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Mother Still Knows Best: Cancer-Related Gene Mutations, Familial Privacy, and a Physician's Duty to Warn

Cover Page Footnote

J.D. Candidate, Fordham University School of Law, 1999; B.A., magna cum laude, Barnard College, 1996; A.D.N., University of Hawai'i, Manoa, 1988. I would like to extend my appreciation to Professor Elizabeth Cooper for her valuable insight and advice and Radford Small for providing endless encouragement.

MOTHER STILL KNOWS BEST: CANCER-RELATED GENE MUTATIONS, FAMILIAL PRIVACY, AND A PHYSICIAN'S DUTY TO WARN

*Alissa Brownrigg**

Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.¹

Introduction

At the completion of medical school, graduates embarking on their careers as physicians mark the moment by taking the Hippocratic Oath.² Although the oath originated as early as the fifth century B.C., its vow to abstain from sharing a patient's personal information remains an important tenet of medical care today.³ The oath's assurance of privacy encourages patients to divulge personal information, trusting that their doctors will keep it confidential, even from members of the patients' families.⁴

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1. *Oath and Law of Hippocrates* (visited Nov. 24, 1998) <ftp://ftp.std.com/obi/Hippocrates/HippocraticOath>.

2. See Robert D. Orr & Norman Pang, *The Use of the Hippocratic Oath: A Review of 20th Century Practice and a Content Analysis of Oaths Administered in Medical Schools in the U.S. and Canada in 1993* (visited Feb. 19, 1998) <http://www.sequel.net/twilight/poath9.htm> (noting that while a majority of medical schools do administer a version of the oath that omits outdated content of the traditional oath, some schools do not administer the Hippocratic Oath at all).

3. See Charles Marwick, *Medical Records Privacy a Patient Rights Issue*, 276 JAMA 1861 (1996) ("A patient has a right to keep personal medical information confidential [T]he best guide for steering a path way through today's computerized medical recordkeeping is the Hippocratic oath."); American Medical Association—Institute for Ethics, *Principles of Medical Ethics* (visited Nov. 24, 1998) <http://www.ama-assn.org/ethic/pome.htm> ("A physician shall . . . safeguard patient confidences within the constraints of the law.").

4. See Marwick, *supra* note 3 ("Plans with a more cavalier attitude to privacy will not attract members, who will switch to other plans if they can or withhold information about their health if they can't.") (citation omitted); Bernard Friedland, *Physician-Patient Confidentiality; Time to Re-Examine a Venerable Concept in Light of*

In situations where confidential medical information affects the health of a patient's relatives, however, some assert that physicians should be required to share the information with the family, with or without the patient's consent.⁵ The patient's children particularly may benefit from the medical information, especially where it reveals a genetic disease, because a forewarning of their increased risk of the disease would give them the option of investigating and taking advantage of preventive measures.⁶

This conflict between protecting the integrity of physician-patient confidentiality and protecting at-risk third parties lies at the core of many medical-legal conflicts.⁷ For example, since the turn of the century, physicians treating patients for communicable diseases, such as tuberculosis, have had to decide whether the interest of third parties (or the public at large) to be warned of a risk of infection or harm from the disease supersedes the duty to maintain the confidentiality of the patient's information for the patient.⁸

Contemporary Society and Advances in Medicine, 15 J. LEGAL MED. 249, 256 (1994) ("The patient's most profound secrets are kept confidential. This encourages patients to bare themselves fully to their physicians so that an accurate diagnosis may be made and appropriate treatment instituted.").

5. See Diana Brahams, *Human genetic information: the legal implications*, in HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS 111, 113-14 (Derek Chadwick et al. eds., 1990).

As against the duty of confidentiality which would be owed by a doctor, there may be a duty of disclosure to a partner or child which has to be weighed in the legal balance, particularly if all concerned are patients of the same doctor who owes them all an equal duty of care. In this instance, unless the public are put at risk, any disputes which arise are likely to be private matters.

Id.

6. See Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149, 180 (1992) [hereinafter *Double Helix*] ("The strongest case for a warning exists when there is a high likelihood that the relative has the genetic defect, the defect presents a serious risk to the relative and his or her children, and presumably the disclosure is necessary to prevent serious harm.").

7. See *id.* at 176 ("A major exception to confidentiality, however, should be noted. A physician may, in certain instances, breach confidentiality in order to protect third parties from harm, such as when the patient might transmit a contagious disease or commit violence against an identifiable individual."); see generally Friedland, *supra* note 4 (examining the numerous circumstances where conflict arises between the legal and ethical obligations of physicians to protect the confidentiality of patients' information and the potential benefit to third parties if such information is made available to them).

8. See Susan Fox Buchanan, *Medical Ethics at the Millennium: A Brief Retrospective*, 26 COLO. LAW. 141, 142 (1997) ("[U]rbanization in the late nineteenth and early twentieth centuries led to a growing concern with public health and epidemics in many American new cities [C]onfidentiality had been tempered by the exigencies of contagious disease."); Philip R. Reilly, *Public Policy and Legal Issues Raised*

Although respect for a patient's privacy generally compels doctors to refrain from sharing medical information with anyone uninvolved with the patient's care, the physician must notify health officials when innocent third parties are at risk of certain diseases.⁹ Recently, physicians who treat HIV-positive individuals have faced this conflict because they now may notify at-risk partners or contacts (i.e., intravenous drug users with whom the individual has shared needles) if the patient does not.¹⁰ In the near future, genetic test results may create another exception to physician-patient confidentiality because of their potentially valuable use to close patient relatives.¹¹

Although genetic testing has existed for many years,¹² scientists are presently attempting to identify the patterns created by all human genes.¹³ Researchers are linking these patterns with inher-

by *Advances in Genetic Screening and Testing*, 27 SUFFOLK U.L. REV. 1327, 1334-35 (1993) (comparing genetic privacy considerations with those of HIV information; there, individual privacy rights often outweigh disclosure to third parties with strong interest in information).

9. See *infra* note 95 and accompanying text.

10. See *infra* note 99 and accompanying text.

11. See Sonia M. Suter, *Whose Genes Are Those Anyway? Familial Conflicts Over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1854-55 (1993) ("[T]he identification of disease genes has escalated dramatically . . . [C]onflicts of interest may arise between an individual and her relatives, who may personally benefit from learning about the individual's genetic status."); *Genetics in the Courtroom: An Introduction*, 36 No. 3 JUDGES' J. 1 (1997) (recognizing that genetic discoveries promise to introduce new types of evidence, causes of action and perspectives into courtrooms); Andrews, *Double Helix supra* note 6, at 177.

One can make an argument that health care professionals working in the medical genetics field have disclosure obligations similar to those of the physician whose patient suffers from an infectious disease or a psychotherapist whose patient is a [sic] potentially violent. Because of the inheritable nature of genetic diseases, a health professional who, through research, counseling, examination, testing, or treatment, gains knowledge about an individual's genetic status invariably has information valuable not only to the patient, but also to his or her spouse or relatives.

Id.

12. See ROGER B. DWORKIN, *LIMITS: THE ROLE OF LAW IN BIOETHICAL DECISION MAKING* 85 (1996) (noting that since the 1953 discovery of DNA's structure, genetic screening, counseling, and prenatal diagnosis have become established in medical practices).

13. Genes are the functional units of DNA that combine into various patterns and lead to different appearances and behaviors, or phenotypes, of cells. See Leroy Hood & Lee Rowen, *Genes, Genomes, and Society*, in *GENETIC SECRETS* 4 (Mark A. Rothstein ed., 1997); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *TECHNOLOGIES FOR DETECTING HERITABLE MUTATIONS IN HUMAN BEINGS* 6 (1986) (describing the human genome, which is the complete set of genetic information—each cell of the human body contains forty-six chromosomes, where groups of genes are arranged in sequence to form DNA and proteins).

ited traits, disease, and even an individual's susceptibility to common adult-onset disease.¹⁴ So far, genetic mutations have been identified and linked to several diseases, such as Alzheimer's, various cancers, and Lou Gehrig's Disease.¹⁵ Genetic testing is frequently used in prenatal testing and will increasingly become available to the public as part of routine health care.¹⁶

BRCA1¹⁷ and BRCA2¹⁸ are recently discovered genetic mutations that signal that their carriers face a risk of developing breast and ovarian cancer that is significantly higher than the risk the average woman faces.¹⁹ As more women become aware of the BRCA mutations, there will be an increased demand for BRCA

14. Adult-onset, or late-onset diseases are those that are present in an individual's DNA since conception, but do not manifest themselves until adult life. See Wendy C. McKinnon et al., *Predisposition Genetic Testing for Late-Onset Disorders in Adults: A Position Paper of the National Society of Genetic Counselors*, 278 JAMA 1217, 1217 (1997); OFFICE OF TECHNOLOGY ASSESSMENT *supra* note 13, at 30.

15. See 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, 1224 (1997) ("Recent discoveries include genetic links to Alzheimer's, bladder cancer, cervical cancer, colon cancer, obesity, prostate cancer, and tumor growth associated with a spectrum of common cancers. Researchers are even developing an 'Ides of March' genetic test to serve as a crude indicator of a person's life span."); Julie Holland, *Should Parents be Permitted to Authorize Genetic Testing for their Children?* 31 FAM. L. Q. 321, 324 (1997).

16. See John Bell, *Prenatal Diagnosis: Current Status and Future Trends*, in HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS, SYMPOSIUM ON HUMAN GENETIC INFORMATION; CIBA FOUNDATION SYMPOSIUM 18, 19 (1992).

Genetic Screening, as it is currently applied, relates mostly to the prenatal diagnosis of the major monogenic disorders . . . a number of technological advances . . . will introduce the possibility of effectively screening for many common diseases. In turn, this will alter both the populations needing to be screened and the potential interventions that follow such screening procedures.

Id.; Benjamin S. Wilfond & Kathleen Nolan, *National Policy Development for the Clinical Application of Genetic Diagnostic Technologies: Lessons from Cystic Fibrosis*, 270 JAMA 2948, 2949 (1993) ("It may . . . seem inevitable that virtually every test that is technically feasible will be routinely used. Commercial interests may promote testing; clinicians may use tests to allay fears of legal liability; and patients themselves may demand testing to obtain genetic information.").

17. See *infra* note 35 and accompanying text.

18. See *infra* note 36 and accompanying text.

19. See Wylie Burke, *Recommendations for Follow-up Care of Individuals With an Inherited Predisposition to Cancer: II. BRCA1 and BRCA2*, 277 JAMA 997, 998 (1997) [hereinafter *Recommendations II*]. Although BRCA1 is associated with a six percent lifetime risk of colon cancer in women and men, and an eight percent lifetime risk of prostate cancer in men, both BRCA1 and BRCA2 are blamed for significant increases in breast cancer, a disease most commonly experienced by women, and ovarian cancer, a disease exclusively experienced by women. See *id.* See *infra* notes 35 and 36 and accompanying text. Because I concentrate on breast and ovarian cancers, I will use "patient" to refer to females throughout the Note.

testing.²⁰ Accordingly, physicians will more frequently face the dilemma of whether to notify family members of their increased risk of developing cancer due to their genetic makeup. Geneticists, however, have been unable to decide whether genetic information should be disclosed to relatives because information has the potential for both great benefit and harm to its recipients.²¹ Therefore, a balancing test is needed to govern the release of genetic data.²²

This Note focuses on the BRCA gene mutations and argues that physicians currently have no duty to warn the children²³ of a known BRCA carrier, who has been diagnosed with breast or ovarian cancer, that they also may carry the BRCA mutations that predispose them to cancer. Part I provides a background of current genetic research and testing, including the significance of testing positive for BRCA1 or BRCA2, and the future of BRCA testing. Part II reviews current legislation regulating the dissemination of genetic information, existing exceptions to physician-patient confidentiality, and recent court decisions regarding the physician's duty

20. See Nancy Press et al., *How are Jewish Women Different From All Other Women?*, 7 HEALTH MATRIX 135, 159 (1997).

We suggest that there is an implicit belief in the contemporary United States that a probability statistic, accurately calculated and named, can eliminate its own most essential element—uncertainty. This belief makes Americans see risk information as inherently useful and may be one of the reasons there is often insufficient attention paid to gaps between diagnostic sophistication and treatment options. This is particularly relevant in the case of genetic susceptibility testing for breast cancer because this belief may drive both clinicians and test consumers to opt for genetic testing even in the absence of proven efficacy of treatment sequelae.

Id.

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, 312 (1997) ("Whether or not to inform a patient's relatives that they may be at a genetic risk, against the wishes of that patient, was one of the questions geneticists found most difficult to answer. There was no consensus on this issue anywhere in the world.").

22. Although legislation is forward-looking, and a balancing test would be used by a court after harm has occurred, solutions that succeed today will likely prove unworkable for a long term in the realm of rapid advances in genetic technology. Therefore, physicians could consider factors in the balancing test to determine whether or not to disclose genetic information. See DWORKIN, *supra* note 12, at 12 ("Changing values, advances in science, and unanticipated situations combine to create the possibility that prospective, comprehensive lawmaking will be fundamentally flawed.").

23. Throughout this Note, references to a patient's children mean adult offspring. Warning minor children about the possibility that they may inherit genetically linked diseases raises numerous complex ethical issues that merit their own separate discussion. For an excellent overview of these issues, see Dorothy C. Wertz et al., *Genetic testing for children and adolescents: who decides?*, 272 JAMA 875 (1994); see also Holland, *supra* note 15.

to warn family members of genetic disease. Part III proposes a balancing test which should be used to determine whether a physician is required to notify a patient's children if she tests positive for a BRCA mutation. This test allows the physician's duty to warn to adapt to changes in professional education, cancer prevention, and legislation. This Note concludes that application of the balancing test to BRCA mutations under current conditions indicates that physicians should keep their patients' genetic information confidential because of the substantial harm posed by its release.

I. A Background of Genetic Research

A brief overview of recent genetic research and advances in biotechnology will illuminate areas where new exceptions in the confidential nature of the physician-patient relationship may be permitted. This Part reviews the developments in genetic research, particularly with respect to the BRCA1 and BRCA2 mutations.

A. The Human Genome Project

The Human Genome Project ("HGP") is an international research effort designed to locate and map out all human genes, collectively known as the human genome.²⁴ Once the human genome is completely sequenced, scientists will have a "virtual instruction book" for a human being.²⁵ Genetic information details an individual's behavioral and biological traits, and diagnoses and reveals

24. *Hearings on the National Genome Research Institute*, 105th Cong. (1997) [hereinafter *Hearings on NHGRI*] (Testimony of Francis S. Collins, Director of the National Human Genome Research Institute) ("NHGRI"). In the United States, the project is carried out by the NHGRI and the Department of Energy. The NHGRI, which was established in 1989, funds research laboratories throughout the United States and also has its own in-house laboratories. The HGP researchers intend to sequence all human genes by the year 2005, and at the present time, have mapped out about two percent of human DNA. *See Human Genome Project Information* (visited Nov. 14, 1997) <http://www.ornl.gov/TechResources/Human_Genome/genetics.html> (estimating that about 5800 genes have been mapped to date).

25. *See Hearings on NHGRI*, *supra* note 24. As researchers identify gene patterns and mutations of those patterns, they also hope to determine what role environmental influences may play in conjunction with inherited factors in the development of disease. With this information, scientists may reveal modes of preventing such diseases as cancer, heart disease and diabetes that do not yet exist. *See id.*; *see also* EUGENE B. BRODY, *BIOMEDICAL TECHNOLOGY AND HUMAN RIGHTS* 129 (1993) ("A detailed chart of the genes is essential to ultimate progress in understanding the biology of living organisms and, specifically, to the clinical biotechnology aimed at the prevention and cure of genetic disease.").

predispositions to certain diseases.²⁶ The government, therefore, has recognized that many moral, ethical, and legal issues arising out of genetic research must be addressed in the near future.²⁷

In an effort to identify and confront these questions, the National Human Genome Research Institute ("NHGRI") created and funded the Ethical, Legal, and Social Implications Program ("ELSI").²⁸ ELSI's priorities include ensuring privacy and fair use of genetic information, promoting responsible clinical integration of genetic technologies, addressing ethical issues in research, and educating professionals and the public about genetic issues.²⁹ The stated goals of ELSI are to identify issues resulting from genetic research and develop policies to address these issues.³⁰ The program also seeks to foster an acceptance of genetic variation, and to increase public and professional awareness of genetic testing and the appropriate use of test results.³¹

In addition to mapping normal gene patterns, the process of identifying genes and their components, called nucleotides,³² also

26. McKinnon et al., *supra* note 14, at 1217 (noting that genetic tests which have, in the past, detected rare monogenic conditions, can now identify susceptibility to many complex, adult-onset diseases).

27. See F. Collins & D. Galas, *A new five-year plan for the U.S. Human Genome Project*, 262 *SCIENCE* 43 (1993) (noting that the Department of Energy and the National Institute of Health devote three to five percent of their annual budgets towards ELSI, the world's biggest bioethics program).

28. *Id.*

29. See *Hearings on NHGRI*, *supra* note 24. Responding to the recommendations of the ELSI group and to the National Action Plan on Breast Cancer, President Clinton has stated that his administration will support legislation designed to prevent discrimination by insurance companies on the basis of genetic information. See *id.*

30. See Francis S. Collins, *Preparing Health Professionals for the Genetic Revolution*, 278 *JAMA* 1285, 1285 (1997) [hereinafter *Revolution*].

31. Commentators have expressed great concern about physicians anxious to provide genetic testing to their patients and about the public demanding testing before providers are adequately educated about interpreting test results and are trained to provide sufficient counseling and support for their patients. See Malinowski & Blatt, *supra* note 15, at 1245-1246.

[D]ue to the absence of clinical data, health care providers cannot interpret the results of predictive genetic tests for most of their patients with any reliability even when they are knowledgeable about genetics. This interpretation problem is exacerbated because the current generation of health care providers does not possess such knowledge.

Id.

32. Nucleotides are the building blocks of genes. There are four different components which bind together in pairs to form triplet formations called codons, which make up amino acids, the components of proteins. See OFFICE OF TECHNOLOGY ASSESSMENT *supra* note 13, at 6. When a mutation occurs, one nucleotide substitutes another in its place and creates a different protein. See *id.*

reveals mutations in sequences that contribute to disease.³³ The ability to identify patterns associated with disease may enable scientists to develop treatments and cures.³⁴ Some incurable diseases, such as cystic fibrosis, Huntington's Disease, and Tay-Sachs, are caused by mutations in one chromosome, and thus the probability that offspring will inherit these conditions can be accurately determined.³⁵ Other diseases, such as breast and ovarian cancer, insulin-dependent diabetes, and coronary artery disease, develop if certain genetic mutations exist in combination with environmental factors that have not yet been identified.³⁶ Therefore,

33. See Hood & Rowen, *supra* note 13, at 8-9 (noting that alterations in gene patterns in chromosomes, known as polymorphisms, can identify genes that predispose to disease).

34. See Collins, *Revolution supra* note 30, at 1285.

[K]nowledge of basic biological alterations underlying illnesses also offers the best hope for strategies to override or repair them. Promising gene-based strategies include drug therapy, which is used to nurture defective proteins, and gene therapy, in which the gene is used as a pharmaceutical. Gene discovery also allows elucidation of interactions between genes and between genes and the environment.

Id.; Reilly, *supra* note 8, at 1327-28. The human genome is organized as approximately one hundred pairs of genes patterned on twenty-three pairs of chromosomes. About three billion nucleotides, the building blocks of DNA, encode the genes which instruct cells to produce proteins that carry out cell processes and direct our bodily functions. Mutations in the genes can create disease by sending cells "wrong" information. See *id.* Scientists are able to locate the mutations in genes, replicate the patterns, splice in desired arrangements, and introduce these into cells to correct errors resulting in some diseases. See *id.* Current research may allow scientists to develop this gene therapy for more mutations and make available treatment that will attack diseases in a manner that is more effective and less destructive to the body. See William J. Polvino & W. French Anderson, *Medicine, Gene Therapy, and Society, in THE HUMAN GENOME PROJECT AND THE FUTURE OF HEALTH CARE* 39, 40-42 (Thomas H. Murray et al. eds., 1996).

35. See Paul M. Schwartz, *Privacy and the Economics of Personal Health Care Information*, 76 TEX. L. REV. 1, 19 (1997) ("[S]uch monogenic diseases, which affect only a tiny fraction of the population, can now be effectively predicted, although not cured."). While Huntington's Disease results from a dominant gene and can be passed on from one parent, cystic fibrosis is caused by a recessive gene and is only manifest when both parents are carriers of the trait. See Robert Williamson & Anna M. Kessler, *The Problem of Polygenic Disease, in HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS* 63 (Ciba Foundation 1990).

36. CARSON STRONG, *ETHICS IN REPRODUCTIVE AND PERINATAL MEDICINE* 136 (1997). While certain genetic mutations determine that a person will develop a disease, such as Huntington's Disease, cystic fibrosis and hemophilia, other mutations are multifactorial, meaning that only in combination with other external factors, such as environmental influences, will a particular disease develop. See *id.* Accordingly, these mutations determine that their carriers are susceptible to certain diseases, but cannot conclusively predict their development. Before scientists can discover preventive measures with which to deter the onset of these conditions, the external factors which contribute to disease must also be ascertained. See *id.*

the discovery of these mutations only signals an individual's potential for disease and does not guarantee its development. Moreover, the predictive value of many tests that identify predisposition to disease is currently undetermined due to a dearth of data about the complex nature of these gene mutations.³⁷

B. The BRCA Gene Mutations

Both the BRCA1 and BRCA2 genetic mutations, identified in 1994³⁸ and 1995³⁹ respectively, are associated with breast and ovarian cancer.⁴⁰ Studies show that women carrying one of these mutations, whose families have a history of breast or ovarian cancer, face a seventy-six to eighty-seven percent risk of developing breast cancer, and a thirty-two to eighty-seven percent risk of developing ovarian cancer during their lifetimes.⁴¹ Women in the general population, without either genetic mutation, face approximately a twelve percent risk of breast cancer and a one and a half percent chance of developing ovarian cancer during their lifetimes.⁴² While

37. See *infra* notes 138-139 and accompanying text.

38. See Georgia L. Wiesner, *Clinical Implications of BRCA1 Genetic Testing for Ashkenazi Jewish Women*, 7 HEALTH MATRIX 3, 21-22 (1997) ("The BRCA1 gene is a large, novel gene of unknown function that extends over 100,000 bases of genomic DNA Early studies of breast tumors showed that the BRCA1 region was frequently deleted in approximately twenty percent of breast tumors during the process of tumorigenesis thereby indicating that it may function as a tumor suppressor gene."). BRCA1 increases a woman's risk for both breast and ovarian cancer. Carriers who have had breast cancer also have a forty-four percent chance of developing ovarian cancer by the age of seventy. See Burke et al., *supra* note 19, at 998. This mutation is also associated with prostate cancer in men and colon cancer in both men and women. See *id.*

39. *Breast Cancer (Genetics): Full Sequence of BRCA2 Cancer Gene Published*, CANCER BIOTECHNOLOGY WKLY, Mar. 18, 1996 ("BRCA2 is believed to be responsible for approximately 40 percent of early-onset, hereditary breast cancer."); Wiesner, *supra* note 38, at 23 ("BRCA2 is associated with pre-menopausal female and male breast cancer.").

40. See Burke et al., *supra* note 19, at 998. The BRCA2 mutation creates a similar risk for breast cancer in women as BRCA1. See *id.* Researchers have observed several cases of breast cancer in males carrying the BRCA2 mutation, with one pedigree of the mutation linked to multiple cases of male breast cancer and none in females. See *id.* The risk for ovarian cancer is increased to a lesser extent for women carrying BRCA2 than for those with BRCA1. See *id.*

41. See Wiesner, *supra* note 38, at 21 (stating that cumulative breast cancer risk for BRCA1 carriers is about 50% by age 50 and 85% by age seventy while risk for ovarian cancer is 30-40% by age sixty); Jeffrey Struewing et al., *The Risk of Cancer Associated with Specific Mutations of BRCA1 and BRCA2 Among Ashkenazi Jews*, 336 NEW ENG. J. MED. 1401, 1401 (1997).

42. See Deborah Schrag et al., *Decision Analysis—Effects of Prophylactic Mastectomy and Oophorectomy on Life Expectancy Among Women with BRCA1 or BRCA2 Mutations*, 336 NEW ENG. J. MED. 1465, 1465 (1997).

only five to ten percent of all cases of breast cancer are attributed to the BRCA mutations,⁴³ a woman carrying one of these mutations is twenty times more likely than a woman without the mutations to develop breast cancer before the age of fifty.⁴⁴

C. Advantages of Undergoing Testing for the BRCA Mutations

Women identified as BRCA mutation carriers may take advantage of several suggested measures that may prevent the onset of, or increase the chances of surviving, breast or ovarian cancer.⁴⁵ These preventive steps range from simple dietary or activity changes to surgical intervention.⁴⁶ Low-fat, high-fiber diets, regular exercise, and the avoidance of smoking may decrease the incidence of breast cancer.⁴⁷ Because early detection greatly increases the chances of surviving breast cancer, women are encouraged to perform regular breast self-exams to monitor for any changes in breast tissue.⁴⁸

A health care provider also may perform breast exams during annual check-ups and monitor for any tumorous growths through regular mammograms.⁴⁹ Women with a family history of breast cancer are encouraged to have a baseline mammogram when they reach the age of twenty-five, followed by routinely scheduled mammograms throughout the remainder of their lives.⁵⁰ Although drugs have been proposed as agents to help prevent breast cancer,⁵¹ their efficacy is unproven, and more research is necessary

43. See Wiesner, *supra* note 38, at 15.

44. See Burke et al., *Recommendations II, supra* note 19, at 997, 999.

45. See Jerome Groopman, *Decoding Destiny*, THE NEW YORKER, Feb. 9, 1998, at 44 (stating that measures to prevent cancer range from avoiding alcohol and fats, drinking herbal tonics, and taking megavitamins, to the removal of breasts and ovaries).

46. See *id.*

47. See Wylie Burke et al., *Recommendations for Follow-up Care of Individuals With an Inherited Predisposition to Cancer; I. Hereditary Nonpolyposis Colon Cancer*, 277 JAMA 915, 918 (1997) (emphasizing that lifestyle changes have not been proven effective, but may decrease risk of cancer for those with inherited predisposition to cancer).

48. See Burke, *Recommendations II, supra* note 19, at 998-99 ("The limited sensitivity of mammography, particularly in younger women, makes self-examination potentially of greater value for BRCA1 and BRCA2 mutation carriers than for women of average risk.").

49. See *id.*

50. See *id.* at 999 (warning that, although early testing is recommended for women at high risk of breast cancer, risks and benefits of mammography before age fifty have not yet been established).

51. See *id.* at 1001.

before this strategy is routinely implemented.⁵² At the extreme, women at high risk for breast cancer may even opt to undergo a prophylactic mastectomy.⁵³

Fewer preventive measures exist for ovarian cancer because women diagnosed with this disease usually do not exhibit symptoms until it significantly has advanced.⁵⁴ Regular exercise and low-fat

[O]ral contraceptives may provide a means to reduce ovarian cancer risk. In addition, . . . tamoxifen[] has been shown to reduce rates of recurrent and contralateral breast cancer, suggesting a role for this agent in primary prevention . . . [but it] has been shown to increase endometrial cancer risk, cause bone marrow suppression, promote thrombotic events, and produce an array of other unpleasant adverse effects.

Id. See also Mendel E. Singer & Randall D. Cebul, *BRCA1: To Test or Not to Test, That is the Question*, 7 HEALTH MATRIX 163, 182 (1997).

52. See Joyce O'Shaughnessy, *Chemoprevention of Breast Cancer*, 275 JAMA 1349, 1353 (1996) (citing the identification of breast cancer susceptibility genes and improved diagnostic tools for breast lesions as highlighting the need to develop effective intervention strategies against breast cancer). Because there are more opportunities for women to recognize their increased risk for breast cancer, there is a greater push for scientists to develop pharmaceutical agents that may help prevent the development of the disease. See *id.* While such research is in progress today, much more must be conducted before drug therapy is readily available to those at risk. See *id.* at 1352-53.

53. A prophylactic mastectomy is the elective removal of one or both breasts before any sign of tumor formation occurs for the purpose of preventing the onset of breast cancer. See Schrag et al., *supra* note 42, at 1465. If diagnosed with cancer in one breast, a woman may choose to have her doctor remove both the affected and noncancerous breasts, so that she may avoid a recurrence of the cancer in the healthy breast at some later time. See Diana Keough, *Portraits of Prevention; Women with Family History of Breast Cancer Choose to Have Mastectomies*, THE PLAIN DEALER, Sept. 1, 1997, at IF. Women from families at high risk for breast cancer also may decide to have their breasts removed in an effort to prevent cancer. See *id.* ("Although the procedure has been performed since 1960 on women with a strong family history of breast cancer—defined as two or more relatives with the disease—the number of procedures has increased since the identification of the breast cancer genes . . ."). See also Schrag et al., *supra* note 42, at 1469 ("Until better methods of cancer prevention are developed, women and their physicians are likely to continue to consider the possibility and timing of prophylactic mastectomy and oophorectomy.").

54. See Dennis S. Chi & William J. Hoskins, *Ovarian Cancer Controversy: When and How to Use Available Screening Methods* (visited Feb. 11, 1998) <<http://www.medscape.com/Medscape/womens.health/1996/vOl.n11/wl72.chi/wl72.chi.html#Box1>>.

While screening is available for breast cancer (breast self-examination, clinical breast examination, and mammography) and for colorectal cancers (stool test for occult blood and sigmoidoscopy), no effective method has been devised to screen for ovarian cancer . . . [u]nfortunately, early in the course of the disease, patients are either asymptomatic or have nonspecific symptoms, such as abdominal discomfort, dyspepsia, or urinary frequency, which may go unrecognized by both the patient and her physician for prolonged periods of time. Therefore, approximately 70% of patients present with advanced . . . stage disease.

Id.

diets may help to prevent ovarian cancer,⁵⁵ but there is no self-exam for physical changes (such as the presence of lumps), and clinicians frequently do not detect abdominal masses before the cancer has spread to other areas of the body.⁵⁶ Surveillance for women at high risk for ovarian cancer, however, includes routine ultrasounds and blood tests that may indicate tumor development.⁵⁷ These women also may elect to undergo a prophylactic oophorectomy, or removal of the ovaries.⁵⁸ Indeed, one study shows that roughly one-third of women carrying the BRCA1 mutation who have a strong family history of breast or ovarian cancer plan to have their ovaries removed to prevent cancer.⁵⁹ This option is not available to women who wish either to start a family or have

55. See Burke et al., *Recommendations II*, *supra* note 19, at 1001 (“Dietary and exercise measures are an unproven means to reduce cancer risk, but have a broad range of other health benefits and do not pose the risks of pharmacological or procedural interventions.”).

56. See Chi & Hoskins, *supra* note 53.

[T]he normal ovary is usually not palpable in postmenopausal women. Unfortunately, given the natural history of ovarian cancer, it has been estimated that one must perform more than 10,000 routine pelvic exams to detect 1 case of ovarian cancer . . . [s]uch reports demonstrate that pelvic examination is too insensitive to serve as the sole screening method to detect curable stages of ovarian cancer.

Id.

57. See *id.* (“Prospective trials have provided data supporting the use of serum tumor markers [found in the blood] and sonography in ovarian cancer screening for at-risk patients.”).

58. See Schrag et al., *supra* note 42, at 1470 (“In our analysis, prophylactic oophorectomy resulted in, at most, small gains in life expectancy, and postponing oophorectomy until the completion of childbearing reduces its benefit minimally.”). Prophylactic oophorectomy is the elective removal of both ovaries before any sign of disease is detected. *Id.* Although this procedure currently provides the best mode of prevention for ovarian cancer, it is not foolproof. See Chi & Hoskins, *supra* note 53.

A woman from a family with a hereditary ovarian cancer syndrome should be offered the option of prophylactic oophorectomy after childbearing is completed or by age 35. However, she needs to understand that although prophylactic oophorectomy is presently the only effective method of ovarian cancer prevention, there have been case reports of patients with hereditary ovarian cancer syndromes who have . . . subsequently developed [cancer].

Id.

59. See Caryn Lerman et al., *BRCA1 Testing in Families With Hereditary Breast Ovarian Cancer; A Prospective Study of Patient Decision Making and Outcomes*, 275 *JAMA* 1885, 1891 (1996). When a parent or sibling carries the BRCA1 gene and develops breast or ovarian cancer, other close family members may decide to undergo genetic testing so that they can better determine how aggressive their efforts at preventing the cancer should be. The decision whether or not to have breasts or ovaries removed, a measure some may consider quite drastic, may hinge on the presence of genetic factors. *Id.* (“For members of HBOC [hereditary breast and ovarian cancer] families who do not carry a BRCA1 mutation, receipt of a negative test result may prevent unnecessary prophylactic surgery.”).

another child, however, because the removal of the ovaries results in menopause.⁶⁰

D. The Future of BRCA Testing

While significant attention has focused on the advances in genetic research and the availability of new genetic tests, there has been little discussion about the potential harms that can result from testing and the appropriate ways to deal with genetic information.⁶¹ Despite the lack of thorough analysis regarding the complex social, ethical, and legal implications of genetic testing, the demand for and occurrence of testing will continue to rise.⁶² Breast cancer receives enormous media attention and has been cited as the most important health concern of American women.⁶³ As more women with relatives diagnosed with breast or ovarian

60. See Burke et al., *Recommendations II*, *supra* note 19, at 1001 (“Balanced against the potential but unproven protective effect of oophorectomy are the risks and symptoms of surgical menopause Treatment with hormone therapy to decrease these risks may increase risk of breast cancer.”).

61. See Gail Geller et al., *Genetic Testing for Susceptibility to Adult-Onset Cancer; The Process and Content of Informed Consent*, 277 JAMA 1467, 1468 (1997) (stating that professional societies recommend that genetic testing be confined to clinical research due to complex implications of results warranting special attention for informed consent). Before health practitioners offer genetic testing to their patients, it is important that they are educated about interpreting results and the need to provide adequate counseling to ensure that the decision to learn one’s carrier status is fully informed. See also Susan Gilbert, *Doctors Often Misread Results of Genetic Tests, Study Finds*, N.Y. TIMES, Mar. 26, 1997, at C4.

62. See Lerman et al., *supra* note 58, at 1891 (“[T]o the extent that the public is educated about BRCA1 testing and the potential benefits are emphasized, utilization of BRCA1 testing is likely to increase.”); Malinowski & Blatt, *supra* note 15, at 1217-18 (stating that every person has four or five genetic mutations linked to serious health conditions, and continued research will uncover more links between genes and diseases).

63. See Barbara Brotman, *Fear of Breast Cancer Exaggerates its Impact*, CHI. TRIB., Oct. 5, 1997, at 9. Campaigns designed to increase the interest and awareness of breast cancer have brought the disease to the forefront of public attention. Sometimes criticized for taking the focus off of other serious threats to the health of American women, the attention paid to breast cancer by newspapers, magazines and even political leaders has significantly increased concern about prevention and desire for early detection of the disease. See *id.* (“Breasts are also far more visible than, say, lungs, sites of a cancer that kills more women than breast cancer. Women can hardly avoid their breasts, especially when public health campaigns have turned morning showers into diagnostic sessions.”); see also *Clintons Promote Cancer Detection: President and Wife Share Radio Address*, ST. LOUIS POST-DISPATCH, Oct. 26, 1997, at 06A (announcing higher standards for breast cancer screening); *Celebrating Survivorship: Making a Difference in the Fight Against Breast Cancer*, NEWSWEEK, Oct. 13, 1997, at S1 (finding that outreach and educational resources for breast cancer encourage women to screen for and prevent cancer).

cancer learn about the tests for BRCA mutations, more physicians will be asked to provide such screening.⁶⁴

Physicians soon will find that they have access to these tests, because biotechnology companies already are marketing BRCA testing kits.⁶⁵ Moreover, as testing for BRCA mutations becomes more accessible, people likely will use the information to direct their life decisions, such as where to live, what occupation to choose, and whether to have children.⁶⁶ There even has been speculation that women increasingly will ask to include screening for the BRCA mutations in their prenatal testing.⁶⁷

64. See Press et al., *supra* note 20, at 153.

[W]e have women, especially young, educated women, who are terrified of breast cancer and overestimate their own vulnerability to the disease. Their sense of risk is created and reinforced by media presentations of breast cancer which also accustoms them to thinking in terms of 'risk factors.' Since many of the most frightened women also may be those with the best access to health care services, we would suggest that a highly motivated set of consumers exists for anything which they believe may reduce their risk of breast cancer.

Id.; *Many People Prefer Not to Know if They Have Gene Linked to Cancers*, CANCER WKLY, July 15, 1996 (stating more requests for BRCA1 test results came from study subjects with health insurance, more relatives affected with breast cancer and more knowledge about testing); *but see* George C. Cunningham, *A Public Health Perspective on the Control of Predictive Screening for Breast Cancer*, 7 HEALTH MATRIX 31, 47 (1997).

The media can contribute positively or negatively [B]y reporting new discoveries they raise expectations. By publicizing the commercial availability of tests, the media can create a demand for testing. However, by carefully reporting the limitations of current testing knowledge, they can contribute to informed participation by the public in the formation of policy.

Id.

65. See Malinowski & Blatt, *supra* note 15, at 1212-13 (noting that OncorMed, Genetics & IVF Institute and Myriad have begun marketing tests for the BRCA genes and other community and academic laboratories are introducing their own tests for genetic disorders to assess future disease risk).

66. See Lori Andrews, *Body Science: As Medical Research Unlocks the Secrets of Genetics, the Battle Over Who Can Have Access to your Personal Life Story is Just Getting Under Way in Courts and Legislatures*, 83 ABA JOURNAL 44, 45 (1997) ("People are starting to use genetic information to measure the consequences of major life decisions.").

67. See Johnathon M. Lancaster et al., *An Inevitable Dilemma: Prenatal Testing for mutations in the BRCA1 Breast-Ovarian Cancer Susceptibility Gene*, 87 OBSTETRICS & GYNECOLOGY 306, 306 (1996).

II. Genetics and the Law

A. Legislation Affecting the Dissemination of Genetic Information

Legislation addressing the use of genetic information is inadequate to deal with the recent advances in biotechnology. Several laws attempt to protect individuals from discrimination based on their genetic make-up, but the rights of the family to a close relative's genetic information largely are left untouched. Some argue that the absence of regulation is appropriate and that medical ethics issues are best dealt with by means other than legislation.⁶⁸ However, laws intended to prevent discrimination directly affect the physicians' duty to warn their patients' children of genetic disease. When disclosure of genetic information no longer threatens to subject its patients to discrimination by insurers and employers, a physician will sooner be required to share it with patients' children.

1. Federal Legislation

Congress has attempted to protect those who have undergone genetic testing from discrimination by both insurers and employers. The Health Insurance Portability and Accountability Act of 1996⁶⁹ ("HIPAA") prohibits group health insurance plans from determining clients' eligibility and preexisting conditions based on genetic information.⁷⁰ HIPAA, however, does not protect those who must purchase individual insurance policies⁷¹ and does not prohibit in-

68. See DWORKIN, *supra* note 12, at 12.

Legislators are not oracles. They have no more ability to predict scientific and technological developments than anybody else Those limitations also raise questions about the desirability of prospective lawmaking. While preventing harm is more attractive than cleaning up after harm has occurred, the inability to foretell the future or to envision every possible scenario suggests that advance solutions may turn out to be unwise or even counter-productive.

Id.

69. Pub. L. No. 104-191, 5701, 110 Stat. 1936 (1996) (as codified at 29 U.S.C.A. § 1181 (Supp. 1998)).

70. HIPAA also prohibits insurers from finding preexisting conditions from genetic information "in the absence of a diagnosis of the condition related to such information." *Id.*

71. See *id.*

(a) Limitation on preexisting condition exclusion period; crediting for periods of previous coverage . . . a group health plan, and a health insurance officer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—(1) such exclusion related to a condition . . . for which medical advice, diagnosis,

surers from requiring prospective clients to undergo genetic testing or disclose past test results. Under these circumstances, it would be difficult to prove that insurers used the information to discriminate against clients.⁷² In addition, insurers still may increase policy rates and even deny coverage of specified procedures and treatments, such as prophylactic mastectomies or oophorectomies.⁷³

Federal law addresses employment discrimination with the Americans with Disabilities Act ("ADA").⁷⁴ The ADA prohibits employers from denying employment on the basis of an individual's disability,⁷⁵ and requires that employers provide reasonable accommodations in the workplace for those employees.⁷⁶ The critical question is whether a predisposition to disease, or the diagnosis of a condition without accompanying symptoms, constitutes a disability under the ADA. This issue currently is dividing the courts,⁷⁷ and until the United States Supreme Court rules on it, the ADA may not adequately protect individuals susceptible to genetic disease from employment discrimination.

care, or treatment was recommended or received within the 6 month period ending on the enrollment date . . . (B) . . . [g]enetic information shall not be treated as a condition described in subsection (a)(1) of this section in the absence of a diagnosis of the condition related to such information.

Id.

72. *See id.*; *see also* Karen H. Rothenberg, *Breast Cancer, The Genetic "Quick Fix," And The Jewish Community: Ethical, Legal, and Social Challenges*, 7 HEALTH MATRIX 97, 112 (1997) (noting the inadequacies of the Act to protect individuals).

73. *See* Rothenberg, *supra* note 71, at 112 ("Nor does it prevent a plan from increasing rates, excluding all coverage for a particular condition, or imposing lifetime caps on all benefits or on specific benefits . . . Absent other contractual and legal protections, plans could specifically exclude, for example, prophylactic surgery.").

74. *See* 42 U.S.C.A. §§ 12101 *et seq.*

75. *See* 42 U.S.C.A. § 12112(a) ("No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application processes, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms . . ."). *See also* Mark A. Rothstein, *Genetic Discrimination in Employment and the Americans with Disabilities Act*, 29 HOUS. L. REV. 23, 52-68 (1992) (noting that the Act limits an employer's pre-employment inquiries to an applicant's ability to perform work-related duties).

76. *See* 42 U.S.C.A. § 12112(b)(5). *See* *Abbott v. Bragdon*, 107 F.3d 934 (1st Cir. 1997) (holding that HIV-positive status comprises physical impairment under the ADA), *cert. granted*, 118 S. Ct. 554 (Nov. 26, 1997).

77. *Compare* *Reichle v. Walsh Offshore, Inc.*, 1997 WL 728104 (E.D. La. Nov. 20, 1997) (refusing to find HIV-positive employee terminated from job for unexcused absence physically impaired within definition of the ADA where no symptoms exhibited) with *Hernandez v. Prudential Ins. Co. of America*, 977 F.Supp. 1160 (M.D. Fla. 1997) (holding that HIV-positive employee had physical impairment that substantially limited major life activities of reproduction and caring for himself, and was disabled within the meaning of the ADA).

2. State Legislation

Roughly half of the states have enacted legislation designed to protect the privacy of genetic information and to deter discrimination based on such information.⁷⁸ Many states, for example, have legislation which combines protection against discrimination with protection for the genetic privacy of both individuals and their families.⁷⁹ While these statutes are helpful, the range of their protection is restricted by the Employee Retirement Income Security Act ("ERISA").⁸⁰ By exempting insurance policies provided by employers from the reach of state regulation, ERISA keeps more than one-third of the non-elderly insured out of the reach of state anti-discrimination and genetic privacy laws.⁸¹ Therefore, despite the efforts of states to address the important issues generated by advances in genetic technology, ERISA prevents states from providing universal protection to their citizens.

3. Proposed Federal Legislation

Legislators recently have introduced several bills in Congress that protect individuals from discrimination based on genetic information and ensure that genetic information is kept private.⁸² Only

78. See Robert Pear, *States Pass Laws to Regulate Uses of Genetic Testing*, N.Y. TIMES, Oct. 18, 1997, at A1 ("Concerned that the Federal Government is acting too slowly to protect the confidentiality of genetic information, states are passing their own laws to regulate the use of genetic test results to prevent discrimination by insurers and employers At least 26 states have adopted such laws.").

79. CAL. INS. CODE §10146 (West 1997) (requiring strict confidentiality of genetic information and establishing standards regarding unfair discrimination based on genetic information); C.R.S.A. § 10-3-1104.7 (1)(c) (1997) ("To protect individual privacy and to preserve individual autonomy with regard to the individual's genetic information, it is appropriate to limit the use and availability of genetic information."); GA. ST. § 33-54-1 (1997) (limiting use and availability of genetic information to prevent insurance companies from denying access on basis of genetic information); N.J.S.A. § 10:5-44 (1997) (requiring individual authorization to collect, retain, or disclose genetic information).

80. 29 U.S.C.A. §§ 1001-1461 (1988).

81. See Rothenberg, *supra* note 71, at 109-10 (noting that ERISA exempts self-funded plans from state insurance laws and that more people will be affected by this exemption as more employers are likely to turn to self-funded plans in the future).

82. See, e.g., The Genetic Privacy and Nondiscrimination Act of 1997, H.R. 2198, 105th Cong. (enacted). The proposed act would give the individual undergoing genetic testing the authority to determine who may collect and analyze his DNA, and for what purposes the analysis is to be completed. See *id.* He may refuse to permit his DNA to be used for research or commercial activities, may inspect and obtain records of the test results, may order the destruction of the DNA, and also may delegate another person to order the destruction of the DNA in the event the tested individual dies. See *id.* Anyone providing a genetic test would be required to provide specific information to the individual undergoing testing before performing the DNA

one bill, however, specifically addresses *family members'* access to genetic information, in addition to the access of insurers and employers.⁸³ The Medical Privacy in the Age of Technologies Act of 1997 permits health care providers to furnish an inpatient's next of kin or individual representative with protected health information, including genetic test results unless the patient objects to such disclosure.⁸⁴ Therefore, physicians would be allowed to notify a patient's family of genetic disease absent an explicit demand from the patient that such information be kept confidential. While this legislation would permit, and not require, a physician to disclose genetic information to a patient's children without her consent, it places the burden on the patient to deny disclosure of the information to her children if she wishes to protect her own privacy.⁸⁵

B. The Physician-Patient Relationship and Confidentiality

An ancient principle requires that physicians keep confidential information they learn about a patient during treatment.⁸⁶ The rationale behind this tenet is to protect the privacy of the patient, and to encourage candid sharing of personal information so that the physician may render an accurate diagnosis and effect appropriate treatments.⁸⁷ Without an assurance that potentially embarrassing information will be maintained in confidence, those in need of medical advice or treatment may avoid visiting a health care provider until the problem is advanced and difficult, or perhaps impos-

collection, obtain written authority to carry out the testing from the individual, and abide by instructions given regarding maintenance and destruction of the sample. In addition, the tester would have to restrict access to the genetic information to those authorized by the individual tested to have it. *See id.*

83. *See* Medical Privacy in the Age of New Technology Act of 1997, H.R. 1815, 105th Cong.

[A] health care provider . . . may disclose protected health information regarding an individual who is an inpatient in a health care facility to the individuals' next of kin, to an individual representative of the individual . . . if (1) the individual who is the subject of the information (A) has been notified of the individual's right to object at the time of admission to the facility and has not objected to the disclosure.

Id.

84. *See id.*

85. *See id.*

86. *See* Buchanan, *supra* note 8, at 141-42 (reviewing the requirement in medical codes, starting with the Hippocratic Oath, that physicians are sworn to complete confidentiality); *See* Paul A. Lombardo, *Genetic Confidentiality: What's the Big Secret?* 3 U. CHI. L. SCH. ROUNDTABLE 589, 593 (1996) ("This ancient medical principle . . . has been included in every physician's oath and code of ethics since Hippocratic times."). *See supra* note 2 and accompanying text.

87. *See* Friedland, *supra* note 4 at 256.

sible to treat.⁸⁸ Therefore, the trust a patient develops in her health care provider may prove critical for health maintenance.

Although physicians generally are prohibited from disclosing a patient's medical information without her consent, many exceptions to this rule apply.⁸⁹ In fact, so many exceptions have been made that it has been suggested that the concept of physician-patient confidentiality is a dead letter.⁹⁰ Without direction from federal law, health care providers depend on professional standards, state legislation, and court decisions to determine when they must disclose medical information without the patient's consent.⁹¹

Statutes determining when physicians must maintain or sacrifice confidentiality vary from state to state. In New York, any health care provider authorized to practice in the state may not disclose information obtained in such capacity that is necessary to treat a patient, unless that individual consents to the disclosure.⁹² New York statutes and regulations, however, allow for a number of exceptions to this requirement of confidentiality. For example, where

88. See Elizabeth B. Cooper, *Historical and Analytical Overview of Policy Issues Affecting Women Living with AIDS: A Blueprint for Learning from Our Past*, 72 BULLETIN OF THE NEW YORK ACADEMY OF MEDICINE 283, 290 (1995) (emphasizing the importance of confidentiality in the context of testing for HIV [the virus that causes AIDS] "women, like men, may choose not to know their serostatus because of the many extant barriers to testing, including ongoing fears of breaches of confidentiality, insufficient access to care and services for those who test positive, and continuing discrimination against people (and families) with HIV").

89. See Buchanan, *supra* note 8, at 142.

There are occasions . . . when a physician must determine whether or not his duty to society requires him to take definite action to protect a healthy individual from becoming infected because a physician has knowledge, obtained through the confidences entrusted to him as a physician, of other communicable disease to which to the healthy individual is about to be exposed.

See id.

90. See Lombardo, *supra* note 86, at 593 ("Medical confidentiality, as it has traditionally been understood by patients and doctors, no longer exists. This ancient medical principle, which has been included in every physician's oath and code of ethics since Hippocratic times, has become old, worn-out, and useless; it is a decrepit concept.") (footnote omitted). Because medical information is so easily accessible through computer networks and from insurance providers, confidentiality of medical records is significantly diminished. See David Orenlicher, *Genetic Privacy in the Patient-Physician Relationship*, in *Genetic Secrets* 85-86 (Mark A. Rothstein ed., 1997).

91. See Friedland, *supra* note 4, at 253-54.

92. See N.Y. C.P.L.R. § 4504(a) (McKinney 1992 & Supp. 1998).

Unless the patient waives the privilege, a person authorized to practice medicine, registered professional nursing, licensed practical nursing, dentistry, podiatry or chiropractic shall not be allowed to disclose any information which he acquired in attending a patient in a professional capacity, and which was necessary to enable him to act in that capacity.

See id.

patients are diagnosed with communicable diseases,⁹³ sexually transmitted diseases,⁹⁴ and AIDS,⁹⁵ they are considered threats to the public or community, and thus health care providers must notify the Department of Health to prevent harm to third parties.⁹⁶

As opposed to victims of communicable diseases, a patient with genetic disease may not create a risk for the public at large, but may pass on mutant genes to children who could benefit from genetic information.⁹⁷ For this reason, some argue that another exception to the physician-patient confidential relationship should apply in the context of genetic information. The privacy of genetic information is often analogized to the privacy of one's HIV status because of the potential for stigma and discrimination that is created when an individual is identified as infected or diseased.⁹⁸

In New York, legislators have made great efforts to afford privacy to those undergoing HIV testing.⁹⁹ When a person tests positive for HIV, however, the law permits a physician to encourage the patient to notify his or her partners of their risk of contracting HIV.¹⁰⁰ If the patient refuses to do so, the physician has the discre-

93. See N.Y. PUB. HEALTH LAW § 2101 (McKinney 1993); N.Y. COMP. CODES R. & REGS. tit. 10, § 2.10 (1997).

94. See N.Y. PUB. HEALTH LAW sec. 2300 (McKinney 1993); N.Y. COMP. CODES R. & REGS. tit. 10, § 23.3 (1997).

95. See N.Y. PUB. HEALTH LAW sec. 2782 (McKinney 1993 & Supp. 1998); N.Y. COMP. CODES R. & REGS. tit. 10, § 24-1.2 (1997).

96. See N.Y. PUB. HEALTH LAW § 2101 (1) (McKinney 1993) ("Every physician shall immediately give notice of every case of communicable disease required by the department to be reported to it, to the health officer of the local health district where such disease occurs.").

97. In order to establish the physician-patient privilege, three elements are essential: the existence of a doctor and patient relationship, the information at issue must be obtained in the course of treatment, and the information must be necessary for treatment. As discussed in Part II.C, where family members are the beneficiaries of genetic information, courts have construed the physician-patient relationship as extending to these individuals. See Vincent C. Alexander, *Supplementary Practice Commentaries*, N.Y. C.P.L.R. § 4504(a) (McKinney 1993 & Supp. 1998); See *infra* Part II.C.

98. See Scott Burris & Lawrence O. Gostin, *Genetic Screening from a Public Health Perspective: Some Lessons from the HIV Experience*, in *GENETIC SECRETS* 137, 148-49 (Mark A. Rothstein ed., 1997); see also Cooper, *supra* note 87 and accompanying text.

99. See N.Y. PUB. HEALTH LAW § 2785(2) (McKinney 1993 & Supp. 1997).

100. See N.Y. PUB. HEALTH LAW § 2782(4)(a) (McKinney 1993 & Supp. 1998).

A physician may disclose confidential HIV related information under the following conditions: (1) the disclosure is made to a contact or to a public health officer for the purpose of making the disclosure to said contact; and (2) the physician reasonably believes disclosure is medically appropriate and there is a significant risk of infection to the contact; and (3) the physician has counseled the protected individual regarding the need to notify the contact,

tion to notify the person at risk or may arrange for a state health official to notify the patient's partner, even without the patient's consent.¹⁰¹ With the advent of drug therapies shown to retard the progression of AIDS in people living with HIV, the public has become more receptive to a new exception to physician-patient confidentiality in these circumstances.¹⁰² Apparently, where preventive measures are available to those who may be at risk for disease, the public is better able to accept breaches in the confidential relationship.¹⁰³

C. Conflict in the Courts

Courts have recognized an exception to the physician-patient privilege when revealing confidential medical information prevents foreseeable harm to identifiable third parties.¹⁰⁴ Courts also have

and the physician reasonably believes the protected individual will not inform the contact; and (4) the physician has informed the protected individual of his or her intent to make such disclosure to a contact and has given the protected individual the opportunity to express a preference as to whether disclosure should be made by the physician directly or to a public health officer for the purpose of said disclosure. If the protected individual expresses a preference for disclosure by a public health officer or by the physician, the physician shall honor such preference.

Id.

101. *See id.*

102. Exceptions to physician-patient confidentiality have been made where patients with infectious conditions, such as HIV, threaten the health of third parties, and counseling and treatment may benefit them. *See AIDS: More Reporting of Virus Encouraged*, AMERICAN POLITICAL NETWORK—HEALTH LINE, Aug. 21, 1997, at 13.

Until recently, there was a belief that patient privacy was necessary to encourage 'voluntary testing and counseling to help slow the spread of infection.' Now, however, 'new drug therapies make early detection and treatment more important,' and 'strong legal protections against discrimination have eased some of the pressure for confidentiality.'

Id.; Lawrence O. Gostin et al., *The Public Health Information Infrastructure: A National Review of the Law on Health Information Privacy*, 275 JAMA 1921 (1996) (discussing provisions in the law for disclosure of confidential medical information or partner notification where therapeutic measures are available to third parties at risk of infection).

103. *See* Lynda Richardson, *U.S. Urging Identification of Patients with HIV*, N.Y. TIMES, Oct. 21, 1997, at B5 ("Many advocacy groups have softened their opposition to HIV reporting in recent months because of medical advances."); <<http://www.abcnews.com:80/sections/newsuse/hiv910/index.html>> (noting that "mandatory [HIV] reporting has grown less controversial in recent years, especially with the advent of treatments for people who are infected but not yet sick").

104. *See* *Tarasoff v. Regents of University of California*, 551 P.2d 334 (Cal. 1976) (*en banc*) (special relationship between physician and patient supports duty of reasonable care to protect identifiable third party from harm threatened by patient); *see also* *Bradshaw v. Daniel*, 854 S.W.2d 865 (1993) (holding that physician had duty to warn patient's wife of her risk of contracting Rocky Mountain Spotted Fever when he

determined that psychotherapists, who, while treating patients, learn that the patient is likely to attack or cause serious harm to a third party, have a duty to warn that endangered individual and even take steps to protect that third party from the risk that was revealed through confidential therapy sessions.¹⁰⁵ Moreover, courts have created new exceptions to the confidential physician-patient relationship that cover dangers ranging from acts of violence to exposure to contagious disease.¹⁰⁶ Courts have split, however, on whether to carve out another exception where genetic information may help a patient's family avoid harm.¹⁰⁷

In *Pate v. Threlkel*,¹⁰⁸ the Florida Supreme Court decided whether physicians caring for a woman diagnosed with medullary thyroid carcinoma owed her a duty to warn that her condition was genetically transferable.¹⁰⁹ One factor complicating the case was that the plaintiff was the patient's *daughter*, Heidi Pate. Only after learning that she also suffered from medullary thyroid carcinoma did Pate learn that she inherited the disease from her mother. Holding that the physicians had a duty to warn of the cancer's genetic nature, the court ruled that Pate satisfied the privity require-

should have known patient had such disease); *Hoffmann v. Blackmon*, 241 So.2d 752 (Fla. Dist. Ct. App. 1970) (finding physician negligent for failing to diagnose tuberculosis in father, and failing to warn family of child's risk of contracting such disease).

105. See *Tarasoff*, 551 P.2d at 345 (requiring that a therapist who "reasonably should have determined, that a patient poses a serious danger of violence to others, [] bears a duty to exercise reasonable care to protect the foreseeable victim of that danger").

106. See *supra* note 103.

107. Compare *Pate v. Threlkel*, 661 So.2d 278 (1995) (holding that physician's duty to warn patient's family members of genetic disease satisfied by notifying only patient) with *Safer v. Pack*, 677 A.D. 1188 (N.J. Super. 1996) (rejecting satisfaction of duty to warn with patient notification, but instead requiring that physicians take reasonable steps to ensure that family members are notified of genetic disease).

108. 661 So.2d 278 (1995). Heidi Pate, the adult daughter of a woman diagnosed with medullary thyroid carcinoma, a genetically transferable cancer, filed a complaint against her mother's physicians for failure to warn of the genetic nature of the cancer. Undergoing treatment for her own case of medullary thyroid carcinoma, Pate claimed that the doctors should have been aware of the disease's hereditary character and that given early warning, she could have been closely monitored for the cancer, and could have taken precautionary measures to prevent its onset. The trial court dismissed Pate's complaint for lack of privity with her mother's physicians and the District Court affirmed. Recognizing that in previous cases, intended beneficiaries of the prevailing standards of care were permitted to bring a cause of action against a professional despite a lack of privity, the Florida Supreme Court decided that the more tenuous relationship between plaintiff and defendant in this case did not foreclose liability.

109. See 661 So.2d at 281 (determining that health care providers were under a duty to warn Mrs. New of the importance that her children undergo genetic testing to identify their predisposition to same disease).

ment because she could be considered the intended beneficiary of the duty.¹¹⁰ The *Pate* court, however, specifically noted that the physician's duty to warn would be satisfied by notifying only the patient (who could be expected to share the information with her children) and expressly rejected the requirement that the physician inform the patient's children directly.¹¹¹

In *Safer v. Pack*,¹¹² a New Jersey Superior Court reached a different conclusion when faced with a similar case and held that a physician's duty to warn is not satisfied by informing the patient; rather, reasonable steps must be taken to assure that the information reaches the parties at risk.¹¹³ The *Safer* court emphasized that individuals can begin any treatments or changes in lifestyle necessary to prevent the onset of the disease as soon as they learn that they have a greater risk of developing it.¹¹⁴ The court also noted that in the case of genetic disease, the duty to warn of avertible risk is

110. *Id.* at 282 (expanding requirement in past courts that privity exist between plaintiff and physician to maintain cause of action to third party beneficiaries of relationship).

Here, the alleged prevailing standard of care was obviously developed for the benefit of the patient's children as well as the patient. We conclude that when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties, then the physician's duty runs to those third parties.

Id.

111. *Id.* at 282.

To require the physician to seek out and warn various members of the patient's family would place too heavy a burden upon the physician. Thus, we emphasize that in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient.

Id.

112. 677 A.2d 1188 (N.J. Super. 1996). Donna Safer, whose father was treated for and died of colon cancer during the 1960s, sued the estate of her father's physician for failure to warn of the genetic nature of the condition which led to her father's fatal disease. At the time of the suit, Safer had been diagnosed with multiple polyposis and colon cancer, which had metastasized to her liver. Multiple polyposis is an inherited condition that, if left untreated, leads to colorectal cancer. Because she was a child at the time of her father's illness, Safer only learned that he suffered from the same disease after she reviewed his medical records. The trial court dismissed Safer's case because it required that either a patient-physician relationship exist or that a threat to the public health or community at large exist in order to bring a cause of action in this situation. The New Jersey Superior Court permitted Safer's claim against the physician's estate.

113. *See id.* at 1192 ("We decline to hold . . . that, in all circumstances, the duty to warn will be satisfied by informing the patient.").

114. *Id.* ("The individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning.").

narrow enough to serve the interests of justice.¹¹⁵ The court, in *Safer*, did not define what "reasonable steps" were, however, leaving open the question of how the confidentiality between doctor and patient should be limited in certain circumstances.¹¹⁶

III. Aligning Legal Policy with the Current Status of Biotechnology

Although courts have long encountered breaches of confidentiality for the benefit of at-risk third parties, disclosure of genetic information regarding predisposition to cancer is a new issue to legislators and judges alike. Because developments in genetics are far outpacing the legal system, it is necessary to update the law to manage current conflicts and also anticipate the issues that will accompany future advances. This Part evaluates the rationales employed by the *Pate* and *Safer* courts, suggests other elements that courts should consider, and proposes a balancing test that will determine where disclosure of genetic information is appropriate.

A. *Pate* and *Safer* Reconsidered

The courts in *Pate v. Threlkel* and *Safer v. Pack* reached disparate conclusions because of several significant factors. For example, when physicians diagnosed Heidi Pate's mother with medullary thyroid carcinoma, a genetically transferable disease, Pate was an adult who would have been able to decide for herself how to use the information that she was at risk.¹¹⁷ Donna Safer, however, was a minor at the time her father suffered from colon cancer, and discovered his condition only by researching his medical records after she was diagnosed with cancer.¹¹⁸

The *Pate* court determined that, given the knowledge that her condition was genetically transmissible, Pate's mother likely would

115. *Id.* ("Although an overly broad and general application of the physician's duty to warn might lead to confusion, conflict or unfairness in many types of circumstances, we are confident that the duty to warn of avertible risk from genetic causes, by definition a matter of familial concern, is sufficiently narrow to serve the interests of justice.").

116. *Id.*

We need not decide, in the present posture of this case, how, precisely, that duty is to be discharged, especially with respect to young children who may be at risk, except to require that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit.

Id.

117. See *Pate v. Threlkel*, 661 So.2d at 279.

118. See *Safer v. Pack*, 677 A.2d at 1189.

have passed this information on to her adult daughter.¹¹⁹ In *Safer*, however, notifying the plaintiff would have been much more complicated, and probably best left until she became an adult.¹²⁰ The *Safer* court thus held that additional measures should have been taken to assure that Safer eventually was informed about her father's condition.¹²¹ Accordingly, where complicating factors exist with respect to sharing genetic information with family members (e.g., where such family members are minor children), courts may require additional support from health care professionals to ensure that the situation is handled appropriately.

The nature of the relationship between the physician and the family may be another important distinction for the courts. For example, Donna Safer's mother also was treated by the defendant physician who should have disclosed the genetic nature of her husband's cancer because she specifically asked about the risk to her family.¹²² Heidi Pate, on the other hand, established no relationship with her mother's physicians, and requiring the doctors to seek out and share the genetic information with the patient's children would have been too great a burden.¹²³

Moreover, the plaintiffs' parents were diagnosed with significantly different conditions. While the type of cancer from which Pate's mother suffered has no preliminary warning signals,¹²⁴ Safer's father had multiple polyposis, a genetically linked condition that later develops into colon cancer.¹²⁵ The knowledge of her father's condition would have alerted Safer to monitor closely for polyposis and to undergo the available treatment to avert the onset of colon cancer. The *Safer* court's decision likely was influenced by the fact that such information would have proven extremely useful to the plaintiff, and therefore it held that the treating physicians

119. See *Pate*, 661 So.2d at 282 ("Our holding should not be read to require the physician to warn the patient's children of the disease . . . the patient ordinarily can be expected to pass on the warning.").

120. See *supra* note 115 and accompanying text.

121. See *id.*

122. See *Safer*, 677 A.2d at 1190. Safer's mother claims that the physician reassured her that her husband was being treated for a condition that would not harm the children. See *id.*

123. See *supra* note 110 and accompanying text.

124. See *Pate*, 661 So.2d at 279 (noting that Pate's discovery of her condition occurred only after the cancer had reached an advanced stage).

125. See *Safer*, 677 A.2d at 1190 ("[M]ultiple polyposis is a hereditary condition that, if left undiscovered and untreated, invariably leads to metastatic colorectal cancer.").

were obligated to take the necessary steps to provide the plaintiff with the information.

Although Heidi Pate's disease was not preceded by a "warning" stage, such as polyposis, she also would have benefitted tremendously from a warning from her mother's physicians, because medullary thyroid carcinoma may effectively be prevented.¹²⁶ Without a precancerous condition like polyposis, however, which would signal the need to take appropriate preventive measures, the Pate court may not have believed that breaking physician-patient confidentiality could have prevented Pate's cancer.

Both the *Pate* and *Safer* courts failed to consider several important factors that likely will prove critical to future cases. When testing for genes that indicate a predisposition to disease, courts should consider the accuracy of the test performed and the ability of the physician to interpret its results. A test that cannot provide accurate results with reasonable certainty does not provide physicians with information that will enable patients to make appropriate decisions with respect to their physical and emotional well-being.¹²⁷ Even where genetic tests provide accurate results, to render beneficial counseling to their patients, physicians must adequately be educated about the significance of test results and how to interpret them (training which currently is lacking in primary care providers).¹²⁸

The likelihood of gene transmission to the next generation and the severity of the corresponding condition also must be considered. Finally, the potential for discrimination against and stigmatization of the patient must be carefully restricted.

B. A Balancing Test

Future cases involving the duty to disclose genetic information should be decided by using a balancing test. Where advances in technology and legislation occur so rapidly, a bright-line rule will not be effective for long. The weight attributed to the elements on either side of this test will shift as scientists advance genetic technology, legislators further protect the privacy of genetic informa-

126. See Leslie M. Alexandre, *Genetic Testing for Cancer Susceptibility: What Your Institution Needs to Know* (visited Feb. 11, 1998) <<http://www.medscape.com/ACCC/OncIssues/1997/v12.nO2/oil202.02.alexandre.html>> ("[A] positive [gene] test for mutations in the RET gene is a virtual guarantee of developing medullary thyroid carcinoma, and prophylactic surgery is 100 percent effective in preventing this frequently fatal form of thyroid cancer.").

127. See *infra* note 139 and accompanying text.

128. See *infra* note 142 and accompanying text.

tion, and physicians and the public learn more about genetic testing. Thus, the five factors in this proposed balancing test will have varying levels of significance and will allow for different results when applied to newly discovered mutations linked to diseases.

The following factors will best determine when to permit an exception to physician-patient confidentiality because they will allow courts to adapt to current technological advances and legislation. Courts should weigh:

- (1) the severity of the disease identified by testing;
- (2) the availability of preventive or curative options for that disease;
- (3) the accuracy and reliability of the test performed;
- (4) the ability of the physician or health care provider to interpret and address issues relevant to the test performed; and lastly,
- (5) the protections afforded to the tested individual against discrimination.

C. Applying the Balancing Test to the BRCA Gene Mutations

Although a carrier of genetic mutations diagnosed with breast or ovarian cancer is likely to inform her children that they also may be at increased risk of cancer if they also carry the mutations, currently there is no legal duty to share this information with family members.¹²⁹ Also, the patient may have her own reasons for keeping it confidential. Therefore, the application of the balancing test in the context of the BRCA mutations will provide a useful tool for physicians and courts in determining whether there is a duty to warn a patient's children.

1. Severity of Disease

The severity of the disease or condition to which an individual may be predisposed by inherited genetic mutations is a necessary consideration because breach of confidentiality is a measure of last resort, and can be justified only if the threatened harm is imminent or serious.¹³⁰ A genetic mutation increasing an individual's risk for

129. See Friedland, *supra* note 4, at 271 (“[E]ven though genetic defects may pose a threat of serious harm to others, the common law has never required an individual to come to the aid of another when the other's situation is not that of the individual's making.”).

130. See Lori B. Andrews, *Gen-Etiquette: Genetic Information, Family Relationships, and Adoption*, in *GENETIC SECRETS* 255, 269 (Mark A. Rothstein ed., 1997) (noting that the National Research Council's Commission for the Study of Inborn Errors of Metabolism, the President's Committee on Ethical Issues in Medicine, and

male pattern baldness must be treated differently than one indicating susceptibility to an untreatable form of cancer. Coping with the alterations in self-image that balding may create is less serious than battling a life-threatening disease such as cancer. Statutes and cases support measures other than unauthorized disclosure of a patient's medical information to a third party, unless the disclosure is necessary to avert the threat of substantial harm.¹³¹ Therefore, in applying the proposed balancing test, the more serious the condition, the more heavily it will weigh against maintaining confidentiality.

For example, breast and ovarian cancer are serious diseases, ranking among the top five causes of death in American women, and are difficult to eradicate if not detected in an early stage of development.¹³² Therefore, the application of the severity element related to the BRCA mutations weighs heavily in favor of disclosing this genetic information.

2. *Availability of Preventive or Curative Options*

The second element to consider is the availability of effective preventive or curative measures. Knowing that one is subject to an increased risk of developing serious disease may create significant emotional distress, especially if there are no available means of treating or averting the onset of disease. Although some argue that the mere notification that one is at increased risk may provide some benefit,¹³³ if the available options are limited to "heroic" or

the Institute of Medicine's Committee on Assessing Genetic Risks all recommend limiting disclosure of genetic information to cases of life-threatening, massively disabling, irreversible or fatal conditions).

131. See *id.* at 269; *DiMarco v. Lynch Homes*, 583 A.2d 422 (Pa. 1990) (holding that a physician has a duty to teach safe sex practices to patient with hepatitis in lieu of warning sex partners).

132. The serious nature of breast and ovarian cancer, coupled with more effective treatment with early detection weigh in favor of notifying children of their mother's BRCA carrier status. See *Safer v. Pack*, 677 A.2d 1188, 1192 (1996) ("The individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning."); see also John Bell, *Prenatal Diagnosis: current status and future trends*, in HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS 25 (noting that "screening early in life . . . would permit individuals at high risk to modify their life styles so that they would be exposed to fewer environmental risk factors than otherwise"); but *c.f.* Daniela Altimari, *400 Women Attend Forum on Breast Cancer*, HARTFORD COURANT, Sept. 26, 1997, at B1 (Bella Abzug argues that genetic testing deflects attention from environmental factors).

133. See Groopman, *supra* note 45, at 46 (noting that [the awareness of one's predisposition to disease] "led many people to take better care of themselves—stop smoking, end drug use, improve diet, take up exercise, seek stress reduction . . . [and] the knowledge that one . . . was mortal gave many young people a precocious sense of

drastic measures, this factor will weigh in favor of maintaining confidentiality. However, if researchers discover curative procedures (such as gene therapy or drug treatment) or determine that avoidance of exposure to specific external factors will effectively thwart the onset of disease, then this element will weigh in favor of disclosure to offspring.

Currently, there is no generally accepted method that has been proven to prevent breast or ovarian cancer,¹³⁴ although close surveillance¹³⁵ and measures such as drug therapy, prophylactic mastectomy and oophorectomy promise significantly to reduce the risk.¹³⁶ The removal of the breasts and ovaries may seem like an extreme preventive procedure, but actually may serve to substantially eliminate emotional distress and anxiety.¹³⁷ Many women, however, may eliminate either procedure as a viable option because they hope to have children or decide that surgery is too drastic.

Once identified as a BRCA mutation carrier, an individual's decision about how best to avoid cancer surely is excruciating and very personal. Although the disclosure of genetic information would allow a carrier's children to engage in their own decision making processes, the limited options presently available weigh against disclosure.

maturity and wisdom"); Alexandre, *supra* note 126 ("[W]hen scientific discoveries venture into promising but uncertain new realms, some people understandably react with caution. Although such apprehension can be constructive and can lead to further education and knowledge, the reaction can be harmful when it discourages people from seeking a potentially life-saving approach to health care."). It is interesting to note that the author of this article, Leslie Alexandre, is Vice President of Corporate Affairs at OncorMed, one of the biotechnology companies currently marketing genetic testing kits.

134. See Wendy C. McKinnon et al., *Predisposition genetic testing for late-onset disorders in adults: a position paper of the National Society of Genetic Counselors*, 278 JAMA 1217 (1997) ("For many late-onset disorders, such as cancer, much uncertainty surrounds the molecular biology of predisposition genetic testing. Likewise, there is a dearth of data regarding appropriate medical management for gene mutation carriers and the psychological aspects of testing.").

135. See Singer & Cebul, *supra* note 51, at 178 ("Although many women may be reluctant to participate [in mammographic screenings] due to cancer anxiety, compliance is generally improved when the patient is aware of the risk.").

136. See *id.* at 179 (naming prophylactic mastectomy as the only established preventive option currently available, but warning that cases of breast cancer have occurred in women after having their breasts removed and that no studies of the procedure's efficacy have been conducted yet).

137. See Groopman, *supra* note 45, at 46 (relating a patient's difficult decision to have her breasts and ovaries removed to reduce the anxiety felt by both her family and herself).

3. Accuracy and Reliability of Test

If the genetic test performed on an individual cannot be relied upon to provide accurate results, then such information threatens to bring more harm than benefit. Tests which produce false negative results likely will relieve anxiety and create a false sense of security in individuals who actually are at increased risk for disease. A mistaken belief that they are free of the specific genetic mutation may deter these individuals from obtaining the surveillance or treatment that may save their lives.¹³⁸ On the other hand, false positive results are sure to create significant emotional distress in persons whose risk for disease is no greater than those in the general population. Therefore, where genetic conditions cannot be identified with accuracy, genetic information should be kept confidential.

Today, there is no test available that has been proven to be accurate in identifying risk-predicting BRCA mutations.¹³⁹ Because numerous mutations of the BRCA1 and BRCA2 genes exist, and researchers have not determined which mutations correlate with manifestation of disease, it is quite possible that an individual identified as a BRCA mutation carrier may actually carry a mutation that does not contribute to the onset of cancer.¹⁴⁰ Until these tests

138. See Rothenberg, *supra* note 71, at 103 (fearing that "genetic determinism," where an individual believes her future is defined and predicted by genetic makeup and cannot be changed, will result from genetic testing).

139. See Malinowski & Blatt, *supra* note 15, at 1243 ("The predictive capability of many genetic tests remains scientifically undefined for the general population.").

140. See Cunningham, *supra* note 63, at 34.

[E]ven after correctly detecting the presence of a mutation, there is only a probabilistic likelihood of the actual expression of malignancy. In screening terminology, this could be called a false screening positive for the women who have a mutation but are spared by failure of expression, or who have mutations which do not lead to an increased risk of cancer.

Id.; Singer & Cebul, *supra* note 51, at 175-76 (noting that there are no published data reporting the accuracy of tests for BRCA1 mutations, and that because mutations may be difficult to detect, false negatives could result from testing); See Ruth Hubbard & R.C. Lewontin, *Sounding Board; Pitfalls of Genetic Testing*, 334 NEW ENG. J. MED. 1192, 1192-93 (1996). Because the onset of breast or ovarian cancer depends on numerous factors, depending on DNA patterns to predict disease is problematic. Only a few of the several variants of BRCA1 and BRCA2 are associated with tumor formation. Additionally, even a woman with a family history of cancer who tests positive for one of the mutations may never develop cancer. At present, biotechnology companies that sell tests for the BRCA1 mutation are not required to involve the Food and Drug Administration, and thus there has been no external certification of the tests' quality or the interpretation of their results. See also Heather Bryant, *Genetic Screening for breast cancer in Ashkenazi women*, Commentary, 347 LANCET 1638 (1996).

have been shown to identify predisposition for cancer with sufficient accuracy, this factor will weigh against disclosure.

4. *Education and Training of Physicians*

To render genetic testing beneficial for patients, physicians must have the ability to interpret test results and understand their significance and meaning. Because test results often are not clear, physicians delivering the results should be educated about the identification of gene mutations, as well as their significance. Critics of genetic testing in the clinical environment warn that few primary providers have been adequately trained to determine what genetic test results mean, and what information must be provided to patients undergoing testing.¹⁴¹ Any benefit to the individual being tested results from the physician's advice and direction. If physicians themselves have not learned how to interpret and use test results to promote better health, the patients are not likely to benefit from such information, and thus this element would weigh in favor of maintaining confidentiality.

While plans to further educate physicians and other health care providers about genetic testing are underway,¹⁴² the majority of physicians currently do not possess adequate knowledge or training to benefit their patients who wish to undergo genetic testing.¹⁴³

141. See Malinowski & Blatt, *supra* note 15, at 1245.

142. See Collins, *Preparing Health Professionals*, *supra* note 30 (noting that the National Coalition for Health Professional Education in Genetics plans to provide a national, systematic approach to educating health care providers through internet programs, requiring the inclusion of genetic information on board and licensure exams, and standardized genetics curricula).

143. See *id.*

[M]ost health professionals are not prepared to integrate genetics into clinical practice. A study of DNA-based colon cancer susceptibility testing revealed that nearly one third of physicians who delivered such test results did not fully understand their meaning. Surveys also show that many health professionals have insufficient knowledge of available genetic resources.

Id. Bernadine Healy, *Editorial: BRCA Genes—Bookmaking, Fortunetelling, and Medical Care*, 336 *NEW ENG. J. MED* 1448 (1997) ("It is too early to use BRCA gene testing in every day clinical practice, because it violates a commonsense rule of medicine: don't order a test if you lack the facts to know how to interpret the results."); Malinowski & Blatt, *supra* note 15, at 1245-46.

[D]ue to the absence of adequate clinical data, health care providers cannot interpret the results of predictive genetic tests for most of their patients with any reliability even when they are knowledgeable about genetics. This interpretation problem is exacerbated because the current generation of health care does not possess such knowledge. Their lack of genetic education and the novelty of the technology makes providers dependent upon the developers and manufacturer of these tests . . . for information.

Id.

When more physicians can provide their patients with sufficient explanation and counseling with regard to BRCA testing, then disclosure to patients' offspring will be more acceptable. At this time, however, this element must weigh against such disclosure.

5. *Potential for Discrimination and Stigmatization*

If genetic testing reveals that an individual is susceptible to serious illness, a court must consider the potential that such information will be used to deny that person health insurance or employment. This factor will depend upon the progress made by legislators to enact laws that protect all individuals against such discrimination. Moreover, without adequate protections against unauthorized disclosure of genetic information to third parties, carriers likely will be perceived as "prediseased" or disabled, even before they manifest any signs of illness.¹⁴⁴ Until firm protections are in place, this element should weigh against disclosure.

Although some individuals may be protected by state laws prohibiting discrimination by employers and insurance providers, no current legislation assures that all who may benefit from BRCA testing will be protected from discrimination. Therefore, it is improper to suggest that physicians should disclose genetic information to family members who then may be denied access to insurance or employment. The patients themselves are in the best position to know whether the benefit of disclosure will outweigh the harm to their children, and should, therefore, decide the appropriate time and means to share genetic information with their children. Until universal genetic privacy is afforded by federal legislation, this factor strongly weighs against disclosure by physicians.

The current status of genetic research, professional education, and legislation results in the severity of disease as the only factor of the balancing test that favors disclosure to children of a BRCA mutation carrier. One may argue that breast and ovarian cancer are so serious that individuals should be aware of an increased risk so that they can make informed personal choices about their own genetic testing, lifestyle, and health management. However, because

144. See Joyce Wadler, *Double Exposure*, NEW YORK MAGAZINE, Sept. 18, 1997, at 24, 26 ("I looked after my health and it still didn't matter. I was my own Unabomber, carrying my future from the time I was born, caught in a genetic accident."). The author of this article was a breast cancer survivor who described her experience after being diagnosed with ovarian cancer and learning that she carried genetic mutations which predisposed her to both diseases.

preventive measures are limited and unproven, such information may cause more emotional distress than physical benefit.

The information itself may not reveal as much about predisposition to cancer as one may believe, due to either false positive or false negative results, or simply the inexact nature of determining the probability of disease onset. Moreover, until educational programs for health care providers are implemented, it is likely that the physician who delivers genetic information to a patient's children may not fully understand the meaning of the test results. The chance that the disclosure of genetic information may deny individuals health insurance, and thus access to the medical attention critical to preventing or treating cancer, threatens to cancel out any benefit inured to a patient's child. Therefore, application of the proposed balancing test would result in physician-patient confidentiality outweighing a duty to warn the patient's children of their risk of inheriting the BRCA mutations.

Conclusion

The ability to test for the BRCA1 or BRCA2 mutation is a significant achievement of genetic scientists and marks the start of a medical revolution. Such testing may provide those at risk for hereditary breast or ovarian cancer with invaluable information that will enable them to better maintain health and an optimum quality of life. It also threatens to cause serious harm, however, if offered without assurances of effective treatment for the cancer, accurate testing, adequately informed physicians, and protection against discrimination.

Courts should adopt this balancing test because it takes these important factors into account. Currently, application of the proposed balancing test weighs against requiring physicians to warn a patient's children that they may carry BRCA mutations, and leaves the responsibility with the mother, who still knows best.

