Clara Computer & High Tech. L.J. 145, 148 (1992).

n54. See Suzuki & Knudtson, supra note 4, at 145-47.

n55. A gene probe is defined as a specific sequence of single-stranded DNA, typically labeled with a radioactive atom, which is designed to bind to, and thereby single out, a particular segment of DNA. Judges' Glossary, supra note 19, at 67. Gene probes involve researchers designing short pieces of DNA, called probes, whose sequences are complementary to the mutated sequences. These probes will seek their complement among the three billion base pairs of an individual's genome. If the mutated sequence is present in the patient's genome, the probe will bind to it and flag the mutation. Casey, supra note 28, at 17.

n56. A linkage test is defined as a gene-hunting technique that traces patterns of heredity in large, high risk families, in an attempt to locate a disease-causing gene mutation by identifying traits that are co-inherited with it. Judges' Glossary, supra note 19, at 66.

n57. See Cushing, supra note 28, at 251.

n58. See id.

n59. See id. at 251-52.

n60. See id. at 252. Because of the complexity in determining which sequence of base pairs causes a particular disease, diseases must be studied extensively in order to develop gene probes. See id. at 251. Consequently, gene probes are

e fewer in number than less research intensive linkage tests. See id. \par\par

n61. See Casey, supra note 28, at 17. \par\par

n62. See Gostin, supra note 6, at 116. \par\par

n63. See id. at 116-17. \par\par

n64. See O'Hara, supra note 15, at 1215; Holmes, supra note 10, at 518-19. \

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Genomic information produced by the HGP implicate myriad ethical, social and legal issues. n65 Concerns over the possible ramifications concerning HGP research and subsequent discoveries about the human genome led to the development of a program to address the ethical, legal and social implications (ELSI) of genomic research. n66 Congress allocates between three percent and five percent of the HGP's \$3 billion budget for ELSI. n67 ELSI represents the first coordinated effort to address the ethical, legal and social implications of scientific research conducted prior to the conclusion of such research. n68 Although access to an individual's genetic defect may prove advantageous to the patient for diagnostic purposes, the risk of access by commercial entities, particularly insurance companies, n69 consternates researchers, academics and legislators alike.

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n65. See Patrinos & Drell, supra note 15, at 8 (discussing issues including: (1) fair use of genetic information; (2) impact on genetic counseling and medical practice; (3) effects on personal reproductive decisions; (4) past uses and abuses of genetic information; (5) privacy implications of personal genetic information; and (6) commercialization and intellectual property protection of genome results); see also Holmes, supra note 10, at 519-20 (discussing the patentability of DNA sequences identified by the HGP); James E. Bowman, The Road to Eugenics, 3 U. Chi. L. Sch. Roundtable 491, 491 (1996) (discussing the possibility of a new eugenics movement); Wendy McGoodwin, A Look at ... DNA Dilemmas, Wash. Post, May 5, 1996, at C3 (describing the situation where an health maintenance organization (HMO) told a pregnant woman whose fetus tested positive for CF that the HMO would not cover the infant under the family's medical policy if the expectant mother chose to carry the pregnancy to term). \par\par

n66. See Patrinos & Drell, supra note 15, at 8. \par\par

n67. See O'Hara, supra note 15, at 1215; Holmes, supra note 10, at 518-19.

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n68. See id. (noting that 'the ELSI program can contribute to the integration of HGP results in ways that are less disruptive, painful, or destructive than the manner in which genetic information has been used' in the past'). \par\par

n69. See O'Hara, supra note 15, at 1215. \par\par

n70. See Paul Recer, Group Warns Against Genetic Bias, Denv. Post, Mar. 21, 1997, at A14, available in 1996 WL 6067905 (noting concerns expressed by researchers); Slaughter Testimony, supra note 3, at 10 (discussing several cases of genetic discrimination by health insurers); Nancy E. Kass, The Implications of Genetic Testing for Health and Life Insurance, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 299, 299 (Mark A. Rothstein ed., 1997) (noting concerns expressed by academics). \par

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III. CONSEQUENCES OF THE HGP\par

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Technological advances in genomic research and electronic manipulation of information make access to genetic information potentially unlimited. n71 Furthermore, a generally porous medical information system in which the traditional norm of confidentiality has all but deteriorated, inadequately protects privacy interests in medical records. n72 Concerns about maintaining the privacy, integrity and accuracy of genetic information are further exacerbated by the establishment of genomic databases such as the Genome Data Base (GDB), a global repository for genome mapping data. n73 For example, genetic databases containing identifiers linking individuals with their genetic traits would seriously jeopardize genetic privacy. n74 Consequently, as detailed genetic information becomes widely available, many entities would have a financial stake in obtaining this information. n75\par

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n71. See Barrad, *supra* note 15, at 1047; Paul A. Lombardo, Genetic Confidentiality: What's the Big Secret?, 3 U. Chi. L. Sch. Roundtable 589, 589 (1996); see also Patrinos & Drell, *supra* note 15, at 7-8 (stating that electronic archives facilitate genetic data storage, provide increased access to research results and foster dissemination of information, leading to substantial increases in the number of individuals having access to medical information in electronic form). \par\par

n72. Lombardo, *supra* note 71, at 590; Mark Siegler, Confidentiality in Medicine - A Decrepit Concept, 1307 New. Eng. J. Med. 1518, 1518-19 (1982).\i0 \par\par

n73. See Patrinos & Drell, *supra* note 15, at 7. Genomic databases are in formantics tools developed to manipulate genetic information concerning the human genome, which if printed out in its complete letter sequence would fill 200 major city phone books. See *id.* at 7-8; see also The Consumer Protection and Medical Record Confidentiality Act of 1998: Hearing before the Subcomm. on Gov't Management, Info., and Tech. of the House Comm. on Gov't Reform and Oversight, 105th Cong. (1998) (testimony of Janlori Goldman, Director, Health Privacy Project Institute) (discussing concerns regarding the integrity of genetic information); David Brown, Individual Genetic Privacy' Seen as Threatened: Officials Say Explosion of Scientific Knowledge Could Lead to Misuse of Information, Wash. Post, Oct. 20, 1991, at A6 (discussing privacy concerns with respect to use of genetic information); Sally Lehrman, Genetic Privacy Debated Rapidly Developing New Technology Raises Questions, S.F. Examiner, Nov. 21, 1990, at B1, available in 1990 WL 7773740\i0 (discussing concerns over the accuracy of genetic information). \par\par

n74. See George J. Annas, Privacy Rules for DNA Databanks: Protecting Coded Future Diaries, 270 JAMA 2346, 2346 (1993).\i0 But cf. Lisa L. Dahm, Using DNA Profile as the Unique Patient Identifier in the Community Health Information Network: Legal Implications, 15 J. Marshall J. Computer & Info. L. 227, 254-55 (1997) (arguing that the effect of electronic medical records and DNA fingerprints on individual privacy would be minimal). \par\par

n75. See Mark A. Rothstein, Discrimination Based on Genetic Information, 133 Jurimetrics J. 13, 13-14 (1992)\i0 \i5Bhereinafter Jurimetrics\i5D (listing entities interested in receiving genetic information, including insurers, employers, mortgage lenders, educational institutions, adoption agencies, potential

business partners and courts involved in custodial disputes).

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Unveiling vast amounts of information about the human genome will invariably lead to various forms of genetic discrimination.ⁿ⁷⁶ Specifically, employees and insurers may believe that genetic discrimination is warranted for business profitability.ⁿ⁷⁷ Therefore, people taking genetic tests may face a serious risk of genetic discrimination.ⁿ⁷⁸ The risks of discrimination can adversely affect them as well because families share genomic information.ⁿ⁷⁹ The potential abuse of genetic discrimination in the employment and insurance contexts concerns some scholars,ⁿ⁸⁰ and may be the civil rights battle of the next century.ⁿ⁸¹

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ⁿ⁷⁶. Genetic discrimination has been defined as discrimination against an individual or against members of that individual's family solely because of real or perceived differences from the 'normal' genome in the genetic constitution of the individual.ⁿ⁷⁷ George P. Smith II, Accessing Genomic Information or Safeguarding Genetic Privacy, 9 J.L. & Health 121, 124 (1994-95) (quoting Marvin R. Natowicz et al., Genetic Discrimination and the Law, 50 Am. J. Hum. Genetics 465, 466 (1992)). Genetic discrimination is not based on any notion of the present function of the individual, because the discriminating party relies on that individual's genotype to assess the probability of future risks. See id. at 124 n.15. For examples of various forms of genetic discrimination, see Berry, supra note 43, at 209; Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 11-12 (1996) (statement of Rep. Jim McDermott) ⁿ⁷⁸hereinafter McDermott Testimonyⁿ⁷⁹. \par\par

ⁿ⁷⁷. Smith, supra note 76, at 124. Employers and insurers normally have access to detailed medical records of employees and customers. See id. at 124-25. Consequently, discrimination cases based on the dissemination of genetic information to official or private entities will shortly be heard in courts across the country. See Patrinos & Drell, supra note 15, at 5. \par\par

ⁿ⁷⁸. See Casey, supra note 28, at 14; see also infra text accompanying notes 82-85 (noting how genetic discrimination may arise). \par\par

ⁿ⁷⁹. See Casey, supra note 28, at 14; see also Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 79 (1996) (statement of Karen Rothenberg, Director, Law & Healthcare Program, University of Maryland School of Law) ⁿ⁸⁰hereinafter Rothenberg Testimonyⁿ⁸¹ (stating that the risk of misusing genetic information is significant and unique because of the information's intergenerational impact); Hudson et al., supra note 4, at 393 (discussing third parties' ability to obtain sensitive genetic information about individuals, families and even populations). \par\par

ⁿ⁸⁰. See Hudson et al., supra note 4, at 391 (describing the plight of a father unable to obtain insurance for his four-year-old son who was fatally diagnosed with a genetic predisposition for long QT syndrome); Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 Hous. L. Rev. 23, 27 (1992) (reporting on considerable anecdotal evidence of genetic discrimination in employment); see also Bornstein, supra note 20, at 564-68 (reporting various studies detailing genetic discrimination by health insurers, concluding that millions of Americans are at risk of losing h

health coverage as a result of carrying genes that make them vulnerable to diseases); Joyce Lain Kennedy, Genetic Testing in the Workplace Holds Potential for Discrimination, Buff. News, Aug. 23, 1997, at A13 (expressing concerns about the potential impact of employer-mandated testing). \par\par

n81. Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing on H.R. 2690 Before the Subcomm. on Tech. of the House Comm. on Science, 104th Cong. 4 (1996) (statement of Rep. Cliff Stearns) \5Bhereinafter Stearns Testimony\5D. \par

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Insurers have already genetically discriminated against consumers by declining coverage. n82 The extent and degree of such genetic discrimination by insurers will increase absent preventative legislation because HGP developments in predicting a person's health will greatly affect the pricing and availability of individual and group insurance. n83 Accordingly, several major insurers have made substantial investments in developing genetic tests for potential screening programs and will likely increase such investments as genetic testing of applicants becomes more feasible. n84 Therefore, the HGP and the knowledge that it reveals about the human genome have had, and will continue to have, serious implications for the health insurance industry. n85\par

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n82. For example, a young attorney from Ohio, Theresa Morelli, was denied disability insurance because her father suffers from HD. See Myk Cherskov, Fighting Genetic Discrimination, A.B.A. J., June 1992, at 38, 38. Although Morelli has not received genetic test results indicating that she has the Huntington's genotype, she has a 50% chance of inheriting the debilitating disorder. See id.; see also Theresa E. Morelli, Genetic Discrimination by Insurers: Legal Protections Needed from Abuse, HealthSpan, Sept. 1992, at 8 (describing Morelli's experience with genetic discrimination); Bornstein, supra note 20, at 565-66 (describing example of an eight-year-old girl who tested positive for phenylketonuria at birth who was denied insurance, despite the fact that she is asymptomatic).

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n83. See Cherskov, supra note 82, at 38; see also O'Hara, supra note 15, at 1220 (noting that genetic discrimination by insurers will likely increase because experts predict genetic screening will seep into insurance underwriting); Morelli, supra note 82, at 10 (stating that unless state and federal laws ban genetic discrimination, insurance companies will continue to insure only the genetically healthy in order to maximize profits). \par\par

n84. See Morelli, supra note 82, at 10. \par\par

n85. See Berry, supra note 43, at 209. Inevitable genetic discrimination litigation will likely affect insurance industry practices. See George J. Annas, Genetic Prophecy and Genetic Privacy, Trial, Jan. 1, 1996, at 19, 20. Furthermore, the genomic information age may bring other profound changes to the insurance industry. See Berry, supra note 43, at 209. For example, if insurance companies are not given access to genetic information, the consequence may be the end of insurance because insureds predisposed to cost-intensive afflictions will not be assessed a proportional premium and \22an adverse selection spiral will result ... \5Bthat\5D may well conclude with the insurance company's insolvency.\22 Id. at 218. However, even if insurance companies have access to the genetic information, the consequence may still be the end of insurance, because the insurance mechanism is premised on the insureds' guarding against financial loss.

ss associated with vulnerability and ignorance about diseases, which will inevitably be reduced with increased knowledge through genetic testing. See id. at 209.

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The specter of genetic discrimination by insurers extends beyond the problem of health care availability for genetic discrimination victims. First, people may refuse potentially life-saving genetic testing services because they fear repercussions to their health insurance coverage.⁸⁶ Second, cost-containment pressures may compel insurers to refuse to pay medical costs if an individual elects not to undergo a certain treatment, or if a child with a prenatally identified genetic defect is born.⁸⁷ Fear of genetic discrimination may also chill voluntary participation in genomic research, ironically hampering the research providing insurers with the means to discriminate.⁸⁸ Finally, genetic discrimination by employers is a byproduct of genetic discrimination by health insurers.⁸⁹

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⁸⁶. See Rothstein, supra note 80, at 66-67. Alternatively, some people pay cash for their genetic testing so that no insurance claim is submitted, which keeps insurers and employers ignorant of the existence of any genetic test results that may be used for discriminatory purposes. See id.; see also O'Hara, supra note 15, at 1222 (stating that some people who believe that they may be carriers of disease-causing genes have declined new genetic testing for fear of putting "black marks" on their medical records and losing insurance coverage).

⁸⁷. Barrad, supra note 15, at 1046. For a discussion of cost-containment pressures on insurance providers, see Jurimetrics, supra note 75, at 15-16 (reporting the findings of a study indicating that about 5% of health insurance claimants represent about 50% of healthcare expenditures, while the top 10% of health insurance claimants represent 75% of expenditures. Excluding even a few of these potential claimants could save substantial sums of money for insurers and self-insured employers).⁸⁸

⁸⁸. See Stearns Testimony, supra note 81, at 4.

⁸⁹. See Barrad, supra note 15, at 1046 (discussing the problem of genetic discrimination by insurers and employers).

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Genetic discrimination by employers may be viewed as a subset of health-based genetic discrimination ... and is already a significant problem and likely to get much worse because of the economic pressures placed on employers to reduce health care expenditures.⁹⁰ A 1990 report issued by the congressional Office of Technology Assessment found that although companies did not intend to screen applicants genetically in the near future, cost-containment pressures would eventually lead employers to genetically discriminate.⁹¹ Furthermore, employers may genetically discriminate against employees or job applicants for reasons indirectly related to job performance and health care cost containment.⁹² Genetic discrimination by employers decreases the availability of health care and thus places greater strain on the public treasury.⁹³ Public reaction decrying genetic discrimination prompted state

legislators to respond with various genetic discrimination laws and bills. n94

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n90. Rothstein, *supra* note 80, at 28. For example, from 1985 to 1991, employer health insurance costs per employee increased from \$1,724 to \$3,605 per year. See *id.* Moreover, insurance costs continue to increase at least 10% to 20% a year. See *id.* To streamline costs, both large, self-insured companies and small-to-medium sized, experience rated companies are acting much like commercial health insurers who have financial incentives to screen out health risks. *Id.* at 29-30; see also Jurimetrics, *supra* note 75, at 15 (remarking that if employers have been placed in the role of health insurance underwriters, then it is hardly surprising that some of them are behaving as an insurance company behaves - limiting costs by excluding those at high risk. Furthermore, if some employers are willing to screen out people based on the factors ... then scientific genetic screening would have great appeal.). \par\par

n91. See Rothstein, *supra* note 80, at 26-28 (discussing the 1989 survey Office of Technology Assessment (OTA) conducted of Fortune 500 companies, large utilities and major unions). This study found that of the 330 companies that responded, only 12 reported using biochemical genetic screening and none anticipated using direct DNA screening over the next five years. See *id.* at 26. However, OTA's separately published survey data indicated that 42% of employers considered applicants' health risks in hiring decisions. See *id.* at 27. Additionally, 36% of employers took a proactive role in assessing applicants' health insurance risks. See *id.* These numbers are evidence of the growing concern among employers over the rising costs of employee health insurance, and the increased efforts to reduce these costs to the employer, which is likely to increase the scope of health insurance screening in the workplace. *Id.* at 28. Thus, OTA concluded that employers may increase genetic testing to identify applicants with atypical subsequent health care demands as a means of health insurance cost-containment. See *id.* at 27-28. \par\par

n92. See Smith, *supra* note 76, at 125-26. Reasons for genetic discrimination by employers include increased medical and insurance premiums, absenteeism, lowered productivity, increased risk in the line of duty and increased liability for workers compensation. See *id.*; see also Melanie Payne, Genetic Fears, *Chi. Trib.*, Apr. 29, 1998, at 7 (quoting Mark Rothstein as stating that employers have a tremendous economic incentive to discriminate based on perceived future health status ... because the key motivation for employers is to save money on health costs.). \par\par

n93. See Jurimetrics, *supra* note 75, at 15. If the employment system is unable to create adequate levels of health care coverage, more people will become uninsured, underinsured, or placed on public health finance, leading to more cost-shifting to the remaining private payers underwriting uncompensated care. See *id.* Furthermore, genetic discrimination seems to fly in the face of the letter and spirit of our antidiscrimination laws. *Id.* \par\par

n94. See O'Hara, *supra* note 15, at 1224. See *infra* Part VI for discussion of various legislative proposals targeting genetic discrimination. \par
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IV. ARGUMENTS FOR LEGISLATION PROHIBITING GENETIC DISCRIMINATION\par

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Proponents of legislation prohibiting genetic discrimination make several pers

uasive arguments to support their position. First, they argue that genetic information creates too much potential abuse by insurers and employers. n95 Genetic discrimination by insurers would increase the number of uninsurable people, n96 and would unfairly limit affordable health care to people already genetically predisposed to remain healthy. n97 Likewise, employers may increasingly use genetic tests to screen applicants and employees. n98 Reports of genetic discrimination already abound in the popular press. n99 Consequently, those individuals born with 'defective' genes may face denial of both health insurance and employment opportunities, creating a 'biologic underclass.' n100 Moreover, not only will genetic discrimination deny people employment and insurance, but it may also shift costs onto society. n101

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n95. See Holmes, supra note 10, at 558-63 (discussing abuses by insurers); Katherine Brokaw, Genetic Screening in the Workplace and Employer's Liability, 23 Colum. J.L. & Soc. Probs. 317, 317-18 (1990) (discussing abuses by employers). \par\par

n96. See McDermott Testimony, supra note 76, 11 (stating that 'since we all carry some genetic mutations, the scenario of genetic discrimination by health insurers' carried to its conclusion would leave us all uninsurable'). \par\par

n97. See Holmes, supra note 10, at 558. Individuals with the least need for health insurance will be able to obtain comprehensive coverage at reasonable rates, whereas those with genetic predispositions for illness may be unable to afford their insurance premiums or may be denied insurance altogether. See id.; see also Berry, supra note 43, at 254 (predicting that as 'the HGP progresses and genetic testing advances in its wake, the class of those excluded from the benefits of insurance will grow'). \par\par

n98. See Barrad, supra note 15, at 1046-47. Employers may attempt to use genetic information to ascertain whether a prospective employee is 'predisposed to job-related disabilities, low productivity, or absenteeism.' See id. Employers will be increasingly tempted to use genetic screening tests 'in the face of pressure from insurers and top management to cut medical costs.' See Brokaw, supra note 95, at 318. \par\par

n99. See, e.g., Dana Hawkins, Dangerous Legacies: New Gene Tests Provide Fresh Grounds for Discrimination, U.S. News & World Rep., Nov. 10, 1997, at 7; David Stipp, Health: Genetic Testing May Mark Some People as Undesirable to Employers, Insurers, Wall St. J., July 9, 1990, at B1; David Smith, Rite and Reason, Irish Times, June 4, 1996, at 12, available in WL 10575420. \par\par

n100. See O'Hara, supra note 15, at 1212. In essence, genetic discrimination by insurers and employers 'penalizes those who do not conform to the institutional norm of 'healthy' individuals.' See id.; see also Brokaw, supra note 95, at 319 (stating that 'genetic screening in the workplace has undeniable potential for ... the 'leperizing' of hundreds of thousands of American workers ... 'And that genetic information could' become a substantial barrier to employment with little basis other than the fears, prejudices and misunderstandings of people who know little about genetics'). \par\par

n101. See Brokaw, supra note 95, at 320; see also Morelli, supra note 82, at 8 (stating that insurers 'shift the risk to individuals and ultimately to the taxpayers when uninsurable and impoverished people are forced onto Medicaid'). \par

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For many people, denial of health insurance may be the equivalent of denying them health care itself. n102 Denial of insurance based on genetic test results seriously threatens access to health care, n103 something greatly valued by Americans. n104 Concern about continued access to health insurance, and thus health care, is a major reason for many genetic discrimination bills. n105 Therefore, the public policy of maintaining health care access for most Americans represents an underlying rationale for genetic discrimination bills.

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n102. See Morelli, *supra* note 82, at 8. \par\par

n103. See *id.* Because private health insurance is the means by which many Americans pay for health care, genetic discrimination resulting in uninsurability leads to a denial of health care for a large number of people. See Bornstein, *supra* note 20, at 577; Kass, *supra* note 70, at 299, 305. \par\par

n104. See Alan I. Widiss & Larry Gostin, What's Wrong with the ERISA '22 Vacuum'?: The Case Against Unrestricted Freedom for Employers to Terminate Employee Health Care Plans and to Decide What Coverage is to be Provided When Risk Retention Plans are Established for Health Care, 41 Drake L. Rev. 635, 636 (1992). \par\par

n105. See Lombardo, *supra* note 71, at 613. Genetic discrimination is one part of a much larger problem of competitive risk-rating, which puts many potential policyholders beyond the ambit of insurance coverage. See *id.* Until this problem is fixed, 'the attempt to carve out some portion of the public for unfavorable treatment because of medical condition - genetic or not - will remain endemic.' See *id.* \par\par

n106. See Holmes, *supra* note 10, at 565. If insurers are not permitted to calculate known genetic risks of individuals seeking health insurance coverage in rate setting, then the insurers will be forced to distribute the costs for present and future diseases more evenly among their insureds. See *id.* at 567. \par

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The majority of genetic diseases are polygenic n107 and multi-factorial. n108 This complexity undermines the utility of genetic testing because test results may only indicate a predisposition for a disease, not a conclusive diagnosis.

n109 Furthermore, genetic tests inaccurately predict 'an illness' severity or age of onset, and do not reflect the role environmental factors play in the manifestation of diseases with a genetic component. n110 Therefore, because many people have genes for various diseases that may or may not develop into illnesses, insurers may incorrectly place unwarranted reliance on genetic tests.

n111 Genetic tests only indicate a genetic predisposition for disease based on the presence or absence of a specified genotype. n112 The ambiguous nature of the test results, because of the multi-factorial nature of most genetic diseases, strongly supports legislation prohibiting genetic discrimination. n113\par

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n107. See Suzuki & Knudtson, *supra* note 4, at 347. Polygenic means 'controlled by or associated with more than one gene.' See *id.* \par\par

n108. See Holmes, *supra* note 10, at 527. There are basically four types of genetic anomalies. See *id.* at 527-29. First, monogenic disorders involve 'one improperly functioning gene.' See *id.* at 527-28. Although there are 3,600 monogenic disorders, only 'three percent of the population will develop a single gene disease.' See *id.* at 528. Second, chromosomal disorders result from an abnormal chromosomal number or structure (i.e., Down's Syndrome). See *id.* Third, there are noninherited disorders with 'genetic changes occurring during one's lifetime,' such as cell mutation leading to cancer. See *id.* at 528-29. Finally, multi-factorial disorders comprise the 'largest genetic-disorder classification' and are diseases that 'result from the interaction of environmental factors and many abnormal genes presumably on different chromosomes.' See *id.* at 528. Heart disease is an example of a multi-factorial genetic disorder. See *id.* \par\par

n109. See *id.* at 529. In the majority of cases, the results of genetic tests simply reflect an increased or decreased susceptibility to a particular disease or to diseases associated with environmental influences. See *id.* Furthermore, despite links made between diseases and genes, 'the degree of severity, timing of onset, or whether the disease will ever manifest itself at all, remain a matter of statistical probability.' See *id.* Therefore, most genetic test results reflect probabilities and are less conclusive than one may assume. See *id.* \par\par

n110. See Bornstein, *supra* note 20, at 569-71. \par\par

n111. See O'Hara, *supra* note 15, at 1218-19. \par\par

n112. See Holmes, *supra* note 10, at 524; Frances H. Miller & Philip A. Huvos, Genetic Blueprints, Employer Cost-Cutting, and the Americans with Disabilities Act, 46 Admin. L. Rev. 369, 372 (1994). \par\par

n113. See Graves, *supra* note 45, at 3. For example, gene tests 'rarely provide definitive information about the function of particular genes' because they only indicate an abnormality in one gene, and are thus unable to predict the onset of a disease caused by the interaction of several genes. See *id.* \par

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'456' Furthermore, the ambiguities inherent in genetic test results make them unreliable for use in insurance and employment decisions because 'insurers may misunderstand, misinterpret, and misuse genetic information in creating risk classifications and excluding or limiting insurance coverages.'

n114 Genetic test results do not accurately indicate health risk because such testing fails to provide information about a person's 'actual state of health.'

n115 Additionally, genetic tests are often given greater weight than they deserve, and thus 'what frightens many people is that given scientists' limited understanding of how genetic systems work, insurers will misuse genetic information.'

n116 Genetic tests differ from other medical tests in that they do not reveal existing health problems, only a likelihood of susceptibility. n117

Accordingly, a 1995 report issued by NIH's National Center for Human Genome Research cautioned against over-reliance on genetic test results. n118\par

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n114. See Holmes, *supra* note 10, at 530. Historically, misinterpretation and subsequent misuse of genetic information has caused unreasonable discrimination, most notably in the 1970s among the population carrying the sickle cell trait. See Cushing, *supra* note 28, at 258. \par\par

n115. See Holmes, supra note 10, at 530. \par\par

n116. Cushing, supra note 28, at 258. Despite their imperfections, genetic tests are accorded an illusion of precision. See O'Hara, supra note 15, at 1215-16. Thus, the danger in genetic testing lies not in the test's imperfect powers of prediction, but rather in the hasty adoption of unreliable test results by institutions eager to minimize costs in a health care system where costs are rising at the rate of twenty percent per annum.'22 See id. at 1216.

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n117. See Bornstein, supra note 20, at 559; see also Casey, supra note 28, at 17 (explaining that genetic test results are difficult to interpret because they only provide a predictive guess). \par\par

n118. See Holmes, supra note 10, at 530-31. The report further warned against two major misinterpretations of genetic information: reductionism and determinism. See id. at 531. Reductionism occurs when genetic test results reduce particular traits to the '22expression of particular genes'22 and neglect to consider fully the importance of external factors. See id. Determinism occurs when an individual is '22inappropriately'22 labeled as '22sick or abnormal.'22 See id. \par

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Everyone has a few bad genes. n119 Given the universality of genetic defects, genetic discrimination by insurers '22will threaten the viability of the insurance industry.'22 n120 As '22insurance companies force individuals to gain and reveal knowledge about their health futures,'22 insurers will increasingly eliminate potential insurance consumers. n121 However, assuming that insurers have an interest in balancing genetic information with their financial self-interest, insurers will more likely attempt to use genetic information to eliminate claims rather than consumers. n122 Thus, because everyone has a few bad genes, insurers would not eliminate all insureds from the insurance pool, but would probably eliminate coverage for specific conditions for each insured. n123\par

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n119. See O'Hara, supra note 15, at 1224. It is estimated that every human being has between four to eight genetic defects. See id. \par\par

n120. See Berry, supra note 43, at 232. \par\par

n121. See id. \par\par

n122. See id. at 236. \par\par

n123. See id. at 235-36. For example, insurers may agree to insure an individual genetically predisposed to heart disease, but contractually exclude coverage for claims involving heart disease. See id. The strategy reflects the fact that insurers lack the economic motivation to eliminate every insured with genetic defects because that would completely eliminate the market for insurance, and that insurers have an economic incentive to write as many policies as possible. See id. at 232. \par

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Insurers contend that the threat of adverse selection makes necessary underwriters' use of genetic information. n124 However, this argument is unpersuasive. '5B*457'5D First, if all insurers were denied the use of genetic information, then insurers as a class would be equally subject to the additional cost

s associated with adverse selection. n125 Thus, if all insurers were proportionally affected by adverse selection, then no single insurer would be at a competitive disadvantage relative to the health insurance industry as a whole. n126 Furthermore, insurance is a method of risk-sharing against the unknown, and the more the unknown becomes knowable in advance, the less the current system makes sense. n127 Accordingly, the insurance system should be restructured to accommodate the ability to predict future risks. n128 Denying insurers the use of genetic information provides a powerful economic incentive to develop alternative insurance mechanisms accommodating both insurers' desire to avoid adverse selection and insureds' desire to protect genetic information. n129 The insurance industry must develop a system that spreads genetic risk across the entire pool of insureds to ensure the continued insurability of people with genetic predispositions. n130\par

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n124. See infra notes 157-62 and accompanying text (discussing the use of adverse selection by insurers). \par\par

n125. See Richard H. Underwood & Ronald G. Cadle, Genetics, Genetic Testing, and the Specter of Discrimination: A Discussion Using Hypothetical Cases, 85 Ky. L.J. 665, 686 (1996-97). \par\par

n126. See id. \par\par

n127. Bornstein, supra note 20, at 609. \par\par

n128. See id. \par\par

n129. Universal health care may alleviate the problem of adverse selection caused by genetic discrimination legislation. See Bornstein, supra note 20, at 609 n.299. Since medical underwriting is unnecessary in universal health care, it would eliminate the need for the disclosure of genetic information. See id. Insurers could also adopt genetic community rating, a variant of community rating. Cf. John V. Jacobi, The Ends of Health Insurance, 30 U.C. Davis L. Rev. 311, 316 (1997) (discussing use of community rating by Blue Cross in the 1930s). Community rating involves charging all insureds a premium based on the average risk experienced by people living in a particular community. See id. Genetic community rating, however, would only be successful in a competitive insurance market if legislation prevents insurers from using genetic information to offer cheaper insurance to insureds. Cf. Jacobi, supra, at 316 (discussing commercial insurers' attempt to undermine Blue Cross's market by charging low-risk groups based on experience rating rather than community rating). Moreover, insurers could adopt insurance pooling arrangements to cover high-risk insureds. Cf. Robert Lowe, Genetic Testing and Insurance: Apocalypse Now?, 40 Drake L. Rev. 507, 515 (1991) (discussing state plans pooling those who have been rejected by insurers and whose premiums are exorbitantly high, require insurers to pay into the pool and then charge the insurers a separate fee to make up for any shortfalls in the pool). State legislatures could require insurers to cover a percentage of high-risk insureds in proportion to each insurer's market share thereby eliminating adverse selection. See id. Pooling insurance for genetic risk assumes that genetic information would be available to insurers and would thus be a compromise between absolute genetic privacy and unrestricted access to genetic information. Cf. Holmes, supra note 10, at 543 (suggesting that insurers and insureds should have equal access to relevant genetic data to avoid unfairness to insurers and adverse selection by insureds). Alternatively, insurers could determine the average or median levels of insurance and charge a premium reflecting the increased costs of health insurance associated with adverse selection to all insureds purchasing insurance coverage who fall too

far outside of a predetermined range. Cf. *id.* at 540 (suggesting that rates should discriminate fairly among insureds to reflect their health status). \par\par

n130. Otherwise, the people most in need of health insurance will be unable to acquire it. See Cushing, *supra* note 28, at 257. \par

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Genetic discrimination unfairly discriminates because of the involuntary and presently immutable nature of our genetic endowment. n131 Accordingly, this immutability provides an inequitable basis on which to make insurance and employment decisions. n132 Furthermore, insurance availability predicated on genetic effects exacerbates the present inequality of health care distribution n133 by providing \5B*458\5D health care to those people least in need of it. n134

It is inherently unfair to require people to pay more for insurance because of poor genetic make-up because the \22American concept of fairness centers on our right of voluntary choice and our correlative responsibility for the freedom to choose\22 and because the human genome is not a product of volition. n135\par

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n131. See Holmes, *supra* note 10, at 563-64. However, gene therapies may soon change this immutable nature. See *supra* notes 48-49 and accompanying text (noting the promise of gene therapy). \par\par

n132. See Holmes, *supra* note 10, at 516. Moreover, because \22genetic differences are morally arbitrary, the notion of good or bad genetic luck ought not be the reason that one person receives better or worse insurance\22 coverage. *Id.* at 564. \par\par

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n133. See Hudson et al., *supra* note 4, at 391. The high costs of health care in the United States make insurance coverage necessary in order to access health care. See *id.* \par\par

n134. See Cushing, *supra* note 28, at 258. Essentially, \22\22genetically healthy\22 people who do not need health insurance will be able to get it at a reduced premium rate, \5Bwhile\5D the vast majority who do not need health insurance will not be offered the chance or will not be able to afford what's offered.\22 *Id.* at 257. \par\par

n135. See Holmes, *supra* note 10, at 563. \par

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Americans have an expectation of privacy, or the \22right to be let alone.\22 n136 Genomic privacy is the right to make an informed determination regarding whether to release genomic information and to whom. n137 The HGP and contemporary technological abilities to store, retrieve and transmit data will seriously challenge our right to genetic privacy, and will likely lead to widespread dissemination of genetic information. n138 Therefore, \22the sensitivity of genetic information and the importance Americans historically place on privacy and self-determination argue strongly for a policy that does not hold access to health care hostage to one's willingness to reveal or to discover intimate facts about oneself.\22 n139 Consequently, insurers' access to genetic information threatens genetic privacy and people's right to determine whether they want to be genetically tested.\par

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n136. See Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 Harv. L. Rev. 193, 193 (1890).

n137. See Bornstein, *supra* note 20, at 572; see also Cushing, *supra* note 28, at 258-59 (noting that "genetic information is fundamentally different from other types of medical information readily accessible to insurers because the immutable quality of genetic information sets it apart from other sorts of medical information, such as a person's blood pressure or cholesterol level").

n138. See Annas, *supra* note 74, at 2346; Holmes, *supra* note 10, at 570-71. Modern technology provides insurers with practical and possibly clandestine means of obtaining, storing, organizing, retrieving and disseminating genetic and other actuarial data about applicants and policyholders. See Holmes, *supra* note 10, at 570-71. A justifiable fear arises that widespread delineation of genotypes and genetic profiles may, like credit information, culminate in centralized genetic information databases.

n139. Holmes, *supra* note 10, at 565 (quoting NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, National Center for Human Genome Research, Genetic Information and Health Insurance, Report of the Task Force on Genetic Information and Insurance 12 (1993)).

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Autonomy represents an individual's right not to know their genetic information. n140 Some choose to avoid knowing their genetic make-up because serious consequences may accompany the acquisition of genomic information. n141 This desire is further exacerbated by the lack of effective treatment for diagnosed diseases and the inability to erase knowledge acquired from genetic test results. n142 Consequently, if insurers and/or employers could mandate genetic testing, individuals would lose their freedom not to know their genomic information. n143 Thus, mandated genetic testing threatens autonomy. Mandated testing also forces people to discover genomic knowledge regarding their future lives and deaths. n144 Such revelations may be damaging to people psychologically if they are unprepared for what they learn about their mortality. n145

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n140. See *id.* at 574. Genetic autonomy is defined as "the right of persons to make an informed, independent judgment about whether they wish to be tested, including whether they wish to know the results of the genetic test." See Bornstein, *supra* note 20, at 572.

n141. See Bornstein, *supra* note 20, at 573.

n142. See *id.*

n143. See *id.* at 575.

n144. See Annas, *supra* note 85, at 19.

n145. See Marilyn Chase, *Genetic Testing Needs Clear Plans for How to Handle Treatment*, Wall St. J., Feb. 26, 1996, at B1.

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Unregulated access by insurers and employers to genetic information, or their abilities to mandate genetic testing, creates potential psychological harm. n

146 Potentially unlimited psychological harms resulting from genetic information abuses include: anxiety caused by inaccurate testing; a stigmatic effect; and the harm caused by revealing information about an individual's immutable genome and, in a sense, their mortality. 147 Unadvised revelation of such information can be devastating, affecting every facet of a person's life. 148

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146. See Holmes, supra note 10, at 571-72. \par\par
147. See id. at 571-73. Although genomic information is not dispositive of a person's future health, people place the same over-reliance on the value of genetic testing results that insurers and employers do, and may thus cause themselves unnecessary angst. See id. at 572-73. Having knowledge about one's own genetic make-up may have a devastating psychological impact when the individual is told that he or she will develop a fatal, incurable disease. See id. Historical experience with sickle cell anemia in the 1970s exemplifies the psychological damage that injudicious use of genetic information can cause. See id. at 572.

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148. See id. at 573. The genetic information may adversely affect an individual's decisions regarding education, work, marriage and reproduction. See id.

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V. ARGUMENTS AGAINST LEGISLATION PROHIBITING GENETIC DISCRIMINATION\par
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Interest groups, primarily insurers and employers, 149 advocating against legislation prohibiting genetic discrimination 22 argue that they should not be legislatively prohibited from including genetic test results in their actuarial assessments 22 and employment decisions. 150 Insurance underwriters 151 attempt to 22 fairly discriminate 22 152 between policyholders to ensure that policyholders presenting 5B*460 5D lower risks pay lower premiums. 153 Insurers contend that genetic information is merely a more refined method of risk classification and therefore more equitable to those insureds posing lower risk. 154 Furthermore, insurers argue that prohibiting the use of genetic information to create accurate risk classifications will ultimately undermine the financial solvency of insurers. 155 Although insurers acknowledge the discriminatory nature of genetic testing in its application to insurance underwriting, they argue that it is a business necessity and that it is 22 fair discrimination because it is based on sound actuarial analysis. 22 156

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149. Although arguments for the right to discriminate genetically against certain individuals are primarily made by insurers, they apply with equal force to employers inasmuch as employers provide health care to employees and are thus similarly interested in containing the cost of health care. See id. at 557. Furthermore, employers are also interested in genetically discriminating against individuals to increase job-related productivity. See Kimberley Nobles, Note, Birthright or Life Sentence: Controlling the Threat of Genetic Testing, 65 S. Cal. L. Rev. 2081, 2089 (1992). 10 \par\par

150. See Holmes, supra note 10, at 557. \par\par
151. For a general discussion of the mechanics of underwriting in the insurance industry, see Berry, supra note 43, at 216-18, and Roberta B. Meyer, Justi

fication for Permitting Life Insurers to Continue to Underwrite on the Basis of Genetic Information and Genetic Test Results, 127 Suffolk U. L. Rev. 1271, 1279 (1993). Underwriting is done in the individual insurance market when the private health insurance industry offers two types of insurance: individual health policies and large employer group health policies. See Holmes, *supra* note 10, at 533-34. Approximately 90% of private health insurance policies are group policies, with the remaining 10% comprised of individual policies or policies for small groups of fewer than 10 to 15 people. See *id.* Medical underwriting generally only occurs for individual and small group policies and not for large group policies. See *id.* at 534. Because of their ability to average utilization over a large number of employees, large employer groups customarily are not medically underwritten. *Id.* Moreover, new employees working for large employers are eligible for coverage without medical underwriting by the insurer. *Id.* The group's insurance premiums will vary based on the group's size because large groups are experience rated, whereby the insureds' premiums change based on their total claims. See *id.* As such, these large groups are typically not denied health insurance due to the poor health of some employees or their dependents. See *id.* Hence, concern over genetic discrimination is greatly diminished when medical premiums are based on experience rather than calculated through underwriting. *Id.*

152. See Holmes, *supra* note 10, at 531-34. Fair discrimination requires efficient, actuarial analysis establishing risk transference and risk distribution, which are the keys to understanding insurance underwriting. See *id.* at 531. Insurance, by its nature, is discriminatory because individuals with a higher risk are routinely charged a higher premium. See *id.* at 533. Consequently, the goal of insurance underwriting is equity; that is, equitable, but not equal, treatment of applicants and policyholders. To achieve that goal, insurers must differentiate among policyholders by risk classifications and discriminate fairly so that each insured will pay a premium at a level consistent with the risk represented by each individual insured. *Id.*; see also Obinata, *supra* note 53, at 146-47 (discussing the necessity of genetic discrimination in the underwriting process to achieve fairness).

153. See Holmes, *supra* note 10, at 532.

154. See *id.* at 538. However, inasmuch as everyone has a few bad genes, no insured poses an absolutely lower risk, because all insureds pose a greater risk for some disease. See O'Hara, *supra* note 15, at 1224. Therefore, insurers would refine the risk classification to such a degree either that no insured would be able to afford health insurance or, alternatively, that no insured would be able to get insurance that covers whatever condition an individual insured would be predisposed to suffer. See Holmes, *supra* note 10, at 558.

155. See Holmes, *supra* note 10, at 534-35. Prohibiting insurers' use of genetic information yields two alternative scenarios:

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(1) If an insurer under-assesses risks, it will have insufficient funds to pay claims submitted unless it overcharges people who represent low risk. If insurers have inadequate funds and are unable to meet their contractual obligations to pay claims, the insurers will go bankrupt, leaving people uninsured. (2) If an insurer over-assesses risk and overcharges, the free market and competitive nature of business logically dictate that people will purchase insurance elsewhere. Thus, accurate risk assessment is essential to the business of insurance.

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Id. at 538; see also Meyer, *supra* note 151, at 1279 (discussing the possibility

y that deficient risk classification systems will make insurers insolvent); Obinata, supra note 53, at 149 (stating that "premium rates must be high enough to assure permanent financial security for the company and, at the same time, low enough to enable the company to be competitive").

n156. See Holmes, supra note 10, at 539 (discussing insurers' arguments supporting the view that genetic tests are efficient and equitably fair). However, the argument for equitable treatment of insureds fails for two reasons. First, risk underwriting is only used for the individual insurance market, which comprises just 10% to 15% of the total insurance market. See id. at 534. This relatively small size undermines the argument that under-assessing insureds will result in financial insolvency for the insurance industry. See id. Rather, insurers may be attempting to hide a naked desire to eliminate expensive policyholders from coverage or at least to limit coverage by excepting an insured's expensive condition. See Jill Gauding, Race, Sex and Genetic Discrimination in Insurance: What's Fair?, 80 Cornell L. Rev. 1646, 1651-52 (1995). Second, if all insurers were denied the ability to use genetic information in their risk classifications, then over-assessing premium rates would not result in a loss of business among insureds because all insurers would be similarly disadvantaged with respect to incorporating genetic information into actuarial analysis. See Jacoby, supra note 129, at 403. Preventing insurers from using genetic information will merely maintain the status quo because insurers have operated profitably for many years without the benefit of genetic information. See, e.g., Philip R. Reilly, Laws to Regulate the Use of Genetic Information, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 369, 374-79 (Mark A. Rothstein ed., 1997).

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Logical extension of the equitable treatment argument leads to the argument that prohibiting insurers from obtaining genetic information will encourage adverse selection, n157 which also evokes concerns of unfair subsidization and premonitions of widespread insurer insolvency. n158 Insurance industry advocates argue that genetic discrimination legislation will create a problem of information inequality between applicants/insureds and insurance companies. n159 Insurers suggest that the resulting imbalance in knowledge will cause them to increase premiums to cover expenses for high-risk insureds who disproportionately buy insurance, thus driving the low-risk insureds out of the market. n160 Consequently, insurers claim that they "would be left with a pool of increasingly unhealthy insureds, many of whom would not be paying appropriately high premiums." n161 Insurers believe that unchecked adverse selection based on an imperfect balance of genetic information will ruin the insurance industry. n162

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n157. Adverse selection is the tendency of insureds to apply for insurance based on the knowledge that the insured is in poor health, while concealing this fact from the insurer. See Cushing, supra note 28, at 254; Berry, supra note 43, at 217; see also Meyer, supra note 151, at 1289 (defining adverse selection as the "tendency of persons who are poorer risks to seek insurance to a greater extent than do persons who are better risks").

n158. See Cushing, supra note 28, at 254-55.

n159. Holmes, supra note 10, at 544.

n160. See Meyer, supra note 151, at 1290. Typically, applicants at a higher

risk for a specific disease would be more likely to seek insurance covering that disease than the average person. See Holmes, *supra* note 10, at 544. 'If insurers charge an equitably rated premium without knowledge of the high risk or charge an equal premium for all applicants, the high risk person will select to apply and obtain insurance in greater proportion than low risk people ... ' leading to a cycle of adverse consequences.' Id. This cycle starts with increased premiums resulting from greater claims made by high-risk individuals, leading to a discontinuance of insurance by low-risk insureds, which in turn leads to a residual of extremely high-risk insureds, which finally leads to another premium increase that renews the cycle. See *id.* However, this argument assumes that there are low-risk insureds to drive out of the health insurance market. See O'Hara, *supra* note 15, at 1224.

n161. Meyer, *supra* note 151, at 1290.

n162. See Holmes, *supra* note 10, at 545; see also Berry, *supra* note 43, at 218 (stating that the genetically spurred adverse selection price spiral may well conclude with ... 'an insurance company's insolvency').

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However, insurers' adverse selection argument has several problems. First, the adverse selection argument assumes that low-risk insureds will discontinue their insurance coverage because of increased premiums, although there is no explanation of where low-risk insureds would get alternative risk management services. n163 Second, insurers profitably insure the existing pool of insureds, a pool composed of the same low- and high- risk insureds whom they would ensure under a system not based on genetic information. n164 Third, adverse selection would only affect the ten percent of the insurance market that is medically underwritten. n165 Fourth, insurers may pool risk across the individual insurance market insureds because 'the actual financial losses for the pool will be close to the aggregate financial losses predicted for the pool by an insurance company.' n166 Finally, insurers may limit the effects of adverse selection by 'charging higher 'unfair' premiums only for policies offering unusually rich benefits that most people would not opt for unless they knew of a genetic defect. n167

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n163. Cf. Jacobi, *supra* note 129, at 389 (suggesting that 'even risk-averse, low-risk people will select the lower price offered by a risk-rated 'health insurance policy' rather than opting for no coverage at all).

n164. See Privacy of Individual Genetic Information, 1998: Hearings on S. 422 Before the Senate Comm. on Labor, 105th Cong. (1998) (statement of Senator Jim Jeffords) 'Hereinafter Jeffords 1998 Testimony'.

n165. See Holmes, *supra* note 10, at 555; Kass, *supra* note 70, at 300. Moreover, only a fraction of this 10% slice of the market involves monogenic diseases, see Holmes, *supra* note 10, at 536, which in turn represent only 3% of diseases. See Casey, *supra* note 28, at 16. Accordingly, insurers will probably only face increased costs from adverse selection by an extremely small fraction of the insurance market, which would not be enough to make the industry insolvent.

n166. Berry, *supra* note 43, at 221.

n167. See Alexandra K. Glazier, Genetic Predispositions, Prophylactic Treatments and Private Health Insurance: Nothing is Better Than a Good Pair of Genes,

23 Am. J.L. & Med. 45, 63-64 (1997); cf. Kirke D. Weaver, Genetic Screening and the Right to Know, 13 Issues in L. & Med. 243, 249 (1997) (discussing the impact of adverse selection on the insurance industry and the industry's response to the problem).

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Insurers also argue that genetic testing is not significantly different from many types of medical testing already used in underwriting. For example, underwriters presently incorporate medical history and tests as well as other risk factors making illness more or less likely. Therefore, employers and insurers contend that they should be allowed continued access to genetic information that they already have.

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n168. See Cushing, supra note 28, at 254.
n169. See Hudson et al., supra note 4, at 391.
n170. See Cushing, supra note 28, at 254.

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In many instances, employers have assumed the role of the insurance companies and thus have a strong financial incentive to reduce their health care expenditures by more accurately assessing health risks. As such, the employers' arguments in favor of genetic discrimination mirror those of the insurance industry. However, inasmuch as employers' interests diverge from those of insurers, they merit discussion. Employers argue that they have traditionally made hiring and promotional decisions predicated on occupationally-relevant physical and character traits, and that employers should be able to incorporate genetic information in making such decisions. Accordingly, employers contend that access to genetic information constitutes a business necessity in a competitive marketplace. Specifically, employers want genetic information in order to reduce potential costs resulting from their employees' job-related illnesses, absenteeism, sick leave, employee turnover and expenses incurred for employee benefits and retirement programs.

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n171. Holmes, supra note 10, at 557.
n172. See Glazier, supra note 167, at 63.
n173. See Holmes, supra note 10, at 556.
n174. See Brokaw, supra note 95, at 326.
n175. See id.

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Employers and insurers make several other arguments in support of their access to genetic information. First, because most insurance is not medically underwritten, most health coverage would be unaffected by the insurers' access to genetic information. Second, insurers and employers contend that they will not rely on genetic tests because the tests' great expense makes them cost ineffective. However, this argument is weakened by the fact that private laboratories already sell genetic tests and that improved technology and market

forces will inevitably make genetic tests more affordable. n179 Finally, employers and insurers argue that proposed genetic discrimination bills define "genetic information" too broadly. n180 Thus, they contend that federal legislation that prevents insurers from using genetic information, as opposed to "genetic testing information" such as family medical history, gender and other factors, would have a devastating impact on insurers who use such information to underwrite individual policies. n181

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n176. See Holmes, *supra* note 10, at 555. However, the marginal effect genetic information will have on insurance availability also undermines the insurers' argument that such information is needed to maintain solvency.

n177. See Cushing, *supra* note 28, at 252. Furthermore, insurers contend that the average price for genetic tests, between \$450 and \$1,000 per test, would be prohibitively expensive if performed on insureds in the aggregate. See *id.*

n178. See generally Michael J. Malinowski & Robin J.R. Blatt, Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards, 71 Tul. L. Rev. 1211 (1997) (discussing the growing market in commercial genetic tests and the need for regulating such tests); Casey, *supra* note 28, at 15 (listing available genetic tests).

n179. See Rothstein, *supra* note 80, at 28.

n180. See Jeffords Continues Push to Markup on Health Bills, Health Legis. & Reg. Wkly., May 27, 1998, available in 1998 WL 10395863 (stating that "insurers argue that, if a bill is passed at all, it must define gene information narrowly to include only knowledge gleaned from directly testing an individual's DNA and ribonucleic acid (RNA), and exclude information about inheritable traits gleaned from family histories or other medical tests").

n181. See *id.*

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VI. LEGISLATION REQUIRED TO PROHIBIT GENETIC DISCRIMINATION

Genetic discrimination, already problematic, will worsen in the near future as the HGP and commercial researchers provide insurers, employers and other institutions with the means to read our genetic profiles. n182 The noble ends of genomic research will be accompanied by ignoble discrimination, and the consequent genetic determinism may outweigh the medical advances and positive aspects of genomic research. Well-drafted legislation can preempt, or at least mitigate, the perils of genetic discrimination on the horizon. n183 This legislation should address the needs of potential genetic discrimination victims, genomic researchers and the institutions likely to discriminate. n184

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n182. See Jeffords 1998 Testimony, *supra* note 164.

n183. See Holmes, *supra* note 10, at 578.

n184. See Smith, *supra* note 76, at 121. However, balancing these divergent interests is easier said than done.

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The McCarran-Ferguson Insurance Regulation Act of 1945 n185 (hereinafter \2 McCarran Act\22) gives the states regulatory power over insurance companies. n186 However, in enacting the McCarran Act, \22Congress explicitly reserved the power to enact legislation relating to the business of insurance.\22 n187 Consequently, congressional enactment of the Employee Retirement Income Security Act of 1974 (ERISA) n188 has exempted health insurers from many state regulations. n189 Although federal and state governments have proposed and or enacted genetic discrimination legislation, only federal genetic discrimination legislation will offer comprehensive coverage. n190\par

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n185. Ch. 20, 59 Stat. 33 (1945) (codified as amended at \i 15 U.S.C. 1011\i 10-1015 (1998)). \par\par

n186. See Cushing, supra note 28, at 260. For a general background of the McCarran-Ferguson Insurance Regulation Act of 1945, see Holmes, supra note 10, at 582-84. \par\par

n187. Holmes, supra note 10, at 584. \par\par

n188. Pub. L. No. 93-406, 88 Stat. 829 (1974). \par\par

n189. Telephone Interview with Brian O'Connor, Communications Director, Office of U.S. Representative Joseph P. Kennedy II (Feb. 18, 1998) (stating that the insurance industry was able to secure freedom from state regulations by lobbying for the McCarran Act); see also Karen Rothenberg, Miracles of Genetics Can Bear Heavy Cost, Balt. Sun, July 20, 1997, at 6F (stating that \22state insurance laws cannot apply to self-funded employer plans because of \5BERISA\5D\22). \par\par

n190. See Rothenberg, supra note 189, at 6F. \par

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A.State Genetic Discrimination Laws and Bills \par\par

There is a trend toward state enactment of genetic discrimination legislation. n191 As of \5B*464\5D October 1, 1998, some form of genetic discrimination legislation existed in thirty- nine states, n192 and numerous other genetic discrimination bills have been introduced in various state legislatures between 1997 and 1998. n193 This bevy of state genetic discrimination \5B*465\5D legislation represents a range of protection. n194 However, state genetic discrimination laws provide an inherently circumscribed solution. n195\par

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n191. See Bornstein, supra note 20, at 589; Holmes, supra note 10, at 644. One source noted that there are genetic discrimination laws in 24 states that restrict insurers' use of genetic information, and that as many as 250 genetic discrimination bills are currently pending in 44 state legislatures. See Laws to Forbid Gene- Test Penalties by Insurers Languish in Congress; Thousands Wanting to Know of Risk Fear Being Denied Coverage, Balt. Sun, Apr. 12, 1998, at 4A. Some states have begun to require insurers to use \22community rates\22 whereby premiums for individual and group policies are based solely on the basis of age, geography and family composition, thus preventing \22any health insurer from seeking genetic testing of applicants and from using genetic information in fixing rates and premiums.\22 See Holmes, supra 10, at 648-69. \par\par

n192. See Ala. Code 27-53-1 to -4 (1998); Alaska Stat. 21.54.100-.54.110 (Mi

chie Supp. 1998); Ariz. Rev. Stat. Ann. 20-448 to -448.02, 20-1379 (West 1997); Ark. Code Ann. 23-86-304 to -306 (Michie Supp. 1997); Cal. Civ. Code 56.17-.18 (West 1998); Cal. Health & Safety Code 1374.7 (West 1990); Cal. Ins. Code 742.405-.407, 10123.3-.35, 10123.9, 10140, 10140.1, 10143, 10146, 10148-10149.1, 10198.9, 10705, 11512.7-11517 (West 1993 & Supp. 1998); Colo. Rev. Stat. Ann. 10-3-1104.7, 25-1-122.5 (1997); Conn. Gen. Stat. 38a-816(19) (1998); Fla. Stat. Ann. 627.4301, 627.65625, 636.0201, 641.31073, 641.438, 760.40 (West 1997 & Supp. 1998); Ga. Code Ann. 33-54-1 to -8 (1996); Haw. Rev. Stat. 431:10A-118, 432:1607, 432D-26 (1998); Idaho Code 41-2221, -3940, -4708 (Michie 1997); 215 Ill. Comp. Stat. 5/356t, 97/20-97/25, 513/45 (West 1998); Ind. Code Ann. 16-39-5-2, 27-8-26-1 to -12 (West Supp. 1998); Iowa Code Ann. 729.6 (West 1993); Kan. Stat. Ann. 40-2259 (1998); La. Rev. Stat. Ann. 22:213.7, :250.3, :1214, 40:1299.6, :2210 (West 1998); Me. Rev. Stat. Ann. tit. 24-A, 2850 (West Supp. 1997); Md. Code Ann., Ins. 27-208, -909 (1997); Minn. Stat. Ann. 72A.139 (West Supp. 1998); Mont. Code Ann. 33-18-206, -22-514, -22-526 (1997); Neb. Rev. Stat. 44-5246.02, -916 (1997); Nev. Rev. Stat. 629.101-.201, 689A.417, .545, .585, 689B.069, .420, .550, 689C.193, .198, .207 (1997); N.H. Rev. Stat. Ann. 141-H:1 to -H:5, 420-G:6 to -G:7 (1996); N.J. Stat. Ann. 10:5-5, :5-12, :5-43 to -49, 17:48-6.18, 17:48A-6.11, 17:48E-15.2, 17B:26-3.2, :27-36.2, :27-57, :30-12, 26:2J-15.1 (West 1993 & Supp. 1998); N.M. Stat. Ann. 24-21-1 to -7, 59A-23E-11 (Michie Supp. 1998); N.Y. Civ. Rights Law 48-a, 48-b, 79-1 (McKinney 1992 & Supp. 1998); N.Y. Exec. Law 296 (McKinney 1993 & Supp. 1997); N.Y. Ins. Law 2612, 3221, 3232, 4305, 4318 (McKinney 1985 & Supp. 1998); N.C. Gen. Stat. 58-68-30, -35, 95-28.1A (Supp. 1997); N.D. Cent. Code 26.1-08-12, -36.3-01, -36.3-06, -36.4-03.1 (1995 & Supp. 1997); Ohio Rev. Code Ann. 1751.18, 1751.65, 3901.21, 3901.49, 3901.491, 3901.50, 3901.501, 3924.031, 3924.27 (Anderson 1997 & Supp. 1997); Or. Rev. Stat. 659.036, 659.227, 659.324, 659.340, 659.700-.720, 746.135 (1997); R.I. Gen. Laws 28-6.7-1 to -4 (1995); S.C. Code Ann. 38-41-45, 38-71-670, -840, -860 (Law Co-op. Supp. 1997); S.D. Codified Laws 58-17-84, 58-18-45, 58-18B-27 (Michie Supp. 1998); Tenn. Code Ann. 56-7-2701-7-2708, 56-7-2802 (Supp. 1997); Tex. Lab. Code Ann. 21.401-.405 (West Supp. 1998); Tex. Rev. Civ. Stat. Ann. art. 9031 (West Supp. 1998); Va. Code Ann. 32.1-67.1 to -69.1, 38.2-508.4, 38.2-613 (Michie 1997 & Supp. 1998); W. Va. Code 33-15-2a, -16-1a, -16-3k (Supp. 1998); Wis. Stat. 111.372, 631.89, 632.746, 632.748 (1998); Wyo. Stat. Ann. 26-19-107, -306 (Michie 1998).

n193. See H.B. 10, 1st Spec. Sess. (Ala. 1997); H.B. 218, Reg. Sess. (Ala. 1997); S.B. 113, Reg. Sess. (Ala. 1997) (enacted); H.B. 415, 20th Leg., 2d Reg. Sess. (Alaska 1998); S.B. 104, 20th Leg., 1st Reg. Sess. (Alaska 1997) (enacted); H.B. 2600, 43d Leg., 2d Reg. Sess. (Ariz. 1998); H.B. 2144, 43rd Leg., 1st Reg. Sess. (Ariz. 1997) (enacted); H.B. 2011, 81st Leg., Reg. Sess. (Ark. 1997); A.B. 2688, 97-98 Reg. Sess. (Cal. 1997); A.B. 310, 97-98 Reg. Sess. (Cal. 1997); A.B. 34, 97-98 Reg. Sess. (Cal. 1997); S.B. 1654, 97-98 Reg. Sess. (Cal. 1997); H.B. 5471, 139th Leg., 2d Reg. Sess. (Conn. 1998); H.B. 6527, 139th Leg., 1st Reg. Sess. (Conn. 1997) (enacted); H.B. 5349, 139th Leg., 1st Reg. Sess. (Conn. 1997); H.B. 5134, 139th Leg., 1st Reg. Sess. (Conn. 1997); H.B. 5053, 139th Leg., 1st Reg. Sess. (Conn. 1997); S.B. 85th, 139th Leg., 2d Reg. Sess. (Conn. 1998); S.B. 80, 139th Leg., 2d Reg. Sess. (Conn. 1998) (enacted); S.B. 89, 139th Leg., 1st Reg. Sess. (Conn. 1997); S.B. 166, 139th Leg., 1st Reg. Sess. (Del. 1997) (enacted); S.B. 153, 139th Leg., 1st Reg. Sess. (Del. 1997) (enacted); S.B. 152, 139th Leg., 1st Reg. Sess. (Del. 1997); H.B. 127, 100th Leg., 1st Reg. Sess. (Fla. 1997); S.B. 1850, 100th Leg., 1st Reg. Sess. (Fla. 1997); S.B. 138, 100th Leg., 1st Reg. Sess. (Fla. 1997); H.B. 386, 144th Leg., Reg. Sess. (Ga. 1997); H.B. 1822, 19th Leg., Reg. Sess. (Haw. 1997); H.B. 1566, 19th Leg., Reg. Sess. (Haw. 1997); H.B. 476, 19th Leg., Reg. Sess. (Haw. 1997); S.B. 2160, 1

9th Leg., Reg. Sess. (Haw. 1997); S.B. 1565, 19th Leg., Reg. Sess. (Haw. 1997) (enacted); S.B. 112, 19th Leg., Reg. Sess. (Haw. 1997); H.B. 388, 90th Leg., 1st Reg. Sess. (Ill. 1997); H.B. 8, 90th Leg., 1st Reg. Sess. (Ill. 1997) (enacted); S.B. 802, 90th Leg., 1st Reg. Sess. (Ill. 1997) (enacted); S.B. 672, 90th Leg., 1st Reg. Sess. (Ill. 1997); S.B. 165, 110th Leg., 1st Reg. Sess. (Ind. 1997); H.F. 701, 77th Leg., 1st Reg. Sess. (Iowa 1997) (enacted); H.F. 171, 77th Leg., 1st Reg. Sess. (Iowa 1997); S.F. 100, 77th Leg., 1st Reg. Sess. (Iowa 1997); H.B. 2734, 77th Leg., 1st Reg. Sess. (Kan. 1997); H.B. 2417, 77th Leg., 1st Reg. Sess. (Kan. 1997); S.B. 463, 77th Leg., 1st Reg. Sess. (Kan. 1997); S.B. 204, 77th Leg., 1st Reg. Sess. (Kan. 1997) (enacted); S.B. 334, 97-98 Reg. Sess. (Ky. 1998); H.B. 2071, 97-98 Reg. Sess. (La. 1997); S.B. 771, 97-98 Reg. Sess. (La. 1997); S.B. 526, 97-98 Reg. Sess. (La. 1997); H.B. 893, 118th Leg., 1st Reg. Sess. (Me. 1997); H.B. 845, 118th Leg., 1st Reg. Sess. (Me. 1997); S.B. 384, 118th Leg., 1st Reg. Sess. (Me. 1997) (enacted); H.B. 297, 412th Leg., 1998 Reg. Sess. (Md. 1998); H.B. 920, 411th Leg., 1997 Reg. Sess. (Md. 1997); H.B. 776, 411th Leg., 1997 Reg. Sess. (Md. 1997); S.B. 324, 412th Leg., 1998 Reg. Sess. (Md. 1998); H.B. 4485, 180th Gen. Ct., Reg. Sess. (Mass. 1997); H.B. 4419, 180th Gen. Ct., Reg. Sess. (Mass. 1997); H.B. 4162, 180th Gen. Ct., Reg. Sess. (Mass. 1997); H.B. 2669, 180th Gen. Ct., Reg. Sess. (Mass. 1997); H.B. 2668, 180th Gen. Ct., Reg. Sess. (Mass. 1997); S.B. 2018, 180th Gen. Ct., Reg. Sess. (Mass. 1997); S.B. 1933, 180th Gen. Ct., Reg. Sess. (Mass. 1997); S.B. 659, 180th Gen. Ct., Reg. Sess. (Mass. 1997); H.B. 5963, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 5960, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 5462, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 5461, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 5460, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4991, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4990, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4882, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4881, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4880, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4836, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 4118, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 134, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 110, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 109, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 108, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 107, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 70, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 69, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 68, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 67, 89th Leg., Reg. Sess. (Mich. 1997); S.B. 66, 89th Leg., Reg. Sess. (Mich. 1997); H.B. 1316, 89th Gen. Assembly, 2d Reg. Sess. (Mo. 1998); A.B. 549, 69th Leg., Reg. Sess. (Nev. 1997) (enacted); H.B. 241, 115th Leg., 1997 Reg. Sess. (N.H. 1997); A.B. 1716, 208th Leg., Reg. Sess. (N.J. 1998); A.B. 1641, 208th Leg., Reg. Sess. (N.J. 1998); A.B. 331, 208th Leg., Reg. Sess. (N.J. 1998); S.B. 565, 208th Leg., Reg. Sess. (N.J. 1998); H.B. 331, 43d Leg., 2d Reg. Sess. (N.M. 1998) (enacted); H.B. 395, 43d Leg., 1st Reg. Sess. (N.M. 1997); S.B. 176, 43d Leg., 2d Reg. Sess. (N.M. 1998) (enacted); A.B. 8412, 220th Leg., Reg. Sess. (N.Y. 1997); A.B. 5553, 220th Leg., Reg. Sess. (N.Y. 1997); A.B. 4512, 220th Leg., Reg. Sess. (N.Y. 1997); A.B. 4510, 220th Leg., Reg. Sess. (N.Y. 1997); S.B. 4009, 220th Leg., Reg. Sess. (N.Y. 1997); S.B. 3284, 220th Leg., Reg. Sess. (N.Y. 1997); S.B. 3283, 220th Leg., Reg. Sess. (N.Y. 1997); S.B. 3198, 220th Leg., Reg. Sess. (N.Y. 1997); S.B. 1497, 220th Leg., Reg. Sess. (N.Y. 1997); H.B. 1495, 141st Leg., 2d Reg. Sess. (N.C. 1998); H.B. 350, 141st Leg., 1st Reg. Sess. (N.C. 1997); S.B. 254, 141st Leg., 1st Reg. Sess. (N.C. 1997) (enacted); H.B. 698, 122d Leg., 2d Reg. Sess. (Ohio 1998); H.B. 3169, 46th Leg., 2d Sess. (Okla. 1998) (enacted); H.C.R. 2021, 46th Leg., 1st Reg. Sess. (Okla. 1997); H.B. 1012, 46th Leg., 1st Reg. Sess. (Okla. 1997); H.B. 2779, 182d Leg., 1997 Reg. Sess. (Pa. 1997); S.B. 100, 182d Leg., 1997 Reg. Sess. (Pa. 1997); H.B. 7590, 97-98 Reg. Sess. (R.I. 1997); H.B. 6349, 97-98 Reg. Sess. (R.I. 1997); H.B. 5157, 97-98 Reg. Sess. (R.I. 1997); S.B. 2805, 97-98 Reg. Sess. (

R.I. 1997); S.B. 2202, 97-98 Reg. Sess. (R.I. 1997); S.B. 181, 112th Leg., Reg. Sess. (S.C. 1997); S.B. 56, 73d Leg., 1998 Reg. Sess. (S.D. 1998); S.B. 989, 100th Leg., 1st Reg. Sess. (Tenn. 1997); H.B. 413, 75th Leg., 1997 Reg. Sess. (Tex. 1997); H.B. 263, 75th Leg., 1997 Reg. Sess. (Tex. 1997); H.B. 39, 75th Leg., 1997 Reg. Sess. (Tex. 1997) (enacted); S.B. 98, 75th Leg., 1997 Reg. Sess. (Tex. 1997); H.B. 271, 52d Leg., 1998 Gen. Sess. (Utah 1998); S.B. 78, 65th Leg., 97-98 Reg. Sess. (Vt. 1997); H.B. 1384, 1998 Reg. Sess. (Va. 1998); H.B. 854, 1998 Reg. Sess. (Va. 1998); H.B. 781, 1998 Reg. Sess. (Va. 1998); S.B. 652, 1998 Reg. Sess. (Va. 1998); S.B. 6663, 55th Leg., 1997 Reg. Sess. (Wash. 1997); S.B. 5298, 55th Leg., 1997 Reg. Sess. (Wash. 1997); A.B. 69, 93d Leg., Reg. Sess. (Wis. 1997); A.B. 157, 93d Leg., Reg. Sess. (Wis. 1997) (enacted). See generally Lisa Seachrist, A Plethora of Genetic Privacy Bills Floods State Legislatures, *Bioworld Today*, Apr. 10, 1997, available in 1997 WL 7473568 (discussing common provisions found in various state genetic privacy bills).

n194. See Bornstein, *supra* note 20, at 589-608; see also Holmes, *supra* note 10, at 629-47 (providing an extensive discussion and examination of state genetic discrimination laws).

n195. See O'Hara, *supra* note 15, at 1224; Sally Lehrman, Clinton Backs Laws Against Genetic Discrimination, *Biotechnology Newswatch*, July 21, 1997, at 1, available in 1996 WL 8791009.

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State genetic discrimination laws have several shortcomings. First, state genetic discrimination laws fail to regulate self-insured employers exempted from state insurance laws by ERISA. n196 Consequently, self-insured plans need not comply with any of the state laws that require health insurance contracts to ... comply with anti-discrimination restrictions. n197 Furthermore, ERISA's failure to prohibit discriminatory distribution of employee benefits in conjunction with ERISA's preemption of state action creates a void where state regulation of employee health insurance would be. n198 Therefore, comprehensive protection from genetic discrimination requires federal legislation. n199 Second, many state genetic discrimination laws focus narrowly on genetic tests rather than more broadly on genetic information generated by family history, physical examination, or the medical record. n200 Third, state genetic discrimination regulations provide only a patchwork of protections. n201 State genetic discrimination laws provide no consistency regarding the types of insurance covered ... because some state laws define genetic testing broadly, some narrowly ... some provide explicit privacy protection, some do not. n202 Therefore, because state genetic discrimination laws only protect insureds not covered by self-insured employers and because the people who are protected by state laws only receive disjointed protection, federal legislation would fill these state legislative gaps. n203 Two federal laws that fill some of the legislative gaps left by state genetic discrimination laws include the Americans with Disabilities Act of 1990 (ADA) n204 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). n205

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n196. See Collins 1997 Testimony, *supra* note 6, at 19. Almost two-thirds of U.S. employers are self-insured. See Morelli, *supra* note 82 at 9. Therefore, even if every state passed comprehensive genetic discrimination laws, millions of American employees with employer self-funded plans would not be protected. See

Holmes, supra note 10, at 648. \par\par
n197. O'Hara, supra note 15, at 1225. \par\par
n198. See Holmes, supra note 10, at 586. \par\par
n199. See O'Hara, supra note 15, at 1225. \par\par
n200. Collins 1997 Testimony, supra note 6, at 14. Thus, insurers may still be permitted to use phenotype indicators, pattern of inheriting genetic characteristics or a request for genetic testing as the basis for genetic discrimination. See id. Consequently, '\22meaningful protection against genetic discrimination requires that insurers be prohibited from using all information about genes, gene products, or inherited characteristics to deny or limit health insurance coverage.\22 Id. \par\par
n201. See Holmes, supra note 10, at 645. When compared with a comprehensive approach to protecting genetic privacy, '\22piecemeal approach in enacting hundreds of statutes seems politically impractical and ineffective.\22 See id. \par\par
n202. Id. at 647. \par\par
n203. See id. at 663. \par\par
n204. Pub. L. No. 101-336, 104 Stat. 327 (1990). See also Charles B. Gurd, Whether a Genetic Defect is a Disability Under the Americans with Disabilities Act: Preventing Genetic Discrimination by Employers, 1 Annals Health L. 107, 111 (1992) (stating that the ADA '\22prevents discrimination by private employers who hire more than 15 employees ... '\5Band'\5D prohibits discrimination based on a disability'\22). \par\par
n205. Pub. L. No. 104-191, 110 Stat. 1936 (1996). \par\par

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B. Federal Laws Regulating and Prohibiting Genetic Discrimination\par\par
The ADA offers some limited protections from genetic discrimination by employers, n206 specifically preventing employers from discriminating against employees/applicants because of a disability. n207 In 1995, the Equal Employment Opportunity Commission issued a guideline incorporating '\22genetic information relating '\5B*467'\5D to illness, disease, or other disorders'\22 into the ADA's definition of '\22disability.\22 n208 However, discrimination victims may have difficulty invoking the ADA's protections because they must '\22both show that an employer regarded the individual as having a genetic defect, and '\22acted on that basis.\22 n209 It is also presently unclear whether the ADA prevents genetic discrimination predicated on something other than an individual's disability. n210 For example, some employers may have substantial economic incentives to exclude from the workforce individuals with, or who are likely to have, dependents who will incur major health expenses. n211 However, the ADA may not prohibit genetic discrimination based on an employer's desire to eliminate potentially expensive dependent health care. n212 Furthermore, the ADA may not protect asymptomatic carriers of recessive genetic mutations. n213 Finally, the ADA may not protect genetic privacy. n214 Therefore, the ADA offers little protection against genetic discrimination absent judicial delineation of the ADA's scope in this area. n215\par\par

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n206. See Bornstein, supra note 20, at 581-82. However, the ADA may not prohibit the underwriting and classification of risks by employers or insurers, thus permitting employers and insurers to treat employees differently for purposes

of insurance coverage based on their disabilities. See Rothstein, *supra* note 80, at 79. \par\par

n207. See Dee Lord, *Something in the Genes*, A.B.A. J., Apr. 1996, at 86. The ADA provides a three-prong definition of "disability" as follows: (1) a physical or mental impairment that substantially limits one or more of a person's major life activities; (2) a record of such impairment; or (3) being regarded as having such an impairment. See *id.* For a discussion of how the ADA extends protection for people with the gene for HD, see generally Brian R. Gin, Note, *Genetic Discrimination: Huntington's Disease and the Americans with Disabilities Act*, 97 Colum. L. Rev. 1406 (1997). \par\par

n208. See Bornstein, *supra* note 20, at 581; see also Lord, *supra* note 207, at 86 (explaining that the Equal Employment Opportunity Commission (EEOC) compliance manual "categorizes a genetic susceptibility to a disease ... as a "disability". But see Rothstein, *supra* note 80, at 39-43 (arguing that although the ADA protects "qualified individuals who have an already-expressed genetic disease" that substantially limits their major life activities, the ADA does not protect those with minor genetic conditions without such limitations). \par\par

n209. Bornstein, *supra* note 20, at 581-82. Nonetheless, despite the inadequacies of ADA protections from genetic discrimination, the EEOC compliance manual "codifies a principle that you are not to be held responsible for what's in your "basic" genes" See Richard Saltus, *US Ruling Bars Discrimination Based on Genes*, Boston Globe, Apr. 11, 1995, at A4 (quoting Francis Collins, Director, National Center for Human Genome Research). \par\par

n210. See Karen Rothenberg et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Changes*, 275 Science 1755, 1756 (1997). \par\par

n211. See Rothstein, *supra* note 80, at 47. \par\par

n212. See Bornstein, *supra* note 20, at 582. \par\par

n213. See Rothenberg et al., *supra* note 210, at 1756. \par\par

n214. See *Norman-Bloodshaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1273 (9th Cir. 1998). The court in *Norman-Bloodshaw* explained that the ADA does not impose restrictions on the scope of medical entrance exams of employees. See *id.* Thus, genetic make-up information may be disclosed in such examinations. See *id.* \par\par

n215. See Rothenberg et al., *supra* note 210, at 1756. \par\par

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HIPAA amended ERISA, offering several limited protections from genetic discrimination by insurers. n216 First, HIPAA prohibits insurers from treating a genetic predisposition "as a pre-existing condition unless the genetic information results in a medical diagnosis of an actual condition needing medical care or treatment." n217 Second, by prohibiting the use of genetic information by insurers when considering eligibility for enrollment or continuation of coverage, the Act ensures that employees changing jobs will be able to do so without losing their health insurance. n218 Finally, HIPAA implicitly prohibits the use of genetic information in decisions regarding renewal or continuance of coverage. n219 Despite the importance of the protections offered, HIPAA fails to prohibit several types of genetic discrimination. n220 \par\par

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n216. See Patrinos & Drell, *supra* note 15, at 9. \par\par

n217. Holmes, *supra* note 10, at 658-59. The Act prohibits genetic discrimination against asymptomatic people, pre-symptomatic people with a genetic predisposition and unaffected genetic carriers. See *id.* at 659. \par\par

n218. See *id.* \par\par

n219. See *id.* at 658; see also Barbara A. Ryan, Health Law Promises Access, Portability Obstacles to Insurance Coverage Addressed, N.Y.L.J., Feb. 18, 1997, at S5 (stating that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may prevent insurers from denying health insurance coverage based on risk and claims history for a group of employees). \par\par

n220. See Holmes, *supra* note 10, at 659; see also Slaughter Testimony, *supra* note 3, at 8-10 (stating that HIPAA represents an important step toward ending genetic discrimination in health insurance, but fails to close loopholes that leave many people vulnerable to genetic discrimination). \par

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\5B*468\5D First, HIPAA was an amendment to ERISA, and thus fails to address ERISA's shortcomings in preventing genetic discrimination. n221 Specifically, it does not regulate the discriminatory conduct of self-insured employers and health maintenance organizations (HMOs) that ERISA exempts from state insurance laws. n222 Second, the Act does not address genetic privacy concerns such as the dissemination of genetic information. n223 Third, it fails either to prohibit or to regulate genetic testing requirements by insurers. n224 Fourth, it leaves unprotected the self-employed and consumers in the individual health insurance market. n225 Fifth, it does not prohibit the use of genetic information in risk classification and insurance underwriting. n226 Finally, HIPAA fails to prohibit employers from genetically discriminating against people seeking health insurance. n227\par

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n221. See Collins 1997 Testimony, *supra* note 6, at 19; see also Lisa Seachrist, Clinton Endorses Legislation to Protect Genetic Privacy, *Bioworld Today*, July 15, 1997, available in \i 1997 WL 11130570\i0 (noting that HIPAA left loopholes that H.R. 306 would close). \par\par

n222. See Holmes, *supra* note 10, at 659. \par\par

n223. See *id.*; see also Rothenberg Testimony, *supra* note 79, at 85 (stating that HIPAA \22does not require insurers to obtain authorization before disposing genetic information\22); Collins 1997 Testimony, *supra* note 6, at 20 (stating that HIPAA does not protect \22against unauthorized people or institutions having access to the genetic information contained in their medical records\22). \par\par

n224. See Rothenberg Testimony, *supra* note 79, at 83; Collins 1997 Testimony, *supra* note 6, at 20. \par\par

n225. See Slaughter Testimony, *supra* note 3, at 10; Collins 1997 Testimony, *supra* note 6, at 19; see also Rothenberg Testimony, *supra* note 79, at 84 (stating that HIPAA \22provides even less protection for employees not in group plans and provides no coverage for the uninsured\22). \par\par

n226. See Slaughter Testimony, *supra* note 3, at 11; see also Rothenberg, *supra* note 189, at 6F (stating that HIPAA does not prohibit insurers from raising rates, excluding coverage for certain conditions, imposing lifetime caps on benefits, requesting or requiring genetic testing and protecting the privacy of genetic test results); Holmes, *supra* note 10, at 659-60 (stating that the HIPAA \22is only a patchwork solution to the insurance/genetic dilemma\22). \par\par

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n227. See Rothenberg Testimony, *supra* note 79, at 84; see also Collins 1997 Testimony, *supra* note 6, at 19 (stating that HIPAA '22leaves open the possibility that all individuals within a group could be charged a higher premium based on the genetic information of one or more members of the group'22). \par

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C. Genetic Discrimination Bills Introduced by the 104th Congress\par

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Despite the introduction of myriad bills since 1990, n228 Congress has thus far failed to pass genetic discrimination legislation. n229 The Human Genome Privacy Act of '5B*469'5D 1990, introduced during the HGP's infancy, was the first federal genetic discrimination bill. n230 However, this bill only prohibited the disclosure of genetic information by government agencies, and thus failed to address genetic discrimination in either the insurance or the employment contexts. n231 The 104th Congress later introduced bills addressing genetic discrimination in the employment and health insurance contexts. n232\par

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n228. Federal genetic discrimination bills introduced in past sessions of Congress include: The Genetic Confidentiality and Nondiscrimination Act of 1996, S. 1898, 104th Cong.; Genetic Information Nondiscrimination in Health Act of 1996, S. 1694, 104th Cong.; Genetic Fairness Act of 1996, S. 1600, 104th Cong.; Health Insurance Reform Act of 1996, H.R. 3185, 104th Cong.; Health Coverage and Availability and Affordability Act of 1996, H.R. 3160, 104th Cong.; Health Insurance Reform Act of 1996, H.R. 3103, 104th Cong.; Working Families Health Access Act of 1996, H.R. 3043, 104th Cong.; Genetic Information Nondiscrimination in Health Insurance Act of 1995, H.R. 2748, 104th Cong.; The Genetic Privacy and Nondiscrimination Act of 1995, S. 1416, 104th Cong., also introduced in the House as H.R. 2690, 104th Cong. (1995); The Genetic Information Privacy Act of 1992, H.R. 5838, 102d Cong.; The Human Genome Privacy Act of 1990, H.R. 5612, 101st Cong. It should be noted that H.R. Res. 392, 104th Cong. (1996) amended H.R. 3103 by substituting and combining the bill with H.R. 3160, which did not contain any genetic information provisions. See Bornstein, *supra* note 20, at 585 n. 149. For a general discussion of federal genetic discrimination legislation introduced between 1995 and 1996, see Reilly, *supra* note 156, at 379-86. \par\par

n229. Genetic discrimination legislation introduced prior to the 105th Congress failed to pass because of staunch opposition from a '22very powerful insurance industry lobby.'22 See Interview with O'Connor, *supra* note 189. Insurance companies have a strong economic incentive to use genetic discrimination to '22cherry pick'22 the healthiest insureds, thereby eliminating health insurance for those people most in need of it. See *id.* Thus, insurers' opposition to the '22fair and equal access to health care'22 offered by genetic discrimination legislation makes it necessary to include genetic discrimination protection provisions into unrelated bills that are more likely to pass of their own accord. See *id.* However, the strong insurance lobby and the '22ponderous pace of politics'5Bare'5D not the only reasons for the lag'22 in enacting genetic discrimination legislation. See Cindy Schreuder, Can Laws Protect Us From Our Genes?, *Chi. Trib.*, July 20, 1997, at 1. Rather, the '22complexity, uncertainty and the fast pace of genetic research'22 have hampered efforts to enact federal genetic discrimination legislation. See *id.* \par\par

n230. See Bornstein, *supra* note 20, at 579. This bill was introduced by Representative John Conyers (D-MI). See H.R. 5612, 101st Cong. (1990).

n231. See Bornstein, *supra* note 20, at 579-80.

n232. See *id.* at 579. For a list of genetic discrimination bills introduced in the 104th Congress, see *supra* note 228.

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An examination of the 104th Congress's genetic discrimination legislation is beneficial inasmuch as it provides the legislative context for the bills introduced in the 105th Congress. Indeed, many sections of the 105th Congress's genetic discrimination bills are similar, if not verbatim, with those of bills introduced in the 104th Congress. n233 Moreover, genetic discrimination bills introduced in both Congresses similarly define genetic information, n234 genetic test, n235 insurer n236 and other terms necessary for effective prohibition of genetic discrimination. n237 Consequently, because the genetic discrimination bills introduced by the 104th and 105th Congresses are quite similar, this Note discusses in detail the Genetic Privacy and Nondiscrimination Act of 1995 and the Genetic Privacy and Nondiscrimination Act of 1997, because they contain most major genetic discrimination provisions common to all bills. Additionally, this Note discusses other genetic discrimination bills inasmuch as they differ materially from either the Genetic Privacy and Nondiscrimination Act of 1995 or the Genetic Privacy and Nondiscrimination Act of 1997.

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n233. Several legislative findings made by the 104th Congress were expressly made by the 105th Congress. For example, in H.R. 341, the 105th Congress adopted the same legislative findings as those adopted by the 104th Congress in H.R. 2690 and S. 1416. Both Congresses found that:

(1) The DNA molecule contains information about an individual's probable medical future. (2) Genetic information is uniquely private and personal information that should not be disclosed without the authorization of the individual. (3) The improper disclosure of genetic information can lead to significant harm to the individual, including stigmatization and discrimination in areas such as employment, education, health care, and insurance. (4) An analysis of an individual's DNA provides information not only about an individual, but also about the individual's parents, siblings and children. (5) Current legal protections for genetic information, tissue samples and DNA samples are inadequate to protect genetic privacy, and require further attention. (6) Laws for the collection, storage and use of identifiable DNA samples and private genetic information obtained from those samples are needed both to protect individual privacy and to permit legitimate genetic research.

H.R. 341, 105th Cong. 2 (1997); H.R. 2690, 2; S. 1416, 2.

n234. Genetic information is defined as "the information about genes, genetic products or inherited characteristics that may derive from an individual or a family member." H.R. 341, 3; S. 1600, 104th Cong. 2(2) (1996); H.R. 2690, 3; S. 1416, 3.

n235. Genetic test is defined as "a test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose a genetic characteristic." H.R. 341, 3; H.R. 2690, 3; S. 1416,

3. \par\par

n236. An insurer is defined as \22an insurance company, health care service contractor, fraternal benefit organization, insurance agent, third party administrator, insurance support organization or other person subject to regulation under State insurance laws. Such term includes self-funded health plans and health plans regulated under the Employee Retirement Income Security Act of 1974.\22 H.R. 341, 3; H.R. 2690, 3; S. 1416, 3. \par\par

n237. For example, genetic services are defined as \22health services to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.\22 H.R. 306, 105th Cong. 2(a) (1997); H.R. 2748, 104th Cong. 2(e) (1995). Employee health benefit plans are defined as \22any employee welfare benefit plan, governmental plan, or church plan\22 by ERISA. See H.R. 2748, 2(e). \par

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The Genetic Privacy and Nondiscrimination Act of 1995 n238 would have protected genetic privacy by prohibiting employers, insurers, and government agencies from disclosing or redisclosing genetic information. n239 However, the bill also included several narrowly tailored exceptions to the disclosure prohibition.

n240 Several other genetic discrimination bills also included provisions prohibiting unauthorized disclosure of genetic information. n241\par

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n238. H.R. 2690; S. 1416. Representative Clifford Stearns (R-FL) and Senator Mark Hatfield (R-OR) introduced the bill in their respective Houses during the 104th Congress. Representative Stearns re-introduced this bill during the 105th Congress as the Genetic Privacy and Nondiscrimination Act of 1997. See infra text accompanying notes 257-77 (discussing the scope of the proposed Genetic Privacy and Nondiscrimination Act of 1997). Whenever possible, discussion of the Genetic Privacy and Nondiscrimination Act of 1995 hereinafter will reference provisions in both H.R. 2690 and S. 1416. \par\par

n239. See H.R. 2690, 4(a)(1); S. 1416, 4(a)(1)-(2); see also S. 1898, 104th Cong. 201-205 (1996) (stating that entities may not disclose or be compelled to disclose an individual's genetic information unless disclosure is provided for by one of the enumerated exceptions). \par\par

n240. See H.R. 2690, 4(a)(2); S. 1416, 4(a)(2). Both bills specify that an individual's genetic information may be disclosed if authorized under federal or state criminal laws, required under a specific order of a federal or state court, authorized to establish paternity, used for medical diagnosis of a decedent's blood relatives or used to identify a body. See H.R. 2690, 4(a)(2); S. 1416, 4(a)(2). Furthermore, the Genetic Privacy and Nondiscrimination Act of 1995 would have allowed disclosure of genetic information if the individual specifically authorized such disclosure in a writing, indicating the information to be disclosed, the entity authorized to receive the information and the purpose of the disclosure. See H.R. 2690, 4(a)(1); S. 1416, 4(a)(1). \par\par

n241. See H.R. 2748, 2(b); S. 1694, 104th Cong. 2(b) (1996). Both bills prohibit disclosure of an individual's genetic information without the written authorization of the individual or the individual's legal representative, and require the authorization to identify to whom the disclosure is made. See H.R. 2748, 2(b); S. 1694, 2(b). \par

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Furthermore, the Genetic Privacy and Nondiscrimination Act of 1995 would have prohibited employers from seeking or using the genetic information, or requiring genetic testing, of current or prospective employees. n242 The bill would have prohibited employers from obtaining, or using the genetic information of an employee or prospective employee ... to distinguish between or discriminate against or restrict any right or benefit otherwise due or available to the employee or prospective employee. n243 Many of the genetic discrimination bills introduced by the 104th Congress also prohibited employers from altering health benefits offered on the basis of genetic information. n244 Likewise, genetic discrimination bills invariably extend these prohibitions to providers of health care coverage. n245 Accordingly, the Genetic Privacy and Nondiscrimination Act of 1995 would have prohibited health insurers from using genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, or otherwise affect health insurance. n246 Genetic discrimination bills typically extend the prohibition to health insurers, self-insured employers and other ERISA plans such as HMOs. n247 These protections are also often extended to both the individual and group health insurance markets. n248\p

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n242. See H.R. 2690, 5(a); S. 1416, 5(a); see also S. 1898, 104th Cong. 301 (1996) (prohibiting employers or potential employers from using genetic information to discriminate against employees or applicants). \par\par

n243. H.R. 2690, 5(a); S. 1416, 5(a). \par\par

n244. See H.R. 3160, 104th Cong. 101(b) (1996) (prohibiting insurers from classifying genetic predispositions as preexisting conditions that are excluded from coverage); H.R. 3103, 104th Cong. 101 (1996) (prohibiting insurers from using genetic information as a preexisting condition so long as the patient has not sought treatment for the condition to which the genetic information is related during the six-month period before the effective date of the insurance coverage); H.R. 2748, 2(a) (prohibiting insurers from altering any terms of the insurance contract based on genetic information). The Working Families Health Access Act of 1996 would have imposed a tax on health plan providers who use genetic predisposition to establish or impose eligibility, continuation or contribution requirements. See H.R. 3043, 104th Cong. 4986(a) (1996). That bill regulated health insurers, self-insured employers and ERISA plans by imposing a tax of 2.5% on collected premiums, or, in the case of self-insured employers, a tax of 25% on health coverage expenditures. See id. 4986(a)-(b). In addition, the bill protected people in both individual and group health insurance markets. See H.R. 3043, 4987(a)-(b). \par\par

n245. See Bornstein, supra note 20, at 582-88. \par\par

n246. H.R. 2690, 6(a); S. 1416, 6(a). However, insurers other than those providing health care coverage would be able to require applicants to undergo genetic testing. See H.R. 2690, 6(c); S. 1416, 6(c). \par\par

n247. See S. 1694, 104th Cong. 2(c)(1)-(2) (1996); see also S. 1600, 104th Cong. 2(6)(a)-(c) (1996) (defining insurer to include insurance companies, managed care organizations and ERISA plans). \par\par

n248. See H.R. 3185, 104th Cong. 101, 110 (1996); see also supra note 151 (discussing differences between group and individual insurance policies). \par

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Additionally, the Genetic Privacy and Nondiscrimination Act of 1995 would have required the National Bioethics Advisory Commission (NBAC) to submit a report to Congress with recommendations. n249 Some genetic discrimination bills include provisions that contain, relative to the other bills, minor variations or additions. n250 For example, some bills create a private right of action for people who have suffered invasions of genetic privacy or genetic discrimination. n251 Although the genetic discrimination bills of the 104th Congress would have provided greater protection from genetic discrimination and invasions of genetic privacy, n252 none of them became law. However, they are important inasmuch as their provisions have been almost completely reincarnated by the 105th Congress.

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n249. See H.R. 2690, 7; S. 1416, 7. The National Bioethics Advisory Commission (NBAC) report would include recommendations on the development and implementation of standards to provide increased protection for the collection, storage, and use of identifiable DNA samples and genetic information obtained from those samples and for the acquisition and retention of genetic information in all settings, including appropriate exceptions. H.R. 2690, 7; S. 1416, 7.

n250. The Working Families Health Access Act of 1996, for example, varied the provision prohibiting health insurers from genetically discriminating by imposing a substantial tax for noncompliance rather than by commanding an outright ban against genetic discrimination. See H.R. 3043, 104th Cong. 4986(a) (1996). This approach to addressing genetic discrimination by health insurers appears more effective because insurers may be more averse to confronting the Internal Revenue Service than they would individual insureds. However, the approach may also offer less protection from genetic discrimination if the tax imposed was less than the amount saved by genetically discriminating.

n251. See H.R. 2748, 104th Cong. 2(c)(3) (1995).

n252. See Bornstein, *supra* note 20, at 587.

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D. Genetic Discrimination Bills Introduced by the 105th Congress n253

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The 105th Congress n254 introduced fifteen genetic discrimination bills in an attempt to close the legislative gaps between state and federal laws. n255 Many provisions included in the 105th Congress's genetic discrimination bills are similar or identical to those of the 104th Congress's genetic discrimination bills. n256 The Genetic Privacy and Nondiscrimination Act of 1997 will serve as the paradigm for discussion of genetic discrimination bills introduced by the 105th Congress.

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n253. Several other bills introduced during the 105th Congress indirectly address the issue of genetic discrimination, but are beyond the scope of this Note. For example, Congress introduced several bills prohibiting genetic discrimination in the issuance of Medicare supplemental policies. See H.R. 1738, 105th Cong. 1(a)(2) (1997); S. 386, 105th Cong. 103(a)(3) (1997); S. 302, 105th Cong. 2(a)(3) (1997); H.R. 625, 105th Cong. 2(a)(3) (1997); H.R. 598, 105th Cong. 1(b

(2) (1997); H.R. 451, 105th Cong. 1(b)(2) (1997). The 105th Congress also introduced two bills prohibiting genetic discrimination in state-based health care coverage programs for children and uninsured pregnant women. See H.R. 1229, 105th Cong. 2852(a)(5) (1997); S. 13, 105th Cong. 104(b)(1) (1997). \par\par

n254. President Bill Clinton \22urged Congress to pass laws that would prevent health care companies from discriminating against consumers on the basis of genetic information.\22 Lehrman, *supra* note 195, at 1. Furthermore, Senator Pete Domenici (R-NM) \22hopes that the 105th Congress will reach conclusions about \22what we are to set as national standards regarding gene confidentiality and discrimination.\22 M.B., *Genetic Privacy, Discrimination Issues Could Cripple Biotech Industry*, *Biotechnology Newswatch*, Oct. 7, 1996, at 13. \par\par

n255. See Patients' Bill of Rights Act, S. 2330, 105th Cong. (1998); Family Genetic Privacy and Protection Act, H.R. 3299, 105th Cong. (1998); Medical Information Privacy and Security Act, S. 1368, 105th Cong. (1997); Genetic Employment Protection Act of 1997, H.R. 2275, 105th Cong.; Genetic Justice Act, S. 1045, 105th Cong. (1997); Genetic Nondiscrimination in the Workplace Act, H.R. 2215, 105th Cong. (1997); Genetic Protection in Insurance Coverage Act, H.R. 2216, 105th Cong. (1997); Genetic Privacy and Nondiscrimination Act of 1997, H.R. 2198, 105th Cong.; Medical Privacy in the Age of New Technologies Act of 1997, H.R. 1815, 105th Cong.; Children's National Security Act, H.R. 1726, 105th Cong. (1997); Genetic Confidentiality and Nondiscrimination Act of 1997, S. 422, 105th Cong.; Genetic Information Nondiscrimination in Health Insurance Act of 1997, S. 89, 105th Cong. (companion bill to H.R. 306, 105th Cong. (1997)); Genetic Information Health Insurance Nondiscrimination Act of 1997, H.R. 328, 105th Cong.; Genetic Information Nondiscrimination in Health Insurance Act of 1997, H.R. 306, 105th Cong.; Genetic Privacy and Nondiscrimination Act of 1997, H.R. 341, 105th Cong. \par\par

n256. For example, the Genetic Privacy and Nondiscrimination Act of 1995 was reintroduced in 1997 without change. Compare H.R. 2690, 104th Cong. (1995) (The Genetic Privacy and Nondiscrimination Act of 1995) with H.R. 341 (Genetic Privacy and Nondiscrimination Act of 1997). See also *supra* note 233 (discussing similar congressional findings motivating H.R. 2690 and H.R. 341). \par

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The Genetic Privacy and Nondiscrimination Act of 1997 n257 stated that \22genetic information is uniquely private and personal information that should not be disclosed without the authorization of the individual ... \5Bbecause\5D improper disclosure ... can lead to significant harm ... including stigmatization and discrimination in the areas such as employment, education, health care and insurance.\22 n258 The threat to genetic privacy is exacerbated by the existence of the Internet and other electronic means of transmitting information. n259 Accordingly, \5B*473\5D H.R. 341 would prohibit entities from disclosing n260 or being compelled to disclose genetic information n261 within their possession unless \22specifically authorized by the individual involved or the legal representative of the individual.\22 n262 Authorization for disclosure must be in writing and describe \22the information being disclosed, the name of the individual or entity to whom the disclosure is being made, and the purpose of the disclosure.\22 n263 One bill prohibits disclosing genetic information by electronic means, n264 \par

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n257. H.R. 341. Representative Cliff Stearns (R-FL) introduced H.R. 341. See id. Representative Stearns, however, subsequently introduced H.R. 2198 on July 17, 1997, which is also entitled the Genetic Privacy and Nondiscrimination Act of 1997. See H.R. 2198. Unless otherwise stated, the discussion herein involving the Genetic Privacy and Nondiscrimination Act of 1997 will be based on H.R. 341. \par\par

n258. H.R. 341, 2(a). \par\par

n259. See, e.g., The Medical Privacy in the Age of New Technologies Act of 1997, H.R. 1815, 2(a). This Act includes the following legislative findings: \par\par

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(1) Health information plays a vital role in every aspect of an individual's life \5Band\5D ... includes some of the most sensitive information available about an individual. \par\par

(2) An individual's health information is currently accessible to many people who do not need the information to provide health care to the individual, often without the individual's knowledge or consent. \par\par

(3) Individuals will be deterred from using the health care system unless they are assured that the confidentiality of their health information will be respected. \par\par

(4) There exists little Federal protection of the confidentiality of an individual's health information. \par\par

(5) While health information often is transferred across State lines, protection of the confidentiality of health information varies greatly from State to State, with little protection in some States. \par\par

(6) New technologies increase the importance of addressing new threats to the confidentiality of health information. For example, technologies that permit an individual's health information to be computerized increase the possibility of unauthorized electronic access to the information. Technologies that provide genetic information provide information not just about an individual's current health but also about the individual's potential future health and the health of the individual's relatives. This creates potential new uses and abuses of genetic health information that need to be addressed by legislation. \par\par

(7) The potential benefits from new genetic technologies will not be realized if individuals cannot trust that their health information is safe from unauthorized uses. \par\par

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Id. \par\par

n260. See H.R. 341, 4(a)(1); see also S. 422, 3(3) (defining disclose as \2to convey, or provide access to, the genetic information\22 of an individual to someone other than that individual); H.R. 1815, 3(3) (defining disclose as \22to release, transfer, provide access to, or otherwise divulge the \5Bgenetic\5D information to any person other than an individual who is the subject of the information\22). As defined under H.R. 1815, \22disclose\22 includes \22the placement of protected health information into a computerized data base, networked computer system, or any other electronic or magnetic data system, that more than one person may access by any means.\22 H.R. 1815, 3(3). The term, however, \22does not include oral communication between an individual who is the subject of protected health information and a health care provider delivering health care to such individual.\22 Id. \par\par

n261. See H.R. 341, 3(4) (defining genetic information as \22information about genes, gene products or inherited characteristics that may derive from an i

individual or a family member²²). Several other bills defined genetic information with the same or similar language. See S. 2330, 105th Cong. 302(b), 303(c), 304(c) (1998); H.R. 3299, 105th Cong. 2(a)(1)(C), 2(a)(2)(C), 3(d)(3) (1998); H.R. 2216, 105th Cong. 2(2) (1997); H.R. 2198, 2(a)(1)(C); H.R. 1726, 105th Cong. 105(a)(1) (1997); H.R. 328, 105th Cong. 2(a)(1)(C) (1997); H.R. 306, 105th Cong. 3(a)(1) (1997); see also S. 422, 3(10) (defining genetic information as ²²information from a human DNA sample about molecular genotype, information from mutation analysis, or information about nucleotide sequence of a gene²²). However, the Genetic Employment Protection Act of 1997 and its companion bill, the Genetic Justice Act, defined genetic information more broadly to include ²²a physical medical examination, ⁵and/or⁵ a family history ⁵In addition to⁵ a direct analysis of genes or chromosomes.²² H.R. 2275, 105th Cong. 2(2) (1997) (Genetic Employment Protection Act of 1997); S. 1045, 105th Cong. 2(2) (1997) (Genetic Justice Act).

n262. H.R. 341, 105th Cong. 4(a)(1). This prohibition also applies to the redisclosure of genetic information by any entity properly possessing such information. See *id.*; S. 422, 201(b); see also H.R. 3299, 2(a)(1)(B) (detailing prohibitions against the use or disclosure of genetic information that might adversely affect health benefits). The prohibition on disclosure or redisclosure presumably refers to entities with authorized access to genetic information, such as health care professionals requiring genetic information for medical diagnoses and therapy. Several other bills also use the same or similar language as H.R. 341 in prohibiting unauthorized disclosure of genetic information. See S. 2330, 302(b), 303(c), 304(b); H.R. 3299 2(a)(1)(B), 2(a)(2)(B), 3(b); S. 1368, 105th Cong. 202(b) (1997); H.R. 2198, 2(a)(1)(B); H.R. 1726, 105; S. 422, 302; H.R. 328, 2(a)(1)(B); H.R. 306, 3(a)(1). H.R. 341, however, includes several exceptions where competing policy reasons outweigh a blanket prohibition against disclosure. See H.R. 341, 4(a)(2). This section permits disclosure of genetic information under five circumstances: (1) when disclosure is authorized under federal or state criminal laws; (2) when disclosure is required under the specific order of a federal or state court; (3) when disclosure is authorized to establish paternity; (4) when disclosure is needed for the medical diagnosis of a decedent's blood relatives; or (5) when disclosure is needed to identify bodies. See *id.* Other bills also include the same or similar exceptions. See H.R. 3299, 2(a)(1)(B), 2(a)(2)(B), 3(a)(2); H.R. 2198, 2; S. 1368, 211-215; H.R. 328, 2.

n263. H.R. 341, 4(a)(1). For other bills that use the same or similar language in discussing disclosure authorization requirements, see H.R. 3299, 2(a)(1)(B), 2(a)(2)(B); S. 1368, 202; H.R. 2215, 2; H.R. 2198, 2; H.R. 1726, 105; H.R. 306, 3.

n264. See H.R. 1815, 2(b). The Act had seven defined purposes. First, the Act intended to ²²recognize that there is a right to privacy with respect to health information, including genetic information, and that this right must be protected accordingly.²² *Id.* Second, the Act was designed to ²²ensure that an individual's interest in the privacy of ⁵his⁵ health information cannot be overridden without meaningful notice and informed consent, except in limited circumstances where there is a compelling public interest.²² *Id.* Third, the Act aimed to ²²provide individuals ⁵with⁵ access to health information of which they are the subject ⁵and the⁵ power to challenge the accuracy and completeness of, and amend or correct, records containing such information.²² *Id.* Fourth, the Act intended to ²²establish a minimum Federal standard for the protection of health information which will promote confidentiality while allowing efficient transfer of health information between States.²² *Id.* Fifth, the Act aimed to ²²help ensure the confidentiality of computerized or elec

tronically transferred health information.\22 Id. Sixth, the Act was designed to \22restrict the gathering of aggregate health information for financial gain or other purposes without each subject's knowledge or consent.\22 Id. Finally, the Act intended to \22establish strong and effective remedies for \5Bviolators\5D.\22 Id. \par

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\5B*474\5D but others prohibit unauthorized collection of such information. n265\par

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n265. See H.R. 328, 2 (stating that \22health insurance issuers may not request or require an individual to whom the issuer provides health insurance coverage in connection with a group health plan ... to disclose any genetic information or to obtain any genetic test\22); see also H.R. 2275, 3(2) (preventing employers from using genetic information in any way that would deprive an individual employment opportunities or that would affect that status of the individual as an employee); H.R. 1726, 105 (amending ERISA to include exceptions provided in H.R. 306); H.R. 306, 3 (stating that group health plans cannot request or require participants, beneficiaries, or potential participants or beneficiaries to disclose genetic information); S. 422, 101, 202, 203 (requiring written authorization and informed consent to collect an individual's DNA sample and giving individuals the right to inspect and copy the records containing their genetic information, in addition to the right to amend inaccurate records). Moreover, the Genetic Confidentiality and Nondiscrimination Act of 1997 would promulgate standards for scientists engaged in the collection of DNA samples for research purposes. See S. 422, 501. \par

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The Genetic Privacy and Nondiscrimination Act of 1997 would also prohibit employers from seeking or using the genetic information, or requiring genetic testing, of current or prospective employees. n266 The bill would prohibit employers from \22obtaining, or using the genetic information of an employee or a prospective employee ... to distinguish between or discriminate against or restrict any right or benefit otherwise due or available to the employee or prospective employee.\22 n267 To enforce this prohibition, the bill creates a private right of action for victims of genetic discrimination to seek compensatory, consequential and punitive damages. n268 Other genetic discrimination bills would permit employers to use genetic information when such information was \22job related and consistent with business necessity.\22 n269 For example, the Genetic Nondiscrimination in the \5B*475\5D Workplace Act, n270 introduced by Representative Joseph Kennedy II (D-MA) would permit employers to request genetic information. n271 Although the bill appears to give employers enough regulatory room to discriminate genetically, this provision may be predicated on the assumption that the ADA prohibits such genetic discrimination by employers. n272 Other bills also limit benign classifications drawn by employers based on genetic information n273\par

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n266. See H.R. 341, 5(a); see also Geri Aston, Preventing Genetic Discrimina

tion, Am. Med. News, Aug. 4, 1997, at 3. \par\par

n267. H.R. 341, 5(a). Several bills also use similar language to prohibit genetic discrimination by employers. See H.R. 3299, 3; H.R. 2275, 3; S. 1045, 105th Cong. 3 (1997); H.R. 2215, 2; H.R. 2198, 3; S. 422, 401. \par\par

n268. See H.R. 341, 5(b) (incorporating private remedies provided under 705-709 of the Civil Rights Act of 1964). Several other genetic discrimination bills provide a private right of action. See H.R. 3299, 3(c) (incorporating private remedies provided under 705-709 of the Civil Rights Act of 1964); S. 1368, 323 (permitting an individual to recover compensatory, punitive and consequential damages); H.R. 2275, 8 (providing private right of action with equitable and legal relief); S. 1045, 8 (same); H.R. 2215, 2(d) (providing private right of action with remedies including actual damages and equitable relief); H.R. 1815, 302 (providing a private right of action with remedies including equitable relief, actual or liquidated damages, punitive damages and attorney's fees); H.R. 1726, 105 (permitting recovery for compensatory, consequential and punitive damages); S. 422, 701(d) (permitting recovery for: actual damages or a specified amount of money, whichever is greater; treble damages in cases of violations made for pecuniary gain; and/or reasonable attorney's fees and civil penalties). \par\par

n269. See H.R. 2198, 3(a)(2)(A). Three other bills also contain similar exceptions that permit genetic discrimination by employers in cases of 'business necessity.' See H.R. 3299, 3(a)(2)(A); H.R. 2275, 3(3)(B); S. 422, 401(a)(2); see also S. 1045, 3(3) (permitting employers to disclose employees' genetic information if the employer requests the information after an offer of employment, the information requested is a business necessity and the employee voluntarily consented in writing). However, the Genetic Employment Protection Act of 1997 and the Genetic Justice Act would expand protection by prohibiting employment agencies and labor organizations from genetically discriminating. H.R. 2275, 4-5; S. 1045, 4-5. \par\par

n270. H.R. 2215. \par\par

n271. See id. 2 (1997). An employer who wants genetic information about an employee or prospective employee 'shall provide the employee or prospective employee with a written statement of the uses which the employer intends for such genetic information.' Id. The bill also would allow individuals to sue employers who fail to use genetic information in accordance with their stated purpose. See id. \par\par

n272. See id. 2. The section states that 'nothing in this section authorizes an employer to obtain, disclose, or use genetic information about an employee or prospective employee in violation of the Americans with Disabilities Act of 1990 or any other Federal or State law that restricts access to, disclosure of, or use of genetic information.' Id. \par\par

n273. See H.R. 2275, 3(2); see also S. 1045, 3(2) (making it unlawful for employers to 'limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect the status of the individual as an employee, because of genetic information with respect to the individual, including an inquiry by the individual regarding genetic services'). \par\par

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Furthermore, the Genetic Privacy and Nondiscrimination Act of 1997 would prohibit health insurers from 'using genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, or otherwise affect health insurance.' n274 The bill would also prohibit genetic discrimination by health

insurers, self-insured employers and ERISA plans (i.e., HMOs), thus covering both the independent and group insurance markets. n275 Other genetic discrimination bills would protect consumers in both the individual and group health insurance markets. n276 Finally, the Genetic Privacy and Nondiscrimination Act of 1997 would require the NBAC to submit a report to Congress recommending appropriate regulations and standards governing the collection and use of genetic information. n277 This provision would thus provide adequate regulatory adaptability, enabling legislation to keep pace with a growing body of scientific knowledge and terminology.

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n274. H.R. 341, 105th Cong. 6(a) (1997). Similarly, other bills would prohibit health insurers and self-insured employers from denying, cancelling, or refusing to renew such benefits or such coverage, or varying the premiums, terms, or conditions for such benefits or such coverage, for any participant or beneficiary ... on the basis of genetic information ... or on the basis that the participant or beneficiary has requested or received genetic services. H.R. 1726, 105th Cong. 105 (1997); see also S. 2330, 105th Cong. 302(a), 303(a)(1)(A), 304(a) (1998) (providing similar prohibitions as H.R. 1726); H.R. 3299, 2(a)(1)(A), (B) (same); S. 422, 402(a) (same); H.R. 306, 105th Cong. 3 (1997) (same). Genetic services is defined as health services provided to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling. H.R. 1726, 105; H.R. 306, 3. However, the Genetic Privacy and Nondiscrimination Act of 1997 would permit life insurers to require applicants to undergo genetic testing. See H.R. 341, 6(c). But see H.R. 2216, 105th Cong. 3 (1997) (proposing to prohibit life and disability insurers from genetically discriminating). Genetic test is defined as a test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose a genetic characteristic. H.R. 2216, 2(3); H.R. 2198, 2; H.R. 341, 3(5); see also H.R. 328, 105th Cong. 2(a)(1)(B) (1997) (defining genetic test with similar language). \par\par

n275. See H.R. 341, 3(6). The term insurer is defined as insurance company, health care service contractor, fraternal benefit organization, insurance agent, third party administrator ... or other such person subject to regulation under State insurance laws as well as self-funded health plans and health plans regulated under ERISA. Id. Other bills impose similar proscriptions on health insurers and ERISA plans. See S. 2330, 302(a), 303(a)(1)(A), 304(a); H.R. 3299, 2(a)(1)-(2); H.R. 1726, 105(a)-(b); S. 422, 402(b). \par\par

n276. See S. 2330, 303(a)-(b); H.R. 3299, 2(b); H.R. 2198, 2; H.R. 1726, 105; H.R. 328, 2; H.R. 306, 3; see also Collins 1997 Testimony, supra note 6, at 15 (stating that H.R. 328 closed some of the loopholes left by HIPAA by addressing discrimination in the individual health insurance market). \par\par

n277. See H.R. 341, 7(1)-(2). Under a similar bill, H.R. 2198, the NBAC would be required to make recommendations on \par\par

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(1) the development and implantation of standards to provide increased protection for the collection, storage, and use of identifiable DNA samples and genetic information obtained from those samples; and \par\par

(2) the development and implementation of appropriate standards for the acqu

isition and retention of genetic information in all settings, including appropriate exceptions. \par

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H.R. 2198, 4(1)-(2). This provision is also contained in H.R. 2690, 104th Cong. 7 (1995). In addition, H.R. 3299 proposed to establish elaborate procedures for the creation of the National Bipartisan Commission on the Use of Genetic Information. See H.R. 3299, 4. \par

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The Genetic Privacy and Nondiscrimination Act of 1997, however, does not contain provisions permitting people to inspect, copy and correct genetic information lawfully possessed by entities authorized under the Act. n278 Several other bills introduced in the 105th Congress would permit inspection and copying of protected genetic information by the person who furnished such information. n279\par

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n278. See H.R. 341. \par\par
n279. See S. 1368, 105th Cong. 101-103 (1997); H.R. 1815, 105th Cong. 101-103 (1997); S. 422, 202-203. \par
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E. Genetic Discrimination Legislation Recommendations\par
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Federal genetic discrimination legislation must address many issues affecting almost every aspect of society. n280 Revolutionary discoveries and their consequent technology will vastly improve our pharmaceutical and medical abilities to detect, cure, and prevent many, if not all, human afflictions. n281 However, with the influx of potentially life-saving knowledge will come less noble applications as well. n282 Mapping the human genome will facilitate the collection, storage, use and dissemination of individuals' genetic information. n283 Consequently, the potential for abuse of such information, specifically genetic discrimination and invasions of genetic privacy, increases exponentially with scientific progress. n284 Furthermore, the rapidity of such genomic discoveries complicates the legislator's task of drafting laws that adequately anticipates subsequent developments. n285 Nevertheless, there are several basic provisions necessary to make genetic discrimination legislation effective.\par

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n280. The HGP and the genomic information that it reveals implicate various ethical, legal, social, political and economic issues. See Patrinos & Drell, *supra* note 15, at 8. \par\par
n281. See Elizabeth Shogren, *White House to Seek Genetic Test Safeguards*, L.A. Times, Jan. 20, 1998, at A1, available in 1998 WL 2390404 (quoting Chris Jennings, President Clinton's senior health care advisor, as stating that genomic research "has extraordinary potential for diagnoses and treatment"); see also Philip R. Reilly, *Public Policy and Legal Research Issues Raised by Advances in Genetic Screening and Testing*, 27 Suffolk U. L. Rev. 1327, 1333 (1993) (suggesting that genetic testing will revolutionize medicine). \pa

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n282. See Shogren, *supra* note 281 (quoting from a preliminary draft of a study, entitled Genetic Information and the Work Force stating that 'while genetic technology increases the ability to detect and prevent health disorders, it can also be misused to discriminate against or stigmatize individuals'); see also Steve Ginsberg, *The New Resume: Jobs, Schools, Genetic Makeup?*, S.F. *Bus. Times*, Nov. 21, 1997, at 8A, available in 1997 WL 15945933 (discussing workers' fears of genetic discrimination in the workplace). \par\par

n283. See Annas, *supra* note 74, at 2346. The collection, storage and use of genetic information have already created litigation. See *Mayfield v. Dalton*, 109 F.3d 1423, 1424 (9th Cir. 1997). The plaintiffs, two U.S. Marines, challenged the constitutionality of the Department of Defense's DNA registry, fearing that information obtained from the repository samples, regarding the donors' propensities for hereditary diseases and genetic disorders, might be used to discriminate against applicants for jobs, insurance or benefit programs. 2 Id. \par\par

n284. See Rothenberg Testimony, *supra* note 79, at 85-86 (stating that 'as the flow of genetic information increases, so too will the risk of its misuse'); see also *Norman-Bloodshaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1268-70 (9th Cir. 1998) (holding unanimously that the 'constitutionally protected privacy interest in avoiding disclosure of personal matters' and the Fourth Amendment's search and seizure clause prohibit employers from secretly collecting and using employees' genetic information). \par\par

n285. See, e.g., G. J. V. Nossal & Ross L. Coppel, *Reshaping Life: Key Issues in Genetic Engineering* 139 (2d ed. 1989). \par

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First, because everyone has a few bad genes, genetic discrimination legislation should offer protection to all Americans. n286 Consequently, genetic discrimination legislation must apply to insurers regulated under state insurance laws and entities regulated under ERISA, including HMOs and self-insured employers. n287 Moreover, genetic discrimination legislation should protect consumers in both group and individual health insurance markets. n288 Second, health insurers and employers must be prohibited from genetically discriminating against insureds or employees, especially by eliminating health coverage for individuals in the highest risk category. n289 Third, individuals should be free from mandatory genetic testing absent a compelling interest. n290 Fourth, genetic discrimination legislation must prohibit unauthorized disclosure of genetic information, n291 and should allow individuals to inspect and correct their genetic information records. n292 Fifth, such legislation should provide effective measures of enforcement, including, but not limited to, a private right of action for individuals harmed by abuses of genetic information. n293 \B*478\B Finally, genetic discrimination legislation should be adaptable to the changing corpus of scientific knowledge. n294\par

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n286. See Collins 1997 Testimony, *supra* note 6, at 12; see also Stearns Testimony, *supra* note 81, at 3 (stating that 'each and every one of us could be affected once the mapping and sequencing phase of 'BHGP' research has been completed'). \par\par

n287. See H.R. 341, 105th Cong. 3(6) (1997) (defining insurer to include HMOs and self-insured employers); see also Hudson et al., *supra* note 4, at 393 (d

defining "insurance provider" broadly to include "an insurance company, employer, or any other entity providing a plan of health insurance or health benefits").

n288. See Hudson et al., supra note 4, at 393.

n289. See H.R. 341, 5-6; see also Hudson et al., supra note 4, at 393 (listing several legislative recommendations of the Working Group on Ethical, Legal, and Social Implications that would prohibit insurers from "using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements ... or from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services").

n290. See H.R. 341, 5(a); see also Hudson et al., supra note 4, at 393 (recommending that "insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information"). But see H.R. 341, 6(c) (permitting life insurers to request genetic tests). For some compelling reasons that would permit mandatory genetic testing, see Kristin M. Raffone, Note, The Human Genome Project: Genetic Screening and the Fundamental Right of Privacy, 26 Hofstra L. Rev. 503, 534-44 (1997) (citing preventative medicine, inheritable diseases, genetic diversity and societal interest in potential life as compelling reasons given by states for instituting genetic screening programs).

n291. See Laurant Neergaard, Doctor Lobbies for Genetic Privacy Legislation, Buff. News, Sept. 30, 1995, at A4; see also Hudson et al., supra note 4, at 393 (recommending that "insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual" and that written authorization should be required for each disclosure and include to whom the disclosure would be made); H.R. 341, 4(a)(1)-(2) (prohibiting disclosure or redisclosure of genetic information, subject to several narrowly tailored exceptions).

n292. See Lori B. Andrews & Ami S. Jaeger, Confidentiality of Genetic Information in the Workplace, 17 Am. J.L. & Med. 75, 108 (1991).

n293. See bills discussed in supra note 268.

n294. See H.R. 341, 7 (requiring the NBAC to make recommendations to Congress in order to keep genetic legislation adaptable to subsequent scientific developments).

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Many protections are needed against the limitless potential abuse of genetic information. Federal legislation regulating genetic information must prohibit: genetic discrimination by health insurers and employers; unauthorized disclosure of genetic information; mandatory genetic testing; collection of genetic information without informed consent; and other genetic abuses. n295 Although several genetic discrimination bills of the 105th Congress would provide substantial protections, n296 the Genetic Privacy and Nondiscrimination Act of 1997 and the Genetic Confidentiality and Nondiscrimination Act of 1997 both offer comprehensive protection from abuses of genetic information, and should be enacted into law by Congress. Because the 105th Congress failed to enact genetic discrimination legislation, n297 the provisions contained in these bills should be the basis for future bills to be considered in the 106th Congress.

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n295. See id. 4-7. \par\par

n296. Several genetic discrimination bills introduced in the 105th Congress offer adequate protections. Table 1 indicates the protections offered by each of the 105th Congress's genetic discrimination bills. Although different bills may include provisions of the same general type (for example, provisions protecting genetic privacy), not all of the provisions were equally comprehensive. Table 1 does not reflect the superiority of some provisions relative to those in other bills. \par\par

\5BSEE TABLE IN ORIGINAL\5D \par\par

Table 1. 105th Congress's Genetic Discrimination Provisions. * S. 2330, entitled the Patients' Bill of Rights Act, is not strictly a genetic discrimination bill. Title III of S. 2330, cited as Genetic Information Nondiscrimination in Health Insurance Act of 1998, provides the relevant provisions relating to genetic discrimination. Similarly, H.R. 1726, entitled Children's National Security Act, is also not strictly a genetic discrimination bill. \par\par

n297. The odds that any of the 105th Congress's genetic discrimination bills would be enacted were low. See Search of WESTLAW, Billcast (Oct. 6, 1998). Table 2 represents the odds of passing for each of the 105th Congress's genetic discrimination bills. \par\par

\5BSEE TABLE IN ORIGINAL\5D \par\par

Table 2. Odds of Success for 105th Congress's Genetic Discrimination Bills.

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n298. A staff member from Representative Kennedy's office indicated that, in light of heavy opposition from insurance lobbyists, genetic discrimination legislation might have to be inserted as a rider into bills supported by the Republican majority. See Interview with O'Connor, supra note 189. \par

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VII. CONCLUSION\par

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Although federal and state legislatures are beginning to enact genetic discrimination laws, these laws offer inadequate protection. n299 Genomic research and discoveries of disease genes are rapidly producing commercially available genetic tests, ushering in an age of widespread genetic screening. n300 More comprehensive genetic discrimination legislation is needed to prevent an infinite train of abuses made possible by unlocking the human genome. n301 Scientific discoveries made by the HGP provide great potential. Genomic research may lead to a revolution in medicines' ability to heal people at the molecular level through gene therapy. n302 However, this research may concomitantly lead to genetic discrimination and invasions of genetic privacy and autonomy. n303 Therefore, this influx of genetic information should be accompanied by federal legislation designed to limit potential abuses of such information, especially abuses decreasing the availability of health care. Congress should enact legislation that prohibits genetic discrimination by health insurers and employers, and protects genetic privacy and autonomy. Several bills proposed during the 105th Congress would adequately regulate the uses of genetic information, n304 although the Genetic Privacy and Nondiscrimination Act of \5B*480\5D 1997 offers the most comprehensive protection. n305 Although the rapidity of genomic discoveries will likely make comprehensive genetic legislation impossible and will require subsequent legislation to respond to new developments, enactment of any of these bills would provide a necessary foundation for future genetic discrimination law

s and jurisprudence.\par
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n299. See Bornstein, supra note 20, at 609; O'Hara, supra note 15, at 1227.
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n300. See O'Hara, supra note 15, at 1212. \par\par
n301. See Holmes, supra note 10, at 663. \par\par
n302. See Gostin, supra note 6, at 113. \par\par
n303. See supra note 5 (describing a fictional, though plausible, account of a society incorporating genetic discrimination). \par\par
n304. See, e.g., H.R. 2198, 105th Cong. (1997) (limiting '22the disclosure and use of genetic information in connection with group health plans and health insurance coverage,'22 and prohibiting '22employment discrimination on the basis of genetic information and genetic testing, and for other purposes'22); S. 422, 105th Cong. (1997) (defining '22the circumstances under which DNA samples may be collected, stored, and analyzed'22). Restrictions imposed by S. 422 would include genetic discrimination by employers and health insurers, as well as unauthorized disclosure of genetic information by any entity. See S. 422, 201. Moreover, comprehensive genetic discrimination protections would be enacted under two bills introduced by Representative Kennedy. See H.R. 2215, 105th Cong. (1997) (restricting '22employers in obtaining, disclosing, and using genetic information'22); H.R. 2216, 105th Cong. (1997) (limiting the '22disclosure and use of genetic information by life and disability insurers'22). \par\par

n305. See H.R. 341, 105th Cong. (1997). The Genetic Privacy and Nondiscrimination Act of 1997 would prohibit genetic discrimination by employers and health insurers. See id. 5-6. The bill would also prohibit unauthorized disclosure of genetic information. See id. 4. Furthermore, genetic discrimination prohibitions would apply to HMOs and other ERISA-regulated entities. See id. 3(6). Finally, the bill would require the NBAC to prepare subsequent reports for Congress regarding new legislative needs in light of scientific advances. See id. 7. \par
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+ Staff Attorney, Los Alamos National Laboratory. A.B. 1960, J.D. 1963, Harvard. Coordinator of the U.S. Department of Energy Program on the Ethical, Legal, and Social Implications of the Human Genome Project, 1990-1995. The views are the author's. \par\par\pard

SUMMARY: ... This article surveys current legislation related to genetic privacy and discrimination, including Federal and State laws that prohibit, or could be used to prohibit, genetic discrimination in employment and insurance, and laws that protect genetic privacy. The relationship between protecting genetic privacy and prohibiting genetic discrimination is discussed. ... Nearly all the laws on genetic discrimination incorporate measures to protect genetic privacy. ... Not all genetic privacy measures will guard against genetic discrimination, however. ... Finally, prohibiting genetic discrimination does not have to incorporate privacy laws. ... The plethora of genetically significant data makes it difficult, if not impossible, to distinguish what information should be protected by genetic privacy and discrimination laws. ... Indeed, the laws barring genetic discrimination in health insurance are a very slight increment, since they protect only the few persons who purchase individual health coverage. ... The growing number of statutes requiring informed consent for the development or disclosure of genetic information, the Moore court's reading of the common law requirement of informed consent, and, most recently, the Ninth Circuit's application of constitutional privacy protection to genetic testing make it imperative to obtain an individual's authorization of any genetic testing and use of identified test results. ... \par\par\pard

On February 20-21, 1998, the Berkeley Technology Law Journal co-sponsored a symposium with the Berkeley Center for Law and Technology entitled Biotechnology and the Law: New Perspectives on Public Access and Proprietary Rights. The symposium explored the impact of current patent law and policy on biotechnological research, as well as the legal and ethical questions stemming from that research. Mr. Yesley presented this paper during the Information Privacy session, which addressed the social ramifications of lax privacy rules for genetic data and considered whether there should be a property right in this data. \par\par\pard

TEXT: \5B*653\5D \par\par

Abstract\par

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This article surveys current legislation related to genetic privacy and discrimination, including Federal and State laws that prohibit, or could be used to prohibit, genetic discrimination in employment and insurance, and laws that protect genetic privacy. The relationship between protecting genetic privacy and prohibiting genetic discrimination is discussed. \par\par

In part II of the article, the author discusses impediments to the creation of effective legislation to combat genetic discrimination. These include: (1) the difficulty of defining "genetic information," given the variety of information with genetic significance; and (2) the limited usefulness of laws narrowly focused on prohibiting genetic discrimination and the possibility of perverse results from such measures. \par\par

Finally, the article addresses whether a property right in genetic data is needed to address the issue of genetic privacy. The author concludes that, unlike the case where a person's biological materials are used to develop a commercial product, intangible genetic data probably would not generate sufficient value to warrant the cost of enforcement by those affected. As the author explains, "the goal of protecting genetic information is not to preserve any value of

the information, but to control its use and disclosure. For this purpose, requiring informed consent is probably sufficient, and the disincentive of potential recovery for conversion of the property is unnecessary.\22\par

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'5B*654\5D \par\par
I. INTRODUCTION\par

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In the world of biotechnology, John Moore (an unwitting donor of cells for medical research) learned to his surprise that you can be valuable if you are different. n1 But in the rest of the universe, being different is not necessarily an advantage - particularly if one's difference is a basis for discrimination. Genetics provides a new lexicon of difference, for better and for worse. We focus here on \22worse:\22 the possibility that genetic difference can be used as a basis for discrimination in employment and insurance.\par

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-----Footnotes-----
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n1. Moore's cells were obtained in the course of his treatment for leukemia at UCLA Medical Center and, unbeknownst to him, used to establish a cell line that was patented. See \i Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), \i0 cert. denied, \i 499 U.S. 936 (1991).\i0 \par

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Anti-discrimination laws protect many kinds of difference - race, sex, national origin, disability, and more. n2 Privacy rules have also been used as a means to protect difference. n3 and privacy ranks high as an end in itself. But privacy may hinder as well as promote anti-discrimination efforts because one's differences must often be revealed in order to protect them. Also, privacy will not protect a difference that is obvious.\par

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n2. See, e.g. Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (1964); American with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990). \par\par
n3. For example, some genetic anti-discrimination laws bar insurers from requesting individuals to reveal whether they have been tested or the results of any genetic testing. See, e.g., Wis. Stat. 631.89 (1996). \par

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Genetics reintroduces privacy as a potential weapon against discrimination, because unexpressed molecular differences are hidden. However, these differences can be identified by direct tests or inferred from a variety of sources, like family history and routine medical tests. Thus, the veil \5B*655\5D of molecularity can be pierced in many ways. This raises the question of how best to prevent genetic discrimination. Which approach - property, privacy, civil rights, the free market, public subsidy, or some other - will provide the greatest protection against social misuse of genetic difference? \par\par

This article addresses the question of whether the law should recognize a property right in genetic data. There are, of course, more direct ways to prevent the social consequences of losing genetic privacy. We can use privacy measures to control the development and disclosure of genetic information about individ