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GENETIC TESTING, GENETIC MEDICINE, AND MANAGED CARE

Mark A. Rothstein*

Sharona Hoffman**

As modern human genetics moves from the research setting to the clinical setting, it will encounter the managed care system. Issues of cost, access, and quality of care will affect the availability and nature of genetic testing, genetic counseling, and genetic therapies. This Article will explore such issues as professional education, coverage of genetic services, privacy and confidentiality, and liability. It will conclude with a series of recommendations for the practice of genetic medicine in the age of managed care.

INTRODUCTION

The Human Genome Project is an international research effort designed to locate and decipher the estimated 100,000 genes that comprise the human genome.¹ The Project, begun in 1990 and scheduled for completion by 2003, will facilitate the development of genetic tests to predict and diagnose disease and the improvement of treatments to prevent and cure genetic illnesses.²

During the last decade, while genetic research has changed rapidly, health care delivery and reimbursement have undergone their own revolution. The health care system in the United States has been transformed from one in which most physicians were self-employed or members of small group practices to one in which more than three-quarters of physicians practice within managed care

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1. See Leroy Hood & Lee Rowen, *Genes, Genomes and Society*, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA [hereinafter GENETIC SECRETS] 3, 3-4, 8 (Mark A. Rothstein ed., 1997).

2. See Francis S. Collins et al., *New Goals for the U.S. Human Genome Project: 1998-2003*, 282 SCIENCE 682, 682-83 (1998).

organizations or see managed care patients.³ More than sixty million Americans are enrolled in health maintenance organizations; an additional ninety million subscribe to other types of managed care plans.⁴ If enrollment rates continue at their current rate, eight out of ten Americans will receive care through a managed care organization by the year 2000.⁵

Individual physicians practice under a variety of constraints. Doctors often are under pressure to see more patients per day and to use fewer imaging, laboratory, and other resources.⁶ Utilization review and financial incentives may cause physicians to forego diagnostic tests and treatment regimens that they otherwise might have chosen.⁷

Primary care physicians are of particular importance in the managed care system. They typically perform the gatekeeping function of determining when patients should see other doctors and specialists.⁸ In addition, primary care physicians increasingly

3. See Barbara A. Noah, *The Managed Care Dilemma: Can Theories of Tort Liability Adapt to the Realities of Cost Containment?*, 48 MERCER L. REV. 1219, 1219 (1997); see also Bernard Friedland, *Managed Care and the Expanding Scope of Primary Care Physicians' Duties: A Proposal to Redefine Explicitly the Standard of Care*, 26 J.L. MED. & ETHICS 100, 104 (1998) (noting that "between 1986 and 1995, the number of physicians with at least one managed care contract rose from 43 to 83 percent"). One prominent commentator has defined "managed care" as a "system that, in varying degrees, integrates the financing and delivery of medical care through contracts with selected physicians and hospitals that provide comprehensive health care services to enrolled members for a predetermined monthly premium." John K. Iglehart, *Physicians and the Growth of Managed Care*, 331 NEW ENG. J. MED. 1167, 1167 (1994). Another commentator has provided the following definition:

Managed care is a catch-all phrase for a broad variety of activities and organizations. Core to its definition and key to its distinction from indemnity health plans is that managed care is structured to integrate the insurance risk and the direct provision of care. Managed care uses a very large and developing repertoire of tools to influence individual treatment decisions aggregated over a population, including distributing information to providers on relative effectiveness and cost of treatment; providing financial incentives and disincentives based on risk sharing in the cost of treatment decisions; pre-treatment certification; post-treatment review; practice profiles; practice guidelines; and so forth.

Sandra H. Johnson, *Managed Care as Regulation: Functional Ethics for a Regulated Environment*, 23 J.L. MED. & ETHICS 266, 267 (1995).

4. See Robert Pear, *Laws Won't Let H.M.O.'s Tell Doctors What to Say*, N.Y. TIMES, Sept. 17, 1996, at A12; see also Noah, *supra* note 3, at 1219.

5. See Noah, *supra* note 3, at 1220.

6. See Friedland, *supra* note 3, at 100.

7. See *id.*

8. See Noah, *supra* note 3, at 1225; see also PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING 60, 63 (Neil A. Holtzman & Michael S. Watson eds., 1997) [hereinafter SAFE AND EFFECTIVE GENETIC TESTING]; *infra* text accompanying notes 48-51.

perform services such as skin biopsies, oncologic follow-up, and the splinting of simple fractures, procedures that were previously handled by specialists.⁹

As genetic tests and genetic therapies move from the laboratory to the clinical setting, the new technology will have numerous implications for managed care organizations. This Article focuses upon several specific problems that the new genetic technology may cause for managed care organizations.

As genetic tests become cheaper, more automated, and increasingly relevant to common disorders, they will become widely used tools of primary care. Thus, most of the responsibility for requesting and interpreting initial genetic tests will fall on primary care physicians, the overwhelming majority of whom currently lack expertise in genetics.¹⁰ Health insurance providers, managed care organizations, and regulators will be compelled to implement measures to ensure that physicians are adequately educated in genetics, that genetic counseling is provided to patients by well-trained professionals, and that patients receive the education necessary to enable them to make informed decisions regarding whether to have genetic testing and what to do based on test results.¹¹

The cost and financing of genetic testing and counseling has a profound impact on patient access to these services in the managed care system.¹² Group health insurance plans often do not cover screening tests in the absence of symptoms and, thus, exclude coverage of genetic testing for many diseases.¹³ Where coverage exists for genetic testing, reimbursement is rarely provided for the necessary education and counseling that should accompany such tests, especially with respect to prenatal diagnosis.¹⁴ In addition, if genetic predisposition to a disease is detected, the patient may seek expensive periodic screening or prophylactic surgery.¹⁵ As genetic technology becomes increasingly available, managed care

9. See Friedland, *supra* note 3, at 102.

10. See SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 63.

11. See *id.* at 64-73.

12. See ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 234 (Lori B. Andrews et al. eds., 1994) [hereinafter ASSESSING GENETIC RISKS].

13. See *id.* at 234-35, 239.

14. See *id.* at 239.

15. See, e.g., *Katskee v. Blue Cross/Blue Shield*, 515 N.W.2d 645, 647, 653 (Neb. 1994) (reversing the lower court's decision to grant summary judgment to an insurer that had denied coverage for prophylactic surgery to remove the uterus, ovaries, and fallopian tubes of a woman with a genetic predisposition to breast and ovarian cancer); Lynn C. Hartmann et al., *Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer*, 340 NEW ENG. J. MED. 77, 77 (1999) (presenting the results of a study that concluded that prophylactic mastectomies significantly reduce the risk of breast cancer in women with a family history of breast cancer).

organizations will face demands for coverage of genetic services and will have to make important decisions regarding resource allocation.

A serious concern also exists regarding the consequences of genetic information for certain patients.¹⁶ In some instances, genetic screening can lead to medical interventions that achieve effective treatment or prevention. In other instances, genetic testing can reveal that an individual is a carrier of a particular mutation, permitting more options for reproductive planning, including the choice to remain childless. Prenatal diagnosis of fetuses, however, can be ethically and psychologically more complicated. If the fetus is found to be disease free, the parents receive welcomed reassurance regarding their child's future. The possibility that parents may learn that their infant is afflicted with a disorder before he or she is born, however, gives rise to the specter of selective abortions, genetic engineering, and eugenics.¹⁷

For some late-onset disorders, no effective intervention exists, as is the case with Huntington's disease, a late-onset disorder that can now be predicted through genetic testing but still remains untreatable.¹⁸ In the absence of treatment, genetic information may have devastating psychological and social consequences for an individual and his or her family. Consequently, it is essential for individuals who undergo genetic testing to receive genetic counseling from trained professionals. Some patients may find, however, that managed care organizations are unwilling to pay for testing that does not lead to medical intervention and whose main value is psychological or social.

Genetic testing, counseling, and treatment generate new liability issues for medical professionals. Medical malpractice cases may be brought under "wrongful birth" and "wrongful life" theories.¹⁹ In addition, plaintiffs may assert claims based on a physician's failure to warn at-risk relatives.²⁰ Genetic technology,

16. See generally Hood & Rowen, *supra* note 1, at 25-27 (raising issues that are presented when one has genetic information).

17. See *id.*

18. See ASSESSING GENETIC RISKS, *supra* note 12, at 87.

19. The allegation in these suits is that the health care provider is liable for failing to recommend diagnostic tests that might have disclosed a birth defect or genetic risk in time for the parents to avoid conception or choose an abortion. See MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS 215 (1997); see also Michelman v. Ehrlich, 709 A.2d 281, 283 (N.J. Super. Ct. App. Div.), *cert. denied*, 719 A.2d 637 (N.J. 1998) (holding that grandfather did not have cognizable cause of action for wrongful birth); Davis v. Board of Supervisors of La. State Univ., 709 So. 2d 1030, 1035 (La. Ct. App.) (upholding lower court's grant of summary judgment in wrongful life case), *cert. denied*, 719 So. 2d 1288 (La. 1998).

20. See Pate v. Threlkel, 661 So. 2d 278, 282 (Fla. 1995) (holding that the trial court had erred in dismissing the plaintiff's complaint asserting that a physician had a duty to a patient's children to warn them of the genetically transferable nature of the patient's illness); Safer v. Estate of Pack, 677 A.2d

thus, may raise costs for managed care organizations and other providers not only because of enhanced testing and treatment options but also because of new liability claims and theories.

Finally, once genetic information is obtained through testing, its existence raises important concerns about privacy and confidentiality for both patients and healthcare providers.²¹ The concerns include questions regarding the right of family members to be informed about the patient's genetic information, as well as issues of insurance and employment discrimination.²² Congress and many state legislatures have responded to the potential problem of genetic discrimination by enacting statutory non-discrimination mandates.²³ These laws, however, are often simplistic, incomplete, and ineffective.²⁴ Managed care providers must remain sensitive to issues of genetic privacy and confidentiality and implement safeguards to insure that only authorized personnel obtain access to genetic information.

This Article will explore the issues described above and will offer recommendations to address some of the problems that stem from genetic technology. The Article will begin with a description of the Human Genome Project.²⁵ Section III then will discuss the provision of genetic testing and counseling in the managed care setting and the steps needed to ensure that managed care providers are educated sufficiently to furnish genetic services to patients. Section IV will analyze questions relating to the cost of genetic testing and therapy and to the circumstances under which managed care providers should make genetic screening and subsequent follow-up treatment available to patients. Section V will address the potential liability of those providing genetic services to patients, and Section VI will explore privacy and confidentiality concerns.

I. THE HUMAN GENOME PROJECT

The Human Genome Project is a collection of international research studies whose goal is to analyze the structure of DNA and

1188, 1192 (N.J. Super. Ct. App. Div. 1996) (holding that a physician has a duty to warn a patient's immediate family members of the risks of a genetically transmittable disease).

21. See Dorothy C. Wertz, *Society and the Not-So-New Genetics: What Are We Afraid Of? Some Future Predictions from a Social Scientist*, 13 J. CONTEMP. HEALTH L. & POL'Y 299, 308-314 (1997).

22. See *id.*

23. See The Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42 U.S.C. §§ 300gg to 300gg-92 (Supp. 1999); see also Bryce A. Lenox, Comment, *Genetic Discrimination in Insurance and Employment: Spoiled Fruits of the Human Genome Project*, 23 U. DAYTON L. REV. 189, 201 (1997) (citing 14 states with legislation proscribing the use of genetic information).

24. See Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They Are So Hard to Protect*, 26 J.L. MED. & ETHICS 198, 198 (1998).

25. See *infra* Section II.

map and sequence the entire human genome, including the estimated 100,000 human genes.²⁶ In the United States the project is directed by the National Institutes of Health and the U.S. Department of Energy.²⁷ The project was launched in 1990 and was intended for completion in 2005.²⁸ The research, however, is ahead of schedule; approximately half the genes have been at least partially sequenced, and the genetic and physical maps of human chromosomes and the DNA of selected model organisms are close to completion.²⁹

The ultimate goal of the project is to facilitate the treatment and prevention of genetic diseases through the development of effective genetic tests and therapies.³⁰ Currently, it is known that over 5,000 human disorders have a genetic component, and over 1,000 disorders already have been mapped to specific chromosomal regions.³¹

Genetic disorders develop because of changes in the DNA sequence, known as "mutations," which can occur as a result of mistakes in coding of the nucleotides, rearrangements of base pairs within the gene, insertion of new genetic material into the gene, or duplication or deletion of a portion or the entirety of the gene.³² Disorders stemming from changes in only one gene are called "monogenic," and include cystic fibrosis, sickle cell anemia, and Duchenne muscular dystrophy.³³ These diseases, also known as Mendelian disorders, follow well-defined patterns of inheritance and often have clearly defined clinical patterns which are not significantly affected by the environment.³⁴ When mutations in two or more genes acting in combination are needed to cause a disorder, the condition is termed "polygenic."³⁵ Other conditions, such as some

26. See Hood & Rowen, *supra* note 1, at 4, 8-10. The human genome is composed of twenty-three pairs of chromosomes that reside in the nucleus of every nucleated human cell. See *id.* at 3. These chromosomes contain deoxyribonucleic acid, or DNA, which directs human development from one cell at conception to 10¹⁴ cells in adulthood. See *id.* It is estimated that human chromosomes contain 100,000 genes, which are responsible, among other things, for human attributes such as eye color, hair color, and body shape. See *id.* at 4. Each gene consists of DNA and has a unique sequence, comprised of a four-letter code of nucleic acids. See MAXWELL J. MEHLMAN & JEFFREY R. BOTKIN, *ACCESS TO THE GENOME: THE CHALLENGE OF EQUALITY* 10 (1998).

27. See Hood & Rowen, *supra* note 1, at 8.

28. See *id.* at 18.

29. See Collins, *supra* note 2, at 683.

30. See *id.*

31. See Eric S. Lander, *Scientific Commentary: The Scientific Foundations and Medical and Social Prospects of the Human Genome Project*, 26 J.L. MED. & ETHICS 184, 186 (1998).

32. See *ASSESSING GENETIC RISKS*, *supra* note 12, at 60.

33. See *id.*

34. See Eugene Pergament, *A Clinical Geneticist Perspective of the Patient-Physician Relationship*, in *GENETIC SECRETS*, *supra* note 1, at 92, 102.

35. See JOEL DAVIS, *MAPPING THE CODE: THE HUMAN GENOME PROJECT AND*

types of heart disease and most forms of diabetes, result from changes in several genes combined with an environmental influence, and are called "multifactorial."³⁶

Most common disorders, including cancer and cardiovascular disease, have a genetic component.³⁷ In most instances the presence of a gene in a mutated form means that the individual will have an increased risk of developing the disorder.³⁸ The degree of risk varies with the type of mutation and the individual's other genetic and environmental risk factors.³⁹ For example, when a woman has a defective copy of the altered form of the breast cancer 1 gene ("BRCA1"), she has, according to recent estimates, a 56% lifetime risk of breast cancer, though one or more environmental factors may

THE CHOICES OF MODERN SCIENCE 286 (1990) (defining a polygenic disorder).

36. See ASSESSING GENETIC RISKS, *supra* note 12, at 60. Since each person has two copies of each chromosome and, consequently, two copies of each gene, mutations in only one gene, while the other gene remains normal, may produce no adverse effects. See MEHLMAN & BOTKIN, *supra* note 26, at 12. Conditions, such as sickle cell disease, that are present only if there are two abnormal copies of a gene, are termed "recessive." See *id.* If both parents carry the same recessive trait, each of their children has a 25% chance of having the condition, a 50% chance of being an asymptomatic carrier, and a 25% chance of being neither a carrier nor affected by the illness. See ASSESSING GENETIC RISKS, *supra* note 12, at 61.

For some conditions, however, a single abnormal gene produces the illness even though the corresponding gene is normal. See MEHLMAN & BOTKIN, *supra* note 26, at 12. Conditions in which the affected person has one mutant gene and one normal gene are termed "dominant" conditions. See *id.*

Still other disorders are known as "X-linked" disorders. See ASSESSING GENETIC RISKS, *supra* note 12, at 61. Humans have two sex chromosomes; males have an X and a Y chromosome, and females have two X chromosomes. See *id.* In "X-linked" recessive disorders, such as Duchenne muscular dystrophy, fragile X syndrome, and hemophilia, males are disproportionately affected because they possess only one X chromosome, which carries the mutation. See *id.* In "X-linked" dominant diseases, males and females are equally affected since the abnormal gene dominates the normal gene in the second X chromosome in women. See *id.*

Inheritance of a defective gene, however, may result in a variety of consequences, ranging from no effect to an explicit disease. See Hood & Rowen, *supra* note 1, at 20. The severity of some diseases, such as Huntington's disease and fragile X syndrome, which causes mental retardation, correlates with an increase in the number of trinucleotide repeats within the gene. See *id.* If the number of repeats is low enough, no disease symptoms are apparent, but as the number of repeats increases, so does the severity of the disease. See *id.* Geneticists also have identified a phenomenon called "anticipation," where the disease manifests itself earlier and/or with increasing severity as the expanding gene is transmitted from one generation to another. See ASSESSING GENETIC RISKS, *supra* note 12, at 63. Furthermore, mutations that produce disease in one person may generate no detectable effects in another individual. Such mutations are said to have a lower "penetrance." See *id.* at 62.

37. See ASSESSING GENETIC RISKS, *supra* note 12, at 92-94.

38. See Hood & Rowen, *supra* note 1, at 20.

39. See *id.* at 20-21.

be required to trigger the disease process.⁴⁰ In some instances, multiple genes can predispose a person to the same disease, as is the case with BRCA1 and BRCA2, both linked with breast and ovarian cancer, and with the four genes that have been identified as predisposing individuals to Alzheimer's disease.⁴¹ Some illnesses, such as multiple sclerosis, require that two or more different genes be defective for the disease to develop;⁴² other disorders, such as phenylketonuria ("PKU"), require specific environmental cofactors.⁴³

To summarize, "[s]equence variations in genes can . . . lead to diseases that have an all-or-none symptomatology, a degree in the severity of symptoms, or a likelihood of causing symptoms if other genetic or environmental factors exacerbate or fail to ameliorate the effects of the defective genes."⁴⁴ Genetic links have been discovered to Huntington's disease, Alzheimer's disease, several cancers, hemochromatosis, familial hypercholesterolemia, polycystic kidney disease, heart disease, hypertension, diabetes, rheumatoid arthritis, and some psychiatric diseases.⁴⁵ Although genetic research holds out the promise that therapeutic interventions and preventive treatments will be developed to prevent or treat many genetic ailments, a gap now exists between the ability to diagnose susceptibility to genetic diseases and the ability to prevent the illness.⁴⁶ In such cases, genetic testing may have questionable medical efficacy or social value.

If today's trends continue, most genetic testing and genetic treatment will be conducted in a managed care setting. Increasingly, primary care physicians, rather than specialists, will administer tests, counsel patients, and be responsible for safeguarding their patients' genetic information.⁴⁷ The following section will explore the role of primary care physicians in providing genetic services and will discuss the training and education necessary to ensure that patient welfare is not jeopardized by a lack of expertise or sensitivity on the part of health care professionals.

40. Originally, experts estimated that a woman with the BRCA1 mutation had a 90% risk of developing breast cancer. See Muin J. Khoury et al., *From Genes to Public Health: The Applications of Genetic Technology in Disease Prevention*, 86 AM. J. PUB. HEALTH 1717, 1717 (1996). More recently, the estimate has been lowered to 56%. See The Council on Ethical and Judicial Affairs, American Medical Association, *Multiplex Genetic Testing*, HASTINGS CENTER REP., July-Aug. 1998, at 16. The variation underscores the rapidity of change in the field of genetics and the difficulty patients and genetic counselors face in deciding upon a course of action based on test results.

41. See Hood & Rowen, *supra* note 1, at 21.

42. See *id.*

43. See ASSESSING GENETIC RISKS, *supra* note 12, at 39-40.

44. Hood & Rowen, *supra* note 1, at 21.

45. See ASSESSING GENETIC RISKS, *supra* note 12, at 87-99.

46. See Hood & Rowen, *supra* note 1, at 21.

47. See ASSESSING GENETIC RISKS, *supra* note 12, at 2.

II. GENETICS AND PRIMARY CARE

A. *The Role of Primary Care Physicians*1. *The Expanding Role of Primary Care Physicians*

Under managed care systems, primary care physicians have become increasingly important. Managed care organizations seek to control healthcare costs by restricting when, how, where, and from whom patients may obtain medical treatment.⁴⁸ One common cost containment mechanism employed by managed care organizations is to require primary care physicians to serve as gatekeepers for specialist care.⁴⁹ Thus, patients cannot turn directly to a specialist. Rather, the patients must first see primary care physicians who will determine whether they should consult a doctor with greater expertise, a function which is essential to the maintenance of low costs for managed care entities.⁵⁰ Some managed care organizations go so far as to impose maximum utilization quotas for referrals to outside services or to withhold a percentage of physicians' salaries in order to cover overuse of specialist services.⁵¹ If the money withheld is not completely spent during a given year, each physician receives a share of the unspent amount.⁵²

As the role of primary care physicians expands in the managed care setting, so too will their role in genetic medicine. Medical geneticists traditionally have focused on relatively rare monogenic disorders⁵³ and a relatively small number of affected and at-risk individuals.⁵⁴ As the focus of genetic research increasingly has shifted to common, multi-factorial disorders, such as many cancers and cardiovascular disease, the potentially affected and at-risk population now includes all individuals.⁵⁵ Because prevention, screening, and preliminary diagnosis of common disorders are at the heart of primary care, initial genetic risk assessments for common disorders will become a standard aspect of primary care medicine.⁵⁶

In the United States, as of August 1999, only 2741 professionals are certified by the American Board of Medical Genetics or the American Board of Genetic Counseling, including M.D.'s, Ph.D.'s,

48. See Noah, *supra* note 3, at 1225; see also *supra* note 8 and accompanying text.

49. See Noah, *supra* note 3, at 1225.

50. See *id.*

51. See *id.* at 1226.

52. See *id.* at 1227.

53. Monogenic disorders are single-gene diseases such as hyperlipedemic heart disease, Alzheimer's disease, and some cancers. See ASSESSING GENETIC RISKS, *supra* note 12, at 29, 62.

54. See *id.* at 29, 202.

55. See *id.*

56. See *id.* at 202.

and M.S.'s.⁵⁷ The National Society of Genetic Counselors has an enrollment of approximately 1800 members.⁵⁸ A significant number of clinical geneticists practice in major academic medical centers and thus are not accessible to many patients.⁵⁹ While many clinical geneticists work in California and New York, some states have very few trained geneticists and others have none.⁶⁰ As of 1999, only forty-three individuals in New Mexico were members of the American Society of Human Genetics ("ASHG") and Alaska had only three ASHG members.⁶¹ In light of the dearth of genetic professionals available to the general public, responsibility for genetic evaluations will necessarily be allocated to primary care providers.

2. *Education and Training*

A major problem with the "geneticization" of primary care is that many primary care physicians have an inadequate level of education and training in the fast-changing field of genetics.⁶² For example, a 1996 survey on testing for genetic susceptibility to cancer found that 20% of 124 primary care physicians who responded to the survey were not aware that a predisposition to breast cancer could be determined by a genetic test.⁶³

Similarly, in a study published in 1997, researchers analyzed physicians' interpretations of a test for the adenomatous polyposis coli gene mutation, which greatly increases the risk of one form of colon cancer.⁶⁴ A total of 177 physicians ordered the tests, and 80% of the doctors were nongeneticists.⁶⁵ The investigators found that 17% of the tests were not medically indicated, only 18.6% of the patients received formal genetic counseling prior to being tested, and just 16.9% of patients regarding whom information was available had given written informed consent for the testing.⁶⁶ The researchers further concluded that in 31.6% of cases, the physician's faulty interpretation of the test results would have led to communication of erroneous information to the patient.⁶⁷

Several commentators have suggested means by which primary

57. Telephone Interview with Sharon Robinson, American Board of Medical Genetics and American Board of Genetic Counseling (Aug. 5, 1999).

58. Telephone Interview with Bea Leopold, National Society of Genetic Counselors (Aug. 5, 1999).

59. See ASSESSING GENETIC RISKS, *supra* note 12, at 203.

60. See NANCY TOUCHETTE ET AL., TOWARD THE 21ST CENTURY: INCORPORATING GENETICS INTO PRIMARY HEALTH CARE 19-20 (1997).

61. Telephone Interview with Tony Vogel, American Society of Human Genetics (August 5, 1999).

62. See SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 63.

63. See *id.*

64. See *id.*

65. See *id.*

66. See *id.*

67. See *id.*

care physicians could become better educated in the realm of genetics and better able to provide genetic services safely and effectively to their patients.⁶⁸ First, all medical schools and residency training programs should develop genetics curricula to teach physicians to assess the appropriateness of genetic tests, to counsel patients regarding the implications of genetic testing, to interpret test results, to communicate genetic information to patients in an accurate and sensitive manner, and to assist patients who may be profoundly affected or traumatized by the genetic data they receive.⁶⁹ A 1995 survey by the Association of American Medical Colleges revealed that only sixty-eight of 125 medical schools in the United States required students to take genetics courses.⁷⁰ In light of contemporary genetic technology and the imminent completion of the Human Genome Project, all medical schools would be well advised to include instruction in genetics as a mandatory component of medical education.⁷¹

The Task Force on Genetic Testing recommended that genetic questions be included in general licensure and specialty board certification examinations and that students be required to answer a certain portion of the genetics questions correctly in order to attain a passing score.⁷² Such a requirement would serve as a powerful inducement for medical schools to include genetics in their curricula.⁷³ Upon reviewing the United States Medical Licensure Examination in 1995, a delegation from the Association of Professors of Human Medical Genetics and the American Society of Human Genetics found that less than 5% of the questions required knowledge of genetics.⁷⁴ Of these, approximately only one-third addressed important genetic principles and the remainder tested specific facts relating to individual genetic diseases.⁷⁵

Continuing medical education programs regarding genetics are essential to the effort to enhance primary care physicians' knowledge regarding genetic services.⁷⁶ Such programs should be widely available, and attendance for a specific number of hours

68. See *ASSESSING GENETIC RISKS*, *supra* note 12, at 216-224; *SAFE AND EFFECTIVE GENETIC TESTING*, *supra* note 8, at 65-73.

69. See *SAFE AND EFFECTIVE GENETIC TESTING*, *supra* note 8, at 65; *ASSESSING GENETIC RISKS*, *supra* note 12, at 218.

70. See *SAFE AND EFFECTIVE GENETIC TESTING*, *supra* note 8, at 65. Another source indicates that in 1991-92, 79 of 126 medical schools required a human or medical genetics course. See *ASSESSING GENETIC RISKS*, *supra* note 12, at 220.

71. Adding genetics to the medical school curriculum is likely to require that other disciplines concede some of the hours traditionally devoted to their study. Advocates of genetic education may, thus, face resistance from faculty members and specialists.

72. See *SAFE AND EFFECTIVE GENETIC TESTING*, *supra* note 8, at 66.

73. See *id.*

74. See *id.*

75. See *id.*

76. See *id.* at 67.

should be required of any physician who administers genetic tests or cares for patients with genetic disorders.

The Task Force on Genetic Testing also recommended that managed care organizations require providers to submit evidence of their competence before being permitted to order certain predictive genetic tests or to counsel patients about genetic testing.⁷⁷ To ensure compliance, the Task Force recommended periodic, systematic medical record reviews with feedback to providers.⁷⁸ The Task Force noted that if managed care organizations are to require evidence of competence, guidelines must be established to determine which genetic tests necessitate evidence of competence, how "competence" is to be defined, and which educational programs could be utilized to fulfill competence requirements.⁷⁹

The Task Force delineated the following reasons as justifications for an evidence of competence mandate:

People need to have sufficient information about the clinical validity of the test to decide whether the test is appropriate for them. Providers must be able to give them the requisite information.

The implications of a positive or negative test result might influence people's decision to be tested. Providers must be aware of the implications and discuss them with the people considering testing.

People's autonomy must be respected especially when procedures for avoiding the conception or birth of a child with a genetic disease are options following a positive test result. Autonomy [sic] is also crucial when the interventions in those with positive test results have not been proven to be safe and effective. Providers must recognize these situations, understand the need to respect autonomy, and be able to communicate information in the least directive manner possible.

The results of some predictive genetic tests will indicate that relatives might be at risk of genetic disease. Providers must be prepared to discuss why and how the person tested should communicate with relatives and what the relatives should do.

Providers could face legal liability if they order a test inappropriately or if they communicate results to relatives (except in extreme circumstances...) or unrelated third

77. *See id.*

78. *See id.* at 68.

79. *See id.* at 69-70.

parties without the consent of the person tested.

Third parties paying for the test, including managed care organizations, will not want to reimburse if the test has been ordered unnecessarily or inappropriately.⁸⁰

Concerns about genetics education stimulated the formation of the National Coalition for Health Professional Education in Genetics.⁸¹ The Coalition includes, among its many goals, the establishment of genetics education as a top priority for health care professional organizations, development of a comprehensive, Internet-based genetics information center, and the creation of a core curriculum in genetics for health professionals.⁸²

3. *Nondirective Genetic Counseling*

Genetic counseling, a crucial aspect of the process by which a patient obtains and assesses genetic information, was described in 1975 by the American Society of Human Genetics Ad Hoc Subcommittee on Genetic Counseling as follows:

[A] communication process which deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family to (1) comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; (3) understand the alternatives for dealing with the risk of recurrence; (4) choose the course of action which seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and (5) to make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.⁸³

The touchstone of genetic counseling is nondirectiveness, that is, allowing individuals to have the autonomy to make the difficult personal decisions of whether to undergo genetic testing and, if so, what action to take based on the results.⁸⁴ Medical professionals following a nondirective philosophy support whatever decisions their

80. *Id.* at 68.

81. *See id.* at 70.

82. *See id.*

83. ASSESSING GENETIC RISKS, *supra* note 12, at 148.

84. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 151-52, 154-55; Barbara Bowles Biesecker, *Privacy in Genetic Counseling*, in GENETIC SECRETS, *supra* note 1, at 108, 111-12.

patients make, even if they personally disagree with the patients' preferences, and avoid telling those whom they are counseling what they ought to do or what the counselor would do in the particular situation.⁸⁵

Studies have shown that primary care physicians and other doctors are more directive in providing genetic counseling than are geneticists, particularly where reproductive choices are at issue.⁸⁶ For example, in one study, women who were counseled by a general obstetrician were more likely to abort a fetus with a sex chromosome abnormality than those who consulted a geneticist.⁸⁷

Absolute nondirectiveness may be extremely difficult to achieve.⁸⁸ The experience and background of the genetic counselor is likely to influence the way he or she performs genetic counseling and, therefore, the patients' perceptions of the disorder and their options.⁸⁹ Researchers have found that cultural, socioeconomic, educational, and ethical factors significantly affect the way counselors describe genetic disorders and their possible outcomes.⁹⁰ The health professional's orientation and objective in providing the counseling will often determine whether the disorder will be explained to the patient in positive or negative terms.⁹¹

Some critics have concluded that nondirectiveness does not always benefit patients.⁹² It is arguable that patients seek advice, direction, and guidance from counselors in addition to the multitude of facts that they generally receive.⁹³ As one commentator stated, "[Clients] do not really want a value-neutral counselor who acts as an information machine."⁹⁴

Although nondirectiveness may not always be possible or welcomed by patients, primary care physicians should be extremely sensitive to their patients' values and seek to promote their patients' autonomy. The United States has a history of coerced sterilization, designed to deny certain individuals the opportunity to reproduce because it was presumed that their offspring would inherit their undesirable characteristics.⁹⁵ Contemporary doctors should eschew

85. See Wertz, *supra* note 21, at 324-25.

86. See ASSESSING GENETIC RISKS, *supra* note 12, at 152; SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 64.

87. See ASSESSING GENETIC RISKS, *supra* note 12, at 152.

88. See SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 64; Barbara A. Bernhardt, *Empirical Evidence That Genetic Counseling Is Directive: Where Do We Go from Here?* 60 AM. J. HUM. GENETICS 17, 17 (1997).

89. See ASSESSING GENETIC RISKS, *supra* note 12, at 155.

90. See *id.*

91. See *id.*

92. See Wertz, *supra* note 21, at 325; Bernhardt, *supra* note 88, at 19.

93. See Wertz, *supra* note 21, at 325.

94. *Id.*

95. See *Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding Virginia's compulsory sterilization law). See generally DANIEL J. KEVLES, *IN THE NAME OF EUGENICS: GENETICS AND THE USES OF HUMAN HEREDITY* (1985) (detailing the

steering their patients towards particular reproductive decisions, and, instead, advise patients to consult therapists, clergy, family members, and others for purposes of making reproductive choices.⁹⁶ With respect to other issues, such as whether to undergo genetic testing that might indicate susceptibility to a particular disease, medical professionals should provide information about the medical value and limitations of the test, as well as its possible psychological and social consequences.

4. *Time Constraints*

Another concern related to the "geneticization" of primary care is that primary care physicians, working within the constraints of managed care, are unlikely to have the luxury of spending enough time with each patient to provide sufficient genetic counseling.⁹⁷ New patients in genetics or prenatal clinics receive over an hour of personal counseling.⁹⁸ Likewise, the average time spent counseling patients with respect to molecular genetic testing is one hour, which includes the time for record review and administrative duties.⁹⁹

B. *Nursing*

Because primary care physicians often lack the time to provide genetic counseling, some commentators have suggested that the nurses working with the doctors should undertake the counseling role.¹⁰⁰ Indeed, it is difficult to imagine anyone but nurses providing genetic counseling in the offices of primary care physicians. The Task Force on Genetic Testing found that nurses are effective in educating patients regarding genetic testing for susceptibility to cancer and that oncology nurses often view themselves as genetic health care professionals.¹⁰¹ For many years, nurses in the United Kingdom have engaged in significant genetic counseling.¹⁰²

Nevertheless, nurses, like primary care physicians, in the United States receive a sorely deficient education in genetics.¹⁰³ A 1984 survey revealed that most nursing schools dedicated fewer than ten hours to genetics instruction.¹⁰⁴ By 1988, only four of the 200 nursing schools that offered graduate degrees had established programs featuring a master's level genetics major, and by 1994, only a little over 100 nurses were employed in genetics, according to

history of eugenics).

96. See National Society of Genetic Counselors, Inc., *Taking a Stand* (visited June 17, 1999) <http://www.nsgc.org/Taking_a_Stand.html>.

97. See SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 64.

98. See *id.*

99. See *id.*

100. See *id.* at 71-72.

101. See *id.* at 72.

102. See *id.*

103. See ASSESSING GENETIC RISKS, *supra* note 12, at 225.

104. See *id.*

the International Society of Nurses in Genetics.¹⁰⁵ According to another source, only 120 nurses were educated in the field of genetics as of 1998.¹⁰⁶ While nurses constitute an available and valuable resource for the delivery of genetic services, schools of nursing must enrich and strengthen their training programs in genetics so that nurses will be qualified to work with patients who are considering or undergoing genetic testing. In addition, nurses, like primary care physicians, should receive genetics training through continuing education programs.¹⁰⁷

C. Patient Education

Increasingly, genetics education for the general public is recognized as being as important as it is for medical professionals.¹⁰⁸ Studies suggest that patients who receive their first exposure to genetic information in a doctor's office are disadvantaged in their decision-making abilities.¹⁰⁹ Patients with no preexisting knowledge are likely to make uninformed or hasty decisions or to cede all determinations about genetic testing to their doctors.¹¹⁰ This may be especially true in the managed care setting, where doctors have little time to provide thorough counseling or to engage in lengthy discussions with patients.

Several programs have been initiated to expose educators and students to genetic information so that they will be better equipped to grapple with the complexities of modern medicine and genetic technology.¹¹¹ In addition, it is recommended that videos, interactive

105. *See id.*

106. *See* THE SEVERYN GROUP, INC., IMPROVING THE PUBLIC'S HEALTH THROUGH RESEARCH PARTNERSHIPS: BUILDING BRIDGES IV 35 (1998). A 1994 survey conducted by the American Nurses Association revealed that only 9% of nurses had ever taken a course in genetics. *See* TOUCHETTE ET AL., *supra* note 60, at 21.

107. *See* TOUCHETTE ET AL., *supra* note 60, at 54-55 (discussing a continuing education program in genetics developed by the University of Colorado in Denver through its school of nursing).

108. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 190; Hood & Rowen, *supra* note 1, at 28.

109. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 190.

110. *See id.*

111. *See id.* at 92; Hood & Rowen, *supra* note 1, at 28. In Seattle, an extensive program is funded by a \$4.25 million grant from the National Science Foundation. *See* Hood & Rowen, *supra* note 1, at 28. Each of the 1400 elementary public school teachers receives 100 hours of instruction over a period of five years. *See id.* In addition, 20 high schools are working with scientists to sequence an unknown gene that causes deafness in a large Costa Rican family. *See id.* Thus, the high school students are engaging in active, creative learning. *See id.* Other students are asked to imagine that they belong to a family with a history of Huntington's disease. *See id.* They are instructed to decide whether they want to be tested and are asked to analyze the ethical implications of such testing. *See id.*

The DNA Learning Center at Cold Spring Harbor Laboratory has

computer programs, web sites, and other publications and products in various media be developed to give a wide range of patients an adequate knowledge base on which to build individualized genetic discussions.

III. ACCESS AND REIMBURSEMENT ISSUES

A. *Genetic Discrimination in Health Insurance*

The Human Genome Project has generated profound concern that individuals will be denied access to health insurance because of their risk of genetic disorders. A survey of 332 people whose families were at risk for a genetic illness, such as cystic fibrosis or sickle cell anemia, found that 22% believed that either they or their family members had been denied health insurance on the basis of the genetic predisposition.¹¹² This study, however, did not distinguish between expressed disease and genetic predisposition. In addition, the responses represent only the subjective belief of the surveyed individuals and not confirmed evidence of discrimination.¹¹³

Insurers might in fact have rational economic reasons for either excluding high-risk individuals from coverage or at least charging them higher premiums. Individuals who learn, through genetic testing, that they are predisposed to a genetic disease are more likely to purchase maximum insurance coverage.¹¹⁴ As a group, these individuals are more likely to become ill and, consequently, to

opened a "human genome education center," which includes a hands-on student laboratory, a student multimedia computing laboratory, and a research laboratory offering a variety of grant-supported activities and programs to the public. See ASSESSING GENETIC RISKS, *supra* note 12, at 190. The Biological Science Curriculum Studies program in Colorado developed an educational module for high school students entitled *Mapping and Sequencing the Human Genome: Science, Ethics, and Public Policy*. See *id.* at 191. Thanks to a grant from the U.S. Department of Energy, the module was distributed free of charge to over 50,000 biology instructors nationwide in the fall of 1992. See *id.*

Project Genethics enrolls teachers in two-week workshops on human genetics and bioethics taught by the staff of the Human Genetics and Bioethics Laboratory at Ball State University in Indiana. See *id.* Similarly, workshops funded by the Human Genome Project are conducted at the University of Kansas for middle and secondary science teachers recruited from public, parochial, and private schools, as well as special schools for students with disabilities. See *id.* These workshops are designed to expand the use of human genetics materials in school curricula and to prepare participants to serve as resource teachers for others. See *id.* at 191-92.

112. See E. Virginia Lapham et al., *Genetic Discrimination: Perspectives of Consumers*, 274 SCIENCE 621, 622 (1996).

113. See L. Carl Volpe, *Genetic Testing and Health Insurance Practices: An Industry Perspective*, 2 GENETIC TESTING 9, 10 (1998) (criticizing the study).

114. See Roberta M. Berry, *The Genetic Revolution and the Physician's Duty of Confidentiality: The Role of the Old Hippocratic Virtues in the Regulation of the New Genetic Intimacy*, 18 J. LEGAL MED. 401, 438 (1997).

submit insurance claims that far exceed the premiums they have paid.¹¹⁵ If a large number of individuals were to purchase insurance under these circumstances, insurers would have to raise premium prices, forcing small employers and low-risk individuals to drop health insurance coverage.¹¹⁶ The effects of this adverse selection spiral would be less coverage for consumers and perhaps bankruptcy of insurers.¹¹⁷

In reality, however, there is little evidence that health insurers have yet engaged in widespread genetic discrimination. One source notes that to date, "evidence of genetic discrimination remains largely anecdotal."¹¹⁸ In a report issued in December 1995, the Ohio Task Force on Genetic Testing in Health Insurance found no evidence of genetic discrimination by health insurers.¹¹⁹ Similarly, 499 board certified primary care physicians surveyed in 1994-95 reported only "a few instances" of "refusal of health insurance based on genetic information."¹²⁰ However, later studies conducted in an era in which genetic technology is more advanced and widely available may yield different results.

Of greater significance than the few documented cases of discrimination is the widespread fear of genetic discrimination that already has caused many at-risk individuals to forgo genetic testing.¹²¹ In April 1998, the Associated Press reported that 32% of women invited to participate in genetic research on breast cancer chose not to do so.¹²² The majority explained that their decisions stemmed from fear of genetic discrimination.¹²³

Concern about the vulnerability of individuals with adverse

115. *See id.*

116. *See id.*

117. *See id.* Adverse selection is even more likely with life insurance than it is with health insurance. In computing the value of a potentially insured life, life insurers consider factors such as the age, health, and risks of an individual. *See* Mark A. Rothstein, *Genetics, Insurance, and the Ethics of Genetic Counseling*, 3 MOLECULAR GENETIC MED. 159, 167 (1993). Life insurers then use standard mortality tables to calculate the actuarially justified rate at which to insure the individual's life. *See id.* Life insurance, unlike health insurance, is "predominantly individually written and uses medical underwriting of the individual." *Id.*

118. Louise M. Slaughter, *Genetic Information Must Remain Private to Prevent Discrimination, Spur Research*, 2 GENETIC TESTING 17, 17 (1998).

119. *See* Lenox, *supra* note 23, at 199.

120. Wertz, *supra* note 21, at 303, 309; *see also* ASSESSING GENETIC RISKS, *supra* note 12, at 270 & n.100 (discussing surveys conducted in 1992 by Paul Billings and colleagues and the Office of Technology Assessment, which revealed "specific examples of people being denied health insurance coverage based on their genotype," such as a case in which the birth of a child with cystic fibrosis rendered the parents and unaffected siblings unable to obtain insurance).

121. *See* Slaughter, *supra* note 118, at 17.

122. *See id.*

123. *See id.*

genetic information has prompted legislative action in a variety of realms. Several laws have been enacted by both federal and state legislatures to prevent genetic discrimination in the issuance of health insurance.

1. *State Legislation*

Presently, over half of the states have enacted laws prohibiting health insurance companies from requiring genetic testing as a condition of coverage or from denying insurance or charging higher rates based upon the results of genetic tests.¹²⁴ The statutes vary in their breadth and scope. The Texas statute, for example, applies only to group health benefits plans and not to individual health insurance policies.¹²⁵ The Alabama statute pertains only to genetic tests for cancer. Under its terms,

(a) A health benefit plan may not require as a condition of insurability that a person take a genetic test to determine if the person has a predisposition for cancer.

(b) A health benefit plan may not use the results of a genetic test which may show the predisposition of a person for cancer to determine insurability or to otherwise discriminate against the person in rates or benefits based on the genetic test results.¹²⁶

The much broader Oregon law establishes, in relevant part, that:

(1) If an insurance provider asks an applicant for insurance to take a genetic test in connection with an application for

124. See ALA. CODE §§ 27-53-1 to -2 (1998); ALASKA STAT. § 21.54.100 (LEXIS 1998); ARIZ. REV. STAT. ANN. §§ 20-1051, 20-1379 (West 1996 & Supp. 1998); CAL. INS. CODE § 10123.3 (Deering Supp. 1999); CAL. HEALTH & SAFETY CODE § 1374.7 (Deering Supp. 1999); COLO. REV. STAT. § 10-3-1104.7 (1998); CONN. GEN. STAT. ANN. § 38a-816 (West Supp. 1999); FLA. STAT. ANN. § 627.4301 (West Supp. 1999); GA. CODE ANN. § 33-54-4 (1996); HAW. REV. STAT. §§ 431:10A-118, 432:1-607, 432D-26 (Supp. 1998); 215 ILL. COMP. STAT. ANN. 5/356v (West Supp. 1999), 410 ILL. COMP. STAT. ANN. 513/20 (West 1997); IND. CODE ANN. §§ 27-8-26-5 to -9 (LEXIS Supp. 1998); LA. REV. STAT. ANN. §§ 22:213.6-213.7 (West Supp. 1999); MD. CODE ANN., INS. § 27-909 (1997); MINN. STAT. ANN. § 72A.139 (West 1999); NEV. REV. STAT. ANN. 695B.317 (LEXIS 1998); N.H. REV. STAT. ANN. §§ 141-H:1, 141-H:4 (1996); N.J. STAT. ANN. §§ 17:48-6.18, 17:48A-6.11, 17:48E-15.2, 17B:27-36.2 (West Supp. 1999); N.M. STAT. ANN. §§ 24-21-2, 24-21-4 (Michie Supp. 1998); N.Y. INS. LAW §§ 3232, 4305, 4318 (McKinney 1985 and Supp. 1999); N.C. GEN. STAT. § 58-3-215 (Supp. 1998); OHIO REV. CODE ANN. §§ 1751.64, 1751.65, 3901.49.1, 3901.50, 3901.50.1 (Anderson 1996, 1997, & Supp. 1998); OR. REV. STAT. § 746.135 (1997); TENN. CODE ANN. §§ 56-7-2702 to -2704 (Supp. 1998); TEX. INS. CODE ANN. art. 21.73 (West 1998); VA. CODE ANN. § 38.2-508.4 (Michie Supp. 1998); WIS. STAT. ANN. § 631.89 (West Supp. 1998); 13 N.M. ADMIN. CODE tit. 13, § 10.13.22.4 (1997).

125. See TEX. INS. CODE ANN. art. 21.73 § 2(a) (West 1998).

126. ALA. CODE § 27-53-2 (1998).

insurance, the use of the test shall be revealed to the applicant and the provider shall obtain the specific authorization of the applicant using a form prescribed by rules of the Health Division.

(2) An insurance provider may not use a favorable genetic test as an inducement to purchase insurance.

(3) An insurance provider may not use genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy for hospital or medical expenses.¹²⁷

Even the statutes that address the discriminatory use of all genetic test results may leave many individuals unprotected. "Genetic test" is typically defined as "a laboratory test of human chromosomes or DNA that is used to identify the presence or absence of inherited or congenital alterations in genetic material that are associated with disease or illness."¹²⁸ Under this definition, an insurer would not violate the law if it discriminated against an individual based not on a physical genetic test, but on a family history such as a parent's death from Huntington's disease. A better, more inclusive approach is to prohibit discrimination based on any "genetic information."¹²⁹ In contrast to "genetic test," "genetic information" is typically defined as "information about genes, gene products and inherited characteristics that may derive from the individual or a family member, including information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or chromosomes, physical medical examinations, family histories and direct analysis of genes or chromosomes."¹³⁰

Another limitation of the state statutes is that they do not apply to self-funded employer plans. Under the Employee Retirement Security Act of 1974 ("ERISA"),¹³¹ state laws regulating health insurance, including those that prohibit discrimination, are preempted by ERISA insofar as they apply to self-funded employee benefit plans.¹³² Although 98% of employers with over 100 employees offer workers some form of health insurance, the majority

127. OR. REV. STAT. § 746.135(1)-(3) (1997).

128. MD. CODE ANN., INS. § 27-909(a) (1997).

129. See, e.g., ALASKA STAT. § 21.54.100 (LEXIS 1998).

130. ARIZ. REV. STAT. ANN. § 20-1051(5) (West 1996).

131. 29 U.S.C. §§ 1001-1461 (1999 & Supp. 1999).

132. 29 U.S.C. § 1144(b)(2)(B) (1999); *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (reading "deemer clause" to exempt self-funded ERISA plans from state laws that regulate insurance); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 736, n.14 (1985) (conceding that "deemer clause" preempts state law).

of their plans are self-insured.¹³³ Thus, the state laws generally apply only to individual insurance and small group policies that are not self-insured. Consequently, the regulation of insurers' use of genetic information cannot be left to the states alone.

2. *Health Insurance Portability and Accountability Act*

Significant protection for the use of genetic information is provided by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").¹³⁴ HIPAA requires that all group health plans, including ERISA plans, limit to no more than twelve months their period of excluded coverage for preexisting conditions, that is, conditions for which medical advice, diagnosis, care, or treatment was recommended or received in the prior six months.¹³⁵ HIPAA provides, however, that genetic information may not be considered a pre-existing condition "in the absence of a diagnosis of the condition relating to such information."¹³⁶ Thus, a woman whose genetic test reveals that she is at an increased risk of breast cancer may not be excluded from coverage for breast cancer for any period of time unless she has actually been diagnosed with the disease. In addition, HIPAA prohibits group health plans from charging individual beneficiaries higher rates based on preexisting conditions.¹³⁷ These mandates, however, apply only to group health plans and, therefore, do not protect the 10-15% of insureds who have individual policies.¹³⁸

3. *Americans with Disabilities Act*

The Americans with Disabilities Act of 1990 ("ADA")¹³⁹ may also impose constraints upon health insurance providers that want to utilize genetic information in making coverage decisions. The ADA prohibits employers from discriminating against qualified individuals with disabilities with respect to job application procedures, hiring, promotion, termination of employment, compensation, job training, and other terms, conditions, and privileges of employment.¹⁴⁰ The phrase "other terms, conditions and privileges of employment" includes all fringe benefits, such as health insurance, that are available by virtue of employment, whether or not such benefits are administered by the employer.¹⁴¹ Consequently, liability may be imposed under the ADA upon an

133. See HALL, *supra* note 19, at 23.

134. 42 U.S.C. §§ 300gg to 300gg-92 (Supp. 1999).

135. *Id.* § 300gg(a). In the case of a late enrollee, the period of excluded coverage may be extended to 18 months. See *id.*

136. *Id.* § 300gg(b)(1)(B).

137. *Id.* § 300gg-1(b)(1).

138. See Lenox, *supra* note 23, at 208.

139. 42 U.S.C. §§ 12101-12213 (1995 & Supp. 1999).

140. *Id.* § 12112(a).

141. See 29 C.F.R. § 1630.4 (1998).

employer that offers its employees an insurance plan that is found to be discriminatory.

The ADA covers individuals who have a "physical or mental impairment that substantially limits one or more of . . . [their] major life activities" as well as those who have a "record of" a disability or who are "regarded as" having a disability.¹⁴² In March 1995, the Equal Employment Opportunity Commission ("EEOC") issued interpretive guidance regarding the ADA that addressed the issue of genetic discrimination.¹⁴³ According to the EEOC, employers that discriminate against individuals based upon their genetic predisposition are "regarding" the employees as having a disability, and their acts of discrimination constitute violations of the ADA.¹⁴⁴ Thus, where health insurance is provided to an individual through his or her employment, the employee may not be denied health insurance benefits or charged higher premiums based upon genetic information.

The EEOC's interpretive guidance, however, suffers from two major weaknesses. First, administrative interpretations of the law are not binding on the courts, and no court has yet cited the genetic provision of the guidelines.¹⁴⁵ Second, the interpretation applies only to discrimination against employees because of their own genetic predisposition and does not extend protection to individuals who are unaffected carriers of recessive or x-linked disorders, whose children may be at risk of conditions such as cystic fibrosis or Duchenne muscular dystrophy.¹⁴⁶ Under the current guidance, it would not be unlawful for employers to discriminate against such employees based upon concerns regarding health care costs for the employees' children.

4. *Proposed Federal Legislation*

Because both the ADA and HIPAA have significant gaps in coverage, several bills have been introduced in Congress to broaden the scope of the anti-discrimination mandate. In January 1999, the

142. 42 U.S.C. § 12102(2)(A)-(C) (1995).

143. See 3 EEOC COMPLIANCE MANUAL 902-45 (March 1995) (citing definition of disability).

144. See *id.* The EEOC memorandum provides the example of a job applicant whose genetic testing revealed an increased susceptibility to colon cancer, although the individual is asymptomatic and may never develop the disease. See *id.* After extending a job offer to the applicant, the employer learns of the genetic predisposition and withdraws the offer because of concerns regarding productivity, insurance costs, and attendance. See *id.* In such circumstances the applicant is covered by the ADA. See *id.*

145. See Rothstein, *supra* note 24, at 202.

146. Employers that are concerned about the cost of the insurance benefits that they are providing may limit or preclude coverage for affected children in order to prevent an increase in the cost of premiums. See Mark A. Rothstein, *Genetic Discrimination in Employment and the Americans with Disabilities Act*, 29 Hous. L. Rev. 23, 82 (1992).

"Genetic Information Nondiscrimination in Health Insurance Act of 1999" was introduced into the House of Representatives.¹⁴⁷ The bill prohibits group health plans and providers of group and individual insurance from denying, canceling, refusing to renew, or raising premiums for coverage based upon a beneficiary's genetic information or request for or receipt of genetic services.¹⁴⁸ Further, under the bill, insurance providers cannot request or demand that applicants or insureds disclose genetic data about themselves or their family members and cannot disclose genetic information without prior written consent.¹⁴⁹ Genetic information is defined as "information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of the individual."¹⁵⁰ A similar bill, also entitled the "Genetic Information Nondiscrimination in Health Insurance Act of 1999," was introduced in the Senate on March 4, 1999.¹⁵¹

Several other bills to prevent discrimination on the basis of genetic information have been introduced in Congress over the past few years.¹⁵² While none of them have yet become law, further federal legislation regarding genetic discrimination will likely be implemented either on its own or as part of a larger Patient Bill of Rights.¹⁵³ Although there is little current evidence of widespread genetic discrimination in health insurance, additional legislative safeguards are necessary to assure at-risk individuals that they may undergo genetic testing without risking loss of their health coverage. Furthermore, new legislation is necessary to prevent discrimination in future decades, when genetic information will be much more common in clinical practice.

B. Under What Circumstances Should Managed Care Organizations Provide Access to Genetic Testing?

The ultimate goals of the Human Genome Project are the prevention and treatment of genetic diseases.¹⁵⁴ Genetic testing can

147. H.R. 306, 106th Cong. (1999); *see also* H.R. 293, 106th Cong. (1999).

148. *See* H.R. 306 §§ 714(a), 2753.

149. *See* H.R. 306 § 714(b).

150. H.R. 306 § 714(c)(1).

151. S. 543, 106th Cong. (1999).

152. *See* H.R. 306, 105th Cong., 1st Sess. (1997); S. 422, 105th Cong., 1st Sess. (1997).

153. One proposed patient bill of rights included the following nondiscrimination language:

[A] group health plan . . . may not discriminate against a participant, beneficiary, or enrollee in the delivery of health care services consistent with the benefits covered under the plan or coverage or as required by law based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

S. 1890, 105th Cong. § 109 (1998).

154. *See* Hood & Rowen, *supra* note 1, at 18-22; ASSESSING GENETIC RISKS,

be a cost-effective way to diagnose disorders quickly and efficiently. In some cases, a \$200 genetic test can replace a battery of tests that would be conducted over the course of many years.¹⁵⁵ In other instances, however, genetic testing is currently far more expensive and of more dubious value,¹⁵⁶ a reality which is likely to be of great concern to cost-conscious managed care providers.

In 1994, DNA testing cost between \$50 and \$900 per test.¹⁵⁷ It was estimated that with automation and the proliferation of genetic testing, costs could significantly diminish to as low as \$50 to \$150 for a panel of six or more DNA tests.¹⁵⁸ However, commentators noted that the patenting and licensing of genetic tests may greatly increase the costs of genetic testing and that the need for interpretation, education, and genetic counseling relating to such tests also could significantly raise their overall cost.¹⁵⁹

In the future, multiplex testing will also be available. Multiplex screening will allow for multiple genetic tests on a single blood or tissue sample so that disease, carrier status, and susceptibility can all be identified at the same time.¹⁶⁰ In some cases, DNA chips will be used to analyze thousands of genes simultaneously.¹⁶¹ Thus, tests for genetic diseases, cancer, and infectious diseases could be run on the same chip, which would be programmed by software control.¹⁶² Some have suggested that tests for untreatable diseases should not be multiplexed with tests for curable or preventable disorders, so that patients can make separate decisions, which involve very different psychological implications, as to whether to be tested for each type of condition.¹⁶³

Genetic screening for phenylketonuria ("PKU") in newborns is often cited by proponents of genetic testing as "a model for genetic medicine and public health."¹⁶⁴ PKU, a rare genetic disorder, afflicts one in 11,000 to 15,000 infants in the United States, Great Britain, and Western Europe.¹⁶⁵ Those with the disease suffer from a deficiency in a liver enzyme which, absent medical intervention, leads to severe mental retardation, behavioral problems, and other

supra note 12, at 1.

155. *See* THE SEVERYN GROUP, *supra* note 106, at 32.

156. *See id.* at 35.

157. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 235.

158. *See id.*

159. *See id.*; *see generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (arguing that intellectual property rights could lead to the underuse of products that could improve human health).

160. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 2, 27.

161. *See* Stu Borman, *DNA Chips Come of Age*, CHEMICAL & ENGINEERING NEWS, Dec. 9, 1996, at 42.

162. *See id.* at 43.

163. *See* ASSESSING GENETIC RISKS, *supra* note 12, at 27, 102.

164. SAFE AND EFFECTIVE GENETIC TESTING, *supra* note 8, at 137.

165. *See id.*

abnormalities.¹⁶⁶ If newborns with PKU are placed on a special diet, however, mental retardation can be prevented, and other symptoms can be mitigated.¹⁶⁷ Every state in the United States now tests newborns for PKU, and the screening, consisting of a simple blood test, may cost as little as fifty cents.¹⁶⁸

Nevertheless, for most genetic disorders, predictive screening tests will be developed long before effective prevention or therapy can be offered to at-risk individuals and patients.¹⁶⁹ Consequently, health care providers must grapple with the issue of whether, and under what circumstances, predictive genetic testing should be made available to individuals. For example, some providers may question the cost-effectiveness of providing genetic testing services when the only benefits the tests will yield would be satisfying curiosity, relieving anxiety, or the allowing reproductive and life planning.

Those individuals who have undergone genetic testing provide powerful testimony regarding its importance, even in the absence of preventive or therapeutic measures. A patient who was tested for Huntington's disease—an untreatable, fatal neurologic illness—related the following:

It was a long and complex process. Blood samples from numerous members of my family had to be collected and analyzed. I underwent several months of genetic counseling to determine my ability to cope with any possible outcome. After a period of months, nothing remained but the nerve-racking wait for the results Finally, the wait was over: my test was negative. The DNA analysis has shown with 96 percent certainty (later increased to 99 percent, with refinement of the testing process) that I had not inherited the gene for

166. *See id.* In the past, approximately 90% of affected patients had IQs lower than 50. *See id.*

167. *See id.*

168. *See id.* at 138, 140; ASSESSING GENETIC RISKS, *supra* note 12, at 69-70. In addition, all states test newborns for congenital hypothyroidism (subnormal activity of the thyroid gland); 42 states test for sickle cell anemia (a hereditary blood disease that largely affects African-Americans); and 38 test for galactosemia (an inability to use the sugar galactose, which accumulates in the blood and, if untreated, causes mental retardation). *See* 1 THE MERCK MANUAL 932, 1009 (Robert Berkow et al. eds. 16th ed. 1992); 2 THE MERCK MANUAL 604-05. Only five states test for tyrosinemia (a defect of metabolism of the amino acid tyrosine, which affects the urine), three for cystic fibrosis (a hereditary disease affecting the exocrine glands, including mucus-secreting and sweat glands), and two for toxoplasmosis (a disease caused by the organism toxoplasma, which if transmitted to a fetus by its mother can produce blindness or mental retardation). *See* 2 THE MERCK MANUAL 610, 533, 460-61.

169. *See* Hood & Rowen, *supra* note 1, at 21-22; 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, 1225-26 (1997).

Huntington's disease. When I learned the results, I cried and laughed. It took months for the news to sink in. I am still adjusting The incomparable relief I felt at finally being free of the fear and uncertainty . . . was tempered by the painful knowledge that other family members had not been and would not be so lucky.¹⁷⁰

Others, however, may agree with the words of Sophocles, which appear in the tragedy *Oedipus The King*: "Alas, how dreadful to have wisdom where it profits not the wise!"¹⁷¹ To the surprise of many geneticists, only 15% of individuals at risk for Huntington's disease have chosen to be tested.¹⁷² Because the disease is untreatable and fatal, the vast majority prefers not to know that they have the disease. According to one source, for those who seek testing for Huntington's disease and receive positive results, the suicide rate is approximately 35% higher than that found in the general population.¹⁷³

Some of the most difficult issues in the use of contemporary genetic technology are generated by prenatal screening and diagnosis because the discovery of certain genetic disorders in a fetus may induce parents to terminate a pregnancy. The disparity between our ability to detect and our ability to prevent or treat genetic diseases leaves parents with few options, namely, abortion or carrying to term an affected child. Decisions regarding the future of fetuses with genetic disorders are undoubtedly among the most

170. ASSESSING GENETIC RISKS, *supra* note 12, at 146 (quoting a patient named Hayes in 1992).

171. SOPHOCLES, *OEDIPUS THE KING*, THE COMPLETE PLAYS OF SOPHOCLES 84 (Sir Richard Claverhouse Jebb trans. Bantam Books 1982).

172. See Wertz, *supra* note 21, at 319. Some geneticists had predicted that Huntington's disease would be eliminated in one generation since all those at risk would be tested, and carriers would choose not to reproduce. See *id.* In reality only 15% of those eligible have sought testing. See *id.* Similarly, most people consider testing for cystic fibrosis carrier status only if they are actually pregnant, and even those with a family history of the disease must be convinced to undergo testing by a health care professional who visits their homes to do counseling and screening. See *id.* at 319-320. Dr. Wertz concludes that "[n]othing in the overall situation would predict a massive surge in testing unless profit-motivated commercial forces convinced primary care physicians to test patients, especially pregnant women, in order to protect themselves from lawsuits." *Id.* at 320. Another source reports that when non-pregnant individuals with no family history of cystic fibrosis were mailed invitations to obtain testing to determine carrier status, only 3.7% responded by answering a questionnaire, attending a group educational session, and deciding to have the test. See TOUCHETTE ET AL., *supra* note 60, at 23. When they were offered an opportunity by their HMO to have the test immediately, 23.5 % of patients chose to undergo the test. See *id.*; see also Kimberly A. Quaid & Michael Morris, *Reluctance to Undergo Predictive Testing: The Case of Huntington Disease*, 45 AM. J. MED. GENETICS 41, 44 (1993) (discussing the reasons individuals choose not to be tested for Huntington's disease).

173. See Malinowski & Blatt, *supra* note 169, at 1249.

difficult that parents will make over their lifetimes.¹⁷⁴ Managed care providers should be sensitive and supportive rather than directive in their treatment of parents seeking prenatal testing. Although caring for a child with disabilities may be very expensive, managed care providers should not pressure parents to make reproductive decisions based on financial concerns. Unfortunately, concern about "economic eugenics" is not merely theoretical, but is based upon the painful experiences of some patients.

A much-discussed example involves a pregnant Louisiana woman who realized that her fetus was at risk for cystic fibrosis.¹⁷⁵ She was referred by her HMO to an academic genetics unit in Houston for prenatal testing and learned that her unborn child was indeed affected.¹⁷⁶ The woman nonetheless elected to carry the pregnancy to term.¹⁷⁷ Having paid for the genetic testing, the HMO then informed her that if she did not abort the fetus, she must be prepared to absorb all costs related to care for cystic fibrosis since the disease would be considered a preexisting condition not covered by the health plan.¹⁷⁸ Although the HMO eventually was persuaded to change its position,¹⁷⁹ the case constitutes a very disturbing illustration of the economic pressures to which patients might be subjected in a managed care setting. However, it should be noted that HIPAA now prohibits group insurers from imposing preexisting condition exclusions on covered newborns or from discriminating against beneficiaries based on health status or genetic information.¹⁸⁰

Managed care organizations vary widely in their coverage and provision of genetic tests. According to a 1997 survey, of 197 responding HMOs, 45% covered predictive tests for breast cancer.¹⁸¹ In addition, 42% covered tests for colon cancer for some of their subscribers.¹⁸²

174. See Elena A. Gates, *Prenatal Genetic Testing: Does it Benefit Pregnant Women?* in *WOMEN AND PRENATAL TESTING: FACING THE CHALLENGES OF GENETIC TECHNOLOGY* 183-198 (Karen H. Rothenberg & Elizabeth Thomson eds., 1994) (providing a thorough discussion of the positive and negative impact of prenatal genetic testing). See generally BARBARA KATZ ROTHMAN, *THE TENTATIVE PREGNANCY: PRENATAL DIAGNOSIS AND THE FUTURE OF MOTHERHOOD* (1987) (examining issues of prenatal diagnosis).

175. See Mark A. Rothstein, *The Genetic Factor in Health Care Reform: Framing the Policy Debate*, in *THE HUMAN GENOME PROJECT AND THE FUTURE OF HEALTH CARE* 224, 227 (Thomas H. Murray et al. eds., 1996) [hereinafter *THE HUMAN GENOME PROJECT*].

176. See *id.*

177. See *id.*

178. See *id.*

179. See *id.*

180. 42 U.S.C. §§ 300gg(d)(1), 300gg-1(a)(1).

181. M.F. MEYERS ET AL., *COVERAGE AND PROVISION OF GENETIC SERVICES: SURVEYS OF HEALTH MAINTENANCE ORGANIZATIONS (HMOs) AND ACADEMIC GENETIC UNITS (AGUs)* (under submission).

182. See *id.*

Managed care organizations first must decide whether a particular genetic test should be offered at all to their patient population and then whether it is appropriate for any particular individual. On June 29, 1998, the Secretary's Advisory Committee on Genetic Testing was established.¹⁸³ The committee, with an initial term of two years, will advise the Secretary of Health and Human Services regarding all aspects of incorporating genetic testing into the health care system and surely will address questions relating to managed care.¹⁸⁴ In addition, the Task Force on Genetic Information and Insurance issued a report in 1993,¹⁸⁵ and several other groups continue to develop position statements and policy recommendations regarding genetic testing and insurance coverage issues.¹⁸⁶ Ultimately, a clear standard of care regarding the provision of genetic tests should be developed to guide managed care organizations and other medical providers.

A few general principles can be articulated. Managed care entities should not adopt a per se rule of refusing predictive testing in the absence of an effective intervention, because, at times, knowledge itself provides tremendous psychological comfort or invaluable opportunities for life planning in light of a known future.¹⁸⁷ Individuals at-risk should neither be coerced into testing nor discouraged from undergoing appropriate genetic testing. Furthermore, genetic testing must be accompanied by suitable genetic counseling both before and after the testing. Currently, genetic counseling is often not covered by insurance and genetic counselors cannot bill separately for their services.¹⁸⁸ Counseling, however, should be covered by the insurer to ensure its availability to all patients, regardless of their financial resources.

Various commentators have suggested more specific guidelines for the circumstances under which genetic testing should or should not be provided. These guidelines address newborn screening, carrier screening, prenatal screening, testing of minors, and testing for late-onset disorders.¹⁸⁹ These broad ethical statements are valuable, but they do not usually analyze the efficacy of particular tests or provide criteria for evaluating the appropriateness of genetic testing for individual patients.

183. See Notice of Establishment of the Secretary's Advisory Committee on Genetic Testing, 63 Fed. Reg. 35,242 (1998).

184. See *id.*

185. 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* (May 10, 1993) (visited June 17, 1999) <http://www.nhgri.gov/About_NHGRI/Der/Elsi/itf.html>.

186. See *id.*

187. See ASSESSING GENETIC RISKS, *supra* note 12, at 88.

188. See *id.* at 20, 236.

189. See *id.* at 174-77; Wertz, *supra* note 21, at 322.

C. *Under What Circumstances Should Managed Care Organizations Provide Medical Intervention After Genetic Testing?*

Many different types of interventions may be medically indicated after a predictive genetic test. These include dietary and lifestyle changes, frequent self-examination, laboratory testing, diagnostic imaging, invasive diagnostic procedures, and even prophylactic surgery, such as mastectomies, before a diagnosis of breast cancer.¹⁹⁰ Many of these measures raise difficult ethical, legal, and economic issues.

Even though specific genetic tests may be more cost effective than traditional alternatives, and early detection may lead to less expensive care than is necessary for treatment of an advanced disease, most commentators agree that genetic advances will increase, rather than reduce, the cost of healthcare.¹⁹¹ In general, "as medicine advances, so do both medical needs and medical spending."¹⁹² DNA research will produce costly new treatments such as gene therapies and genetic engineering.¹⁹³ Furthermore, beneficial medical treatment often allows individuals to live to an old age, where they become vulnerable to prolonged, complicated, and expensive illnesses.¹⁹⁴ Because of serious cost concerns, insurers increasingly may deny reimbursement to individuals seeking medical intervention in light of genetic test results, and these insurers will likely find themselves mired in litigation and public controversy.

The introduction into clinical practice of genetic testing for certain forms of colon cancer, for example, is a promising development because it permits certain at-risk individuals to undergo more frequent colonoscopies to detect polyps and other abnormal growths at an early stage.¹⁹⁵ Colon cancer is usually treatable if detected early, but colonoscopies are expensive, costing as much as \$3000 each.¹⁹⁶ Some managed care organizations reportedly are refusing to pay for the more frequent colonoscopies recommended for individuals at genetic risk. Allegedly, the denial of coverage is based on the entity's assessment that, because operable colon cancer often takes a long time to develop, and because

190. See *ASSESSING GENETIC RISKS*, *supra* note 12, at 86-87.

191. See *THE SEVERYN GROUP*, *supra* note 106, at 35-36; see also Maxwell J. Mehlman, *Access to the Genome and Federal Entitlement Programs*, in *THE HUMAN GENOME PROJECT*, *supra* note 175, at 113, 116 (noting that, at least in the short term, the Human Genome Project will generate a significant growth in the demand for cost-increasing services).

192. *HALL*, *supra* note 19, at 5.

193. See *ASSESSING GENETIC RISKS*, *supra* note 12, at 80.

194. See Mehlman, *supra* note 191, at 116.

195. See Robert Mullan Cook-Deegan, *Mapping the Human Genome*, 65 S. CAL. L. REV. 579, 587 (1991).

196. Interview with Dr. Melissa Bondy, M.D. Anderson Cancer Center, Houston, Texas (April 1, 1999).

individuals frequently change health plans, the managed care entity is likely to perform expensive testing on a beneficiary who will no longer be enrolled with the plan when treatment is necessary.¹⁹⁷ If these reports are accurate, the conduct of the implicated managed care organizations constitutes unacceptable health policy.

Another issue is whether managed care organizations will pay for prophylactic surgery for patients who learn through genetic testing that they are predisposed to particular diseases. Prophylactic mastectomy with reconstruction costs about \$30,000; prophylactic oophorectomy costs about \$23,000.¹⁹⁸ One well-known case involved a woman with a strong family history of breast and ovarian cancer and a genetic condition known as breast-ovarian carcinoma syndrome.¹⁹⁹ The woman's doctors recommended a total abdominal hysterectomy and bilateral salpingo-oophorectomy, which entails removal of the uterus, ovaries, and fallopian tubes.²⁰⁰ Blue Cross/Blue Shield declined coverage of the surgery, stating that it was not reimbursable under the policy because the patient did not actually have cancer or any bodily illness or disease covered by the plan, and her high-risk status alone did not render the operation "medically necessary."²⁰¹ The Supreme Court of Nebraska ordered Blue Cross/Blue Shield to pay for the surgery.²⁰² The court found that the insured's breast-ovarian carcinoma syndrome was a "bodily disorder" or "disease" within the meaning of the health insurance policy and, thus, a covered "illness," because these terms encompassed any abnormal condition that, in its natural progression, would likely be problematic or any inherent defect of the body.²⁰³ While this is the only reported appellate case on point, it is likely that other such cases have arisen and will continue to generate litigation in the future.

New treatments for genetic conditions are often very expensive as well. Growth hormone ("GH") therapy for childhood short stature costs approximately \$14,000 per year for a child weighing twenty kilograms,²⁰⁴ and high dose chemotherapy with autologous bone

197. See Paul R. Lenz, *The Current State of Genetic Testing in Health Insurance*, in GENETIC TESTING: IMPLICATIONS FOR INSURANCE 11, 13 (1997) (noting that "[s]ince the health care industry turns over a quarter of its population per year, investing in disease state management, where the positive results may occur four years later, means investing in another carrier's improved financial results").

198. See Bondy, *supra* note 196.

199. See *Katskee v. Blue Cross/Blue Shield*, 515 N.W.2d 645, 647 (Neb. 1994).

200. See *id.*

201. *Id.* at 648.

202. See *id.*

203. See *id.* at 651, 653.

204. See Beth S. Finkelstein et al., *Insurance Coverage, Physician Recommendations, and Access to Emerging Treatments: Growth Hormone Therapy for Childhood Short Stature*, 279 JAMA 663, 663 (1998).

marrow transplant ("HDC-ABMT") for breast cancer may cost up to \$200,000.²⁰⁵ Consequently, payment for these services is contentious and varies widely by health care plan.²⁰⁶

A 1998 study examined coverage for GH treatment for children with idiopathic short stature, growth hormone deficiency, Turner syndrome, and chronic renal insufficiency.²⁰⁷ The study concluded that only 10-13% of children with idiopathic short stature would have insurance coverage for GH therapy.²⁰⁸ By contrast, 94% of children with growth hormone deficiency would be covered for the treatment, but only 52% of children with Turner syndrome and fifty-eight percent of those with chronic renal disease would receive reimbursement for GH therapy.²⁰⁹ Coverage varied widely among various kinds of insurance programs. For example, in the case of Turner syndrome, only 25% of Blue Cross/Blue Shield insurers reimbursed for GH treatment, while 81% of Medicaid programs provided coverage.²¹⁰ Similarly, none of the Blue Cross/Blue Shield and private insurers approved GH therapy for children with idiopathic short stature, while 48-50% of the Medicaid agencies provided approval.²¹¹

Traditionally, claims for health services are denied by insurers based on a determination that they are "experimental" or "not medically necessary."²¹² Exclusions of coverage by insurers have generated significant litigation in recent years. One commentator notes that, during the 1990s, twenty judicial decisions have been published each year regarding reimbursement denials based on questions of whether a treatment was medically appropriate.²¹³ Coverage exclusions for allegedly "experimental" treatments have produced their own large body of litigation, most notably in cases involving HDC-ABMT for severe breast cancer.²¹⁴ The courts, however, have reached contradictory and inconsistent conclusions in

205. See Janice M. Maggio, *Determination of HDC-ABMT as Accepted Medical Practice for the Treatment of Breast Cancer*, 22 RUTGERS COMPUTER & TECH. L.J. 551, 557 (1996).

206. See Finkelstein et al., *supra* note 204, at 666-67 ("The data indicate significant variation among US insurers regarding coverage policies for GH therapy, supporting the concept that there are major discrepancies in access to treatment as a function of third-party payers. These findings are consistent with the few earlier retrospective assessments for other conditions.").

207. See *id.* at 666.

208. See *id.*

209. See *id.*

210. See *id.* at 665, Table 2.

211. See *id.* at 665.

212. See HALL, *supra* note 19, at 69-71.

213. See *id.* at 69.

214. See *id.* at 31; Sharon Hoffman, *A Proposal for Federal Legislation Regarding Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. (forthcoming 1999).

health insurance reimbursement cases.²¹⁵ Some scholars have criticized the courts for lacking the medical and insurance expertise necessary to make fully educated decisions in these emotionally charged cases.²¹⁶

The legislative forum may be more appropriate for resolution of insurance coverage issues. Several states have mandated that insurance providers pay for HDC-ABMT for certain kinds of cancer under particular circumstances.²¹⁷ In addition, under federal law, almost all patients with end-stage renal disease receive coverage for treatment of their illness.²¹⁸ Accordingly, as genetic technology becomes increasingly available, legislation is likely to be enacted to mandate insurance coverage of certain treatments for genetic disorders. While federal legislation would avoid the problem of ERISA preemption²¹⁹ and would provide a single mandate for all U.S. patients, state legislatures are likely to enact coverage requirements for genetic services long before any action is taken on the national level.²²⁰

IV. LIABILITY ISSUES

Numerous malpractice lawsuits have been brought in cases involving genetic testing and counseling.²²¹ Although malpractice

215. See J. Gregory Lahr, Commentary, *What is the Method to Their "Madness?" Experimental Treatment Exclusions in Health Insurance Policies*, 13 J. CONTEMP. HEALTH L. & POL'Y 613, 623 (1997); Richard S. Saver, Note, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?* 44 STAN. L. REV. 1095, 1098 (1992).

216. See HALL, *supra* note 19, at 69; Jennifer Barber, Note, *Experimental Treatment Exclusions from Medical Insurance Coverage: Who Should Decide?*, 1 WIDENER L. SYMP. J. 389, 407 (1996).

217. See CAL. HEALTH & SAFETY CODE § 123985 (Deering 1997); CAL. WELF. & INST. CODE § 14133.8 (Deering 1994); FLA. STAT. ANN. § 627.4236 (West Supp. 1999); 1996 Ky. Acts 114; MASS. GEN. LAWS ch. 176B § 40 (1996); MINN. STAT. ANN. § 62A.309 (West 1996); N.H. REV. STAT. ANN. § 419.5-c (Supp. 1997); N.J. STAT. ANN. § 17:48-6f (West 1996).

218. Medicare originally covered only end-stage renal disease patients who were over the age of 65. See Maxwell J. Mehlman, *Rationing Expensive Lifesaving Medical Treatments*, 1985 WIS. L. REV. 239, 248 n.42 (1985). The Social Security Amendments of 1972 extended coverage to patients under 65 by providing Medicare hospital and supplemental medical insurance protection to renal patients under 65 who, under Social Security or railroad retirement plans, were entitled to receive cash disability benefits. See *id.* In addition, the amendments deemed all other patients under 65 who were covered by social security, as well as their spouses and dependents, as disabled and entitled to Medicare coverage. See *id.*; see also 42 U.S.C.A. § 426(b)(2) (1991).

219. See *supra* text accompanying notes 131-33.

220. As noted above, state statutes have mandated coverage for certain "experimental" treatments, whereas federal legislation has yet to address the issue.

221. See HALL, *supra* note 19, at 215 (discussing "wrongful birth" suits); Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149, 152-61 (1992) (same).

concerns are not unique to the managed care setting, managed care and its cost containment constraints have intensified the public's anxiety about negligent care and, many believe, have increased the threat of litigation.²²² Physicians are under pressure to see more patients, to spend less time with each patient, and to use fewer resources.²²³ Utilization review and payment arrangements may induce doctors to undertake less than the full panoply of diagnostic tests and treatment interventions than they might have preferred.²²⁴

A growing debate exists regarding the standard of care to which primary care physicians practicing in a managed care setting should be held.²²⁵ One scholar has proposed that the level of competence expected of primary care physicians, who are required by managed care organizations to perform services traditionally offered by specialists, should be modified.²²⁶ He suggests that they be held to the standard of care of other primary care physicians who are obligated to deliver these services.²²⁷ Others have rejected the notion of a redefined standard of care for primary care physicians.²²⁸ This debate highlights the concern over the primary care physician's malpractice vulnerability.

Many of the malpractice cases involving genetics come under the heading of "wrongful birth" or "wrongful life."²²⁹ The allegation in these suits is that the health care provider is liable for failing to recommend diagnostic tests that might have disclosed a severe birth defect or genetic risk in time for the parents to avoid conception or choose an abortion.²³⁰ Because of the expected increase in preconception and prenatal genetic testing and counseling,²³¹ the potential exists for many more of these lawsuits.

A somewhat newer theory of liability involves the alleged failure to warn at-risk relatives. In a Florida case, *Pate v. Threlkel*,²³² the plaintiff's mother was diagnosed with medullary

222. See Friedland, *supra* note 3, at 100; Gerald B. Hickson, *Commentary: Don't Let Primary Care Physicians Off the Hook So Easily*, 26 J.L. MED. & ETHICS 113, 113 (1998).

223. See Friedland, *supra* note 3, at 100.

224. See *id.*

225. See *id.*; Hickson, *supra* note 222, at 113.

226. See Friedland, *supra* note 3, at 101-02.

227. See *id.* at 102.

228. See Hickson, *supra* note 222, at 113; Edward B. Hirshfeld, *Should Ethical and Legal Standards for Physicians Be Changed to Accommodate New Models for Rationing Health Care?* 140 U. PA. L. REV. 1809, 1818 (1992).

229. See HALL, *supra* note 19, at 215.

230. See, e.g., *Munro v. Regents of the University of California*, 263 Cal. Rptr. 878, 885 (Ct. App. 1989) (holding that a doctor did not have a duty to give plaintiffs, the parents of a child with Tay-Sachs disease, information regarding a prenatal genetic test for Tay-Sachs disease when it was not indicated by any facts that plaintiffs discussed with the doctor).

231. See ASSESSING GENETIC RISKS, *supra* note 12, at 34-37.

232. 661 So. 2d 278 (Fla. 1995).

thyroid carcinoma, an autosomal dominant disease.²³³ Three years later, her adult daughter, the plaintiff, was similarly diagnosed.²³⁴ The daughter sued her mother's physician, alleging that the physician's failure to warn the daughter of her risk of developing the disorder constituted malpractice and that the delay in diagnosis limited the efficacy of her treatment.²³⁵ The Florida Supreme Court held that expert testimony would be needed to determine whether the standard of care imposed upon the physician a duty to warn the patient of the importance of having her children tested for medullary thyroid carcinoma.²³⁶ However, the court found that, under Florida law, even if a duty to warn did exist, it would be satisfied by warning the patient, rather than informing her children directly.²³⁷ The court reasoned that doctors may not disclose their patients' medical data without the patients' permission and that requiring physicians to seek out and caution various members of the patients' families would place too heavy a burden upon the doctors.²³⁸

A New Jersey case, *Safer v. Estate of Pack*,²³⁹ took the analysis one step further. In 1956, the plaintiff's father was diagnosed with adenomatous polyposis coli, a colon cancer of genetic origin.²⁴⁰ At the time of her father's death in 1964, the plaintiff was ten years old.²⁴¹ The physician who diagnosed the plaintiff's father died in 1969.²⁴² In 1990, the plaintiff was diagnosed with the same disorder.²⁴³ The daughter sued the estate of her late father's physician, arguing that the doctor's failure to warn her of the risk to her health prevented her from obtaining prompt diagnosis and treatment.²⁴⁴ Unlike the Florida court, the New Jersey court explicitly recognized a duty on the part of physicians to warn individuals known to be at risk of avoidable harm from a genetically transmitted disease.²⁴⁵ Furthermore, the court declined to adopt the Florida holding that, in all circumstances, the duty to warn is satisfied by communication with the patient rather than family members.²⁴⁶ The court posited that in some cases there may be a conflict between the physician's duty to warn and a patient's insistence that no details of the disease be disclosed to his or her

233. *Id.* at 279.

234. *See id.*

235. *See id.*

236. *See id.* at 281.

237. *See id.* at 282.

238. *See id.*

239. 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

240. *See id.* at 1189-90.

241. *See id.* at 1190.

242. *See id.*

243. *See id.*

244. *See id.*

245. *See id.* at 1191-92.

246. *See id.* at 1192.

family.²⁴⁷ In such cases, it would be clear to the physician that, despite a recommendation to the contrary, the patient will not have relatives tested because the patient will not want to reveal the nature of his or her own illness.²⁴⁸ The court suggested that in these circumstances the physician may have to discuss the matter directly with the patient's children.²⁴⁹

Although the courts have not yet considered the issue, similar questions may arise regarding disclosure to a patient's siblings or other blood relatives. If genetically related family members are not warned of their genetic susceptibility, they may sue the health care provider based on a theory of negligence similar to that used in *Pate* and *Safer*.

While a physician's duty to disclose confidential data to third parties remains murky in the emerging field of genetics, much clearer guidelines exist with respect to disclosure of a patient's HIV status. The American Medical Association's Code of Medical Ethics provides the following guidance:

Exceptions to confidentiality are appropriate when necessary to protect the public health or when necessary to protect individuals, including health care workers, who are endangered by persons infected with HIV. If a physician knows that a seropositive individual is endangering a third party, the physician should, within the constraints of the law: (1) attempt to persuade the infected patient to cease endangering the third party; (2) if persuasion fails, notify authorities; and (3) if the authorities take no action, notify the endangered third party.²⁵⁰

All states require health care providers to report to state public health authorities the names of individuals diagnosed with AIDS and many mandate reporting those diagnosed with HIV infection.²⁵¹ In addition, states seeking federal support for HIV testing programs must certify that they will implement appropriate partner notification programs.²⁵²

More generally, in an effort to provide lucid guidance regarding other medical information, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended, in 1983, that disclosure of a patient's medical data be made only under the following

247. *See id.* at 1192-93.

248. *See id.* at 1193.

249. *See id.*

250. AMERICAN MEDICAL ASSOCIATION COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS 71 (1998).

251. *See* WILLIAM J. CURRAN ET AL., HEALTH CARE LAW AND ETHICS 202 (5th ed. 1998).

252. *See id.* at 989 (citing 42 U.S.C.A. § 300ff-46 (West 1996)).

circumstances:

(1) reasonable attempts to elicit voluntary disclosure are unsuccessful; (2) there is a high probability of serious (e.g., irreversible or fatal) harm to an identifiable relative; (3) there is reason to believe that disclosure of the information will prevent harm to the relative; and (4) the disclosure is limited to the information necessary for diagnosis or treatment of the relative.²⁵³

The Committee on Assessing Genetic Risks recommended that patients be counseled by health care providers regarding the benefits of sharing information about hereditary diseases with relatives.²⁵⁴ With respect to the rare circumstances in which a patient refuses to disclose information about genetic risks to family members, the Committee adopted the guidelines delineated by the President's Commission regarding the circumstances under which breach of confidentiality would be permissible.²⁵⁵

Managed care organizations may also face difficult questions regarding disclosure of genetic information to the spouse of the individual who has been tested. In some instances, a spouse may learn that he or she is a carrier of a serious hereditary disease but may not wish to inform the other spouse of the results of the genetic test prior to making reproductive decisions.²⁵⁶ In other instances, a genetic test of a fetus or infant may reveal misattributed paternity.

The Committee on Assessing Genetic Risks recommended that patients be encouraged and assisted in sharing genetic information with spouses.²⁵⁷ However, the Committee concluded that health care providers should not reveal genetic data about a patient's carrier status to a spouse without the patient's permission.²⁵⁸ In addition, the Committee recommended that a determination of misattributed paternity be revealed to the mother but should not be volunteered to her partner so that genetic services do not become "disruptive to families."²⁵⁹

Courts in the future are likely to face many lawsuits regarding genetic information and its disclosure. The rapid development of genetic technology will undoubtedly generate increasingly complex

253. ASSESSING GENETIC RISKS, *supra* note 12, at 267 (citing The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions* 6 (1983)).

254. *See id.* at 278.

255. *See id.*

256. *See id.* at 265-66.

257. *See id.* at 278.

258. *See id.*

259. *Id.* at 175. Therefore, it is important that the physician have a clear understanding at the outset as to who the patient is (i.e., the wife, the husband, the couple, the child, etc.) and what information will be revealed to whom.

disputes and new theories of liability. Some of these cases will relate not only to disclosure of genetic data to family members, but also to the access third parties may gain to such information. To avoid liability, managed care organizations will need to recognize the social and legal consequences of both withholding and disclosing genetic information.

V. CONFIDENTIALITY

As genetic technology develops, extensive genetic information will be learned about patients in the course of providing health care, and third parties will become increasingly interested in gaining access to such data.²⁶⁰ As discussed earlier,²⁶¹ an individual's genetic secrets may be of value to genetic relatives and to third parties, such as insurers and employers. Both scholars and lawmakers are focusing a considerable amount of attention on the issue of confidentiality.

Confidentiality, especially, may be jeopardized in a managed care setting. Increasingly, physicians, hospitals, and other providers have developed "integrated delivery systems" in order to achieve maximum cost containment through the pooling of capital and management expertise.²⁶² Physicians are joining together to form group practices, independent practice associations, and other networks.²⁶³ Hospitals are merging or forming alliances with other hospitals and are forming associations with physicians in order to facilitate joint contracting with managed care purchasers or to share financial risk and control.²⁶⁴ In addition, many practices utilize management services organizations that provide physicians and hospitals with administrative support services such as billing and office clerical assistance.²⁶⁵ Management services organizations may also purchase the assets of physician practices and negotiate contracts with managed care plans in exchange for a share of gross receipts.²⁶⁶

In an integrated delivery system, where many different health care providers and organizations are part of the same entity, a multitude of individuals may have access to a patient's medical data through documentation or computer-stored files. Disclosure of confidential medical information, thus, may occur not only deliberately, but also through inadvertent error or carelessness. Consequently, managed care entities must be particularly cautious

260. See Mark A. Rothstein, *Genetic Secrets: A Policy Framework*, in *GENETIC SECRETS*, *supra* note 1, at 451, 451-52.

261. See *supra* text accompanying notes 232-59.

262. BARRY R. FURROW ET AL., *HEALTH LAW* 226 (1995).

263. See *id.* at 225-26.

264. See *id.* at 225.

265. See *id.* at 227.

266. See *id.*

in safeguarding the confidentiality of their patients' genetic information.

A. *Preventing Unnecessary Internal Disclosures*

Managed care organizations should ensure that medical information, including genetic information,²⁶⁷ is not shared with, or made accessible to, individuals within the health care setting who do not need access to the data. In order to maximize confidentiality, those in possession of medical records need to determine the following: (1) how can access to information be limited to legitimate users and for legitimate uses; (2) for purposes of billing and other nonclinical uses, to what extent can "de-identified" information be utilized so that patients are not specifically named and their confidentiality is not compromised; and (3) what minimally intrusive data set is necessary to use for outcomes research, quality assurance, utilization review, and other legitimate purposes.

Managed care entities should comply with the following principles related to confidentiality of patient records:

Medical records in any form should be available only to those with a legitimate, essential need to know, and the presumption should be against disclosure.

Medical records subject to disclosure should be disclosed in the least identifiable form consistent with their essential use.

Technologies should be developed to permit removal of identifiers and to prevent unauthorized access.

Patients should be informed about disclosure policies, including the types of individuals who will have access to the records without additional consent.

Patients should have access to their own records.²⁶⁸

B. *Disclosure to Third Parties*

Patient confidentiality may be breached not only through

267. See generally Thomas H. Murray, *Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information?* in GENETIC SECRETS, *supra* note 1, at 60 (arguing that genetic data should not be treated differently from other health-related information).

268. See THE SEVERYN GROUP, *supra* note 106, at 37. One of the authors of this Article, Mark A. Rothstein, has previously suggested these guidelines to the American Association of Health Plans, the HMO Research Network, the Agency for Health Care Policy and Research, and the Centers for Disease Control and Prevention.

inappropriate internal disclosures, but also through divulgence to third parties. There is, for example, significant concern that employers that are self-insured and administer their own health benefits plans without utilizing a third-party administrator will learn a great deal of information about their employees' health status from processing their insurance claims.²⁶⁹ Information that predicts whether an individual is at an increased risk of illness is valuable to any party with an economic or personal interest in the future health of the individual. The list of interested parties may include life insurance companies, long-term care insurance companies, employers, bankers, mortgage companies, educational loan officers, relatives, and others.²⁷⁰ It is beyond the scope of this Article to discuss all of the third-party uses of genetic information. Nevertheless, health care providers and policy-makers should be aware of the issues implicated in the disclosure of genetic information through billing records.

CONCLUSION

Genetics and health care delivery are both areas that are rapidly evolving and which generate significant public angst. The integration of new genetic services into primary care within a managed care system raises important challenges. Genetic information may be very valuable for purposes of health promotion, early diagnosis, and treatment. However, if the integration of genetic information is not performed carefully and in a sensitive manner, a variety of negative consequences could follow. These consequences include psychological harm to individuals, inappropriate provision or denial of services, the sacrificing of reproductive freedom, and nonmedical harms, such as discrimination as a result of the disclosure of genetic data to third parties.

In the managed care setting, genetic technology may be utilized on a large-scale basis with many associated benefits. Large managed care organizations may be able to develop data bases on the prevalence of rare disorders and to follow affected patients throughout their lives. Similarly, large managed care entities may contribute to medical knowledge regarding treatment of genetic diseases through data collected about their patients. For example, it

269. See, e.g., *Doe v. Southeastern Pa. Transp. Auth.*, 72 F.3d 1133, 1143 (3d Cir. 1995) (holding that the employer's need for access to employee prescription records outweighed the confidentiality interests of an employee with AIDS); see also Mark A. Rothstein, *The Law of Medical and Genetic Privacy in the Workplace*, in *GENETIC SECRETS*, *supra* note 1, at 281, 294-95 (noting the potential for at least the employer's benefits department to learn of the medical condition of the employee or his or her dependants).

270. See Rothstein, *supra* note 260, at 468-90 (highlighting the adverse consequences of disclosure of genetic information for insurance, employment, courts, forensics, schools, and commercial and government uses).

may be possible to determine whether women with a genetic predisposition to breast cancer have reduced morbidity and mortality with frequent mammography, tamoxifen, prophylactic mastectomy, or other interventions.²⁷¹ Managed care organizations can also integrate genetic medicine into practice guidelines and thus improve general health care standards. The Center for Disease Control and Prevention is considering a major public health initiative on hemochromatosis.²⁷² If large managed care organizations issued practice guidelines to their physicians mandating that they begin routine screening for hemochromatosis, many individuals could be identified at a time when the condition is easily treatable.

New medical advances frequently lead to speculation regarding whether they will save health care costs. Genetic technologies are no different. It is unlikely that new genetic discoveries, on the whole, will decrease health care costs. With the exception of basic sanitation and immunization, new technologies tend to increase costs, as will certainly be the case with gene therapy and other measures. Health care providers should not embrace genetics as a cost-saving device but rather as a mechanism to improve health. In the arena of genetics, the focus of concern for managed care organizations should be how to provide genetic services to large patient populations in a cost-effective manner that promotes the physician-patient relationship, patient autonomy, and the confidentiality of genetic information.

271. See, e.g., Hartmann et al., *supra* note 15. Such studies would not constitute medical research, which is extensively regulated by Department of Health and Human Services regulations contained in 45 C.F.R. §§ 46.107-.117 (1998), but rather, retrospective, records-based outcomes assessment.

272. Hemochromatosis is a hereditary disorder causing excessive absorption and storage of iron, which commonly leads to impairment of the liver, diabetes mellitus, pituitary failure, and heart problems. See THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1146-47 (Robert Berkow et al. eds. 16th ed. 1992).