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Breast Cancer, the Genetic "QuickFix," and the Jewish Community: Ethical, Legal, and Social Challenges

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BREAST CANCER, THE GENETIC "QUICK FIX," AND THE JEWISH COMMUNITY

ETHICAL, LEGAL, AND SOCIAL CHALLENGES

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I. INTRODUCTION

> Nearly one percent of over 850 DNA samples from Eastern European Jews contained a specific gene mutation that may predispose them to breast and ovarian cancer, according to study results published today in *Nature Genetics*.[1]
>
> This finding offers the first evidence from a large study that an alteration in the gene, called breast cancer 1 (BRCA1), is present at measurable levels not only in families at high risk for the disease, but in a specific group of the general population.[2]
>
> With the publication of today's results, the National Institutes of Health (NIH) also announced its plans to launch a series of clinical studies to evaluate cancer risk in Eastern European, or Ashkenazi, Jews bearing the mutation. The results of these studies will help determine whether BRCA1 testing should be offered to the nation's six million Ashkenazi Jews as a part of their health care.[3]

IT WAS THIS NIH PRESS RELEASE dated September 28, 1995, and the press conference that followed, that would first alert and alarm the Jewish community. The BRCA1 gene had been isolated a year earlier and numerous unique mutations had been detected in the germline of individuals with breast and ovarian cancer.[4] About five to ten percent of all breast

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1. *Scientists Report New Lead in the Genetics of Breast Cancer*, NIH NEWS (Nat'l Inst. of Health, U.S. Dept. of Health & Hum. Serv., Washington, D.C.), Sept. 28, 1995, at 1 (citing Jeffrey P. Struewing et al., *The Carrier Frequency of the BRCA1 185delAG Mutation is Approximately 1 Percent in Ashkenazi Jewish Individuals*, 11 NATURE GENETICS 198, 198 (1995)).

2. *Id.* at 1.

3. *Id.* at 1.

4. *See* Jeffrey P. Struewing et al., *The Carrier Frequency of the BRCA1 185delAG Mutation is Approximately 1 Percent in Ashkenazi Jewish Individuals*, 11 NATURE GENETICS 198, 199 (noting that data has been derived almost exclusively from families with a wide range of mutations ascertained on the basis of a high incidence of breast and ovarian cancer, and that it is

cancers appear to be inherited and a significant proportion were related to the BRCA1 gene.[5] In high-risk families, female carriers of BRCA1 mutations were estimated to have an eighty-five percent lifetime risk of breast cancer and a forty percent risk of ovarian cancer.[6] Because current mutation detection is very difficult, it has not been feasible to analyze large numbers of samples, but the 185delAG mutation had been detected relatively frequently.[7] Of the ten published families with this mutation, it was discovered that all were Ashkenazi Jews.[8] Thus, this association between a specific mutation and a genetic subpopulation prompted the scientists to target the Jewish population for further genetics research on the prevalence of the BRCA1 mutation.[9]

A follow-up population study tested eight hundred fifty-eight stored DNA samples taken from Ashkenazi individuals.[10] These samples had originally been collected for Tay-Sachs and Cystic Fibrosis screening in the United States and Israel, and thus, were not chosen for the presence of breast cancer or positive family history for cancer.[11] All individual identifiers were removed from the samples prior to analysis.[12] Eight of the samples were carriers for the 185delAG, whereas none of the eight hundred fifteen samples in the control group (not selected for ethnic origin) tested positive.[13] Thus, about one percent (0.9%) of the Jewish samples carry this mutation, apparently derived from a common ancestor.[14] This is a surprisingly high frequency, making this mutation "potentially the

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possible that the penetrance will be lower in unselected patients).

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.* It was subsequently reported that over twenty Jewish families with breast or ovarian cancer had been identified with the 185delAG. *See* Francis S. Collins, *BRCA1-- Lots of Mutations, Lots of Dilemmas*, 334 NEW ENG. J. MED. 186, 186 (1996) (presenting issues related to BRCA1 testing including pros and cons of testing individuals).

9. It has also been reported by U.S. and French researchers that at least 3 in 1,000 Ashkenazi Jews might carry one particular alteration in BRCA2. Rita Rubin, *Would I Gain by Being Tested? No*, U.S. NEWS & WORLD REP., May 13, 1996, at 77.

10. *See* Struewing et al., *supra* note 4, at 198 (explaining the methods and results of the genetic sample study).

11. *See id.*

12. *See id.*

13. *See id.*

14. *See id.*

most common serious single-gene disease yet identified in any population group."[15] It is estimated that this rate of alteration is three[16] to eight[17] times higher than all BRCA1 alterations combined in the general population.

The NIH researchers conceded that "[w]hile the finding raises the possibility of testing, it does not provide any data on precise cancer risk."[18] Scientists still do not know to what extent having the altered gene increases a woman's risk of developing breast or ovarian cancer. Nor do they know to what extent it might increase the risk for colon or prostate cancer in men. Thus, NIH scientists, with the support of Jewish community leaders, conducted a follow-up study on blood samples of over five thousand men and women from the Ashkenazi Jewish population in the Washington, D.C. area. The purposes of the study were: "1) to learn how common the 185delAG alteration is, and 2) to see if people with this alteration have more relatives with cancer."[19] The study did not involve testing for cancer and study participants did not receive test results. In addition to a blood sample, participants filled out a questionnaire about family history of cancer and information about ancestry. Jewish leaders actively encouraged people to participate and many synagogues and Jewish community centers served as sites for the study. "In history, Jews have bled for negative reasons,"[20] and this was an opportunity for Jews to give blood to help their people, said Rabbi Matthew Simon, the president of the UJA Federation of Greater Washington.[21] Within less than two months, between February and April, 1996, NIH and the Jewish organizations had recruited over five thousand Jews in the Washington, D.C. area for participation in this study.

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15. Collins, *supra* note 8, at 186.

16. *See The 185delAG Alteration in BRCA1: What does this Mean for Jewish Women,* FACT SHEET (Nat'l. Inst. of Health, U.S. Dep't. of Health & Hum. Serv., Washington, D.C.), 1995, at 5.

17. *See* Collins, *supra* note 8, at 186.

18. *See* Nat'l Inst. of Health, *supra* note 1, at 1 (quoting Dr. Jeffrey Struewing, scientist with the National Cancer Institute and the National Center for Human Genome Research).

19. Nat'l Inst. of Health, *Familial Cancer and the BRCA1 Gene in the Jewish Community of Greater Washington* (1996) (informed consent form from NIH research study) (on file with author).

20. *Doctors Launch New Jewish Cancer Test: Amid Fear and Confusion, Search Facts Begins,* FORWARD, Mar. 1, 1996, at 5 [hereinafter *Doctors Launch New Jewish Cancer Test*].

21. *Id.*

Even though the study results are yet to be reported, targeting Jews for testing is growing in both the research community and in the commercial market. Numerous studies are now in place to test Jewish women for the 185delAG in BRCA1 mutation.[22] For example, four thousand Ashkenazi women with recently diagnosed breast cancer are being recruited from seven metropolitan New York City hospitals. Participants in this study will receive results and will be followed for four years.[23] Even though the essential research on precise cancer risks has not been completed, commercial laboratories are also targeting Jews for testing. The Genetics and In-Vitro Fertilization (IVF) Institute in Fairfax, Virginia advertises on the Internet that it will offer population screening to Ashkenazi Jews for the 185delAG mutation, even though "[t]here are many questions . . . that still need to be answered in careful clinical studies."[24] *The Jewish Week*, a popular Jewish newspaper, suggests that if you want more information on the 185delAG test, "have your doctor contact The Genetics and IVF Institute."[25] Currently, the cost of the test is $295.[26] The Genetics and IVF Institute also advertises that it will test for a few additional mutations in Jewish families, but cannot yet offer such testing to non-Jews, "since no other mutations have yet been identified that are specific for a particular ethnic or racial group."[27]

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22. *See generally* Nancy J. Nelson, *A Burst of Research Activity Follows BRCA1 Finding*, 88 J. NAT'L CANCER INST. 230, 230 (1996) (describing several genetic studies initiated in the aftermath of the discovery of the BRCA1 gene). The Fox Chase Cancer Center in Philadelphia, Pa., was testing for the 185delAG deletion in several hundred Ashkenazi women, both affected and unaffected. *Id.* at 231. The Women's College Hospital in Toronto is testing for the 185delAG deletion in 200 to 300 Jewish women with ovarian cancer. *Id.* The University of Utah, Salt Lake City and Memorial Sloan-Kettering Cancer Center in New York have tested for the 185delAG deletion in young Jewish women with breast cancer or in families with one or two affected first-degree relatives. *Id.*

23. *Id.* at 230-31.

24. *See* Genetics & IVF Institute, *Breast and/or Ovarian Cancer Risk in Jewish Women: Role of the 185delAG and other Mutations in the BRCA1 and BRCA2 Genes* (visited Aug. 25, 1996) (http://www.givf.com/brca1.html) (describing the role of mutations in the BRCA1 and BRCA2 genes and promoting genetic screening for Ashkenazi Jews as a specifically affected group).

25. Diana Willensky, *Optimism in Breast Cancer Fight*, JEWISH WEEK, Mar. 8, 1996, at 45.

26. *See* Ridgely Ochs, *Genetic Findings on Breast Cancer/The Door's Open, Researchers Say, But the Landscape Remains Murky*, NEWSDAY, May 14, 1996, at B23 (describing recent findings related to BRCA1 and options for testing).

27. Genetics & IVF Institute, *supra* note 24.

Most recently, the *Hartford Jewish Ledger* began printing on a regular basis an advertisement entitled, "An Important Message -- Genetic Testing for Breast Cancer in Jewish Women," by Kenneth A. Kern, M.D.[28] Dr. Kern first states that "[s]everal recent cancer studies have confirmed that Jewish women of Ashkenazi (Eastern European) heritage carry damaged genes that lead to breast cancer more commonly than the non-Jewish population."[29] Relying on numerous statistics he declares as *fact*: "if you carry damaged breast cancer genes and you live long enough, you are almost guaranteed to develop breast cancer."[30] Dr. Kern then offers to provide genetic testing "by a blood test"[31] in his office. He concludes that "the decision to undergo testing requires thought, counseling, and *courage*."[32] Obviously, the research agenda has fueled the marketing strategy for the commercialization of predictive genetic testing for breast cancer.

II. GENETIC TESTING IN CONTEXT: EMERGING THEMES

A. Genetic Myopia, the Genetic "Quick-Fix," and the Genetic Underclass

Before the ethical, legal, and social challenges embedded in predictive genetic testing for breast cancer in Jewish women can be addressed, it must first be placed more generally in the context of developing genetic technologies in our society. Three themes emerge which will be briefly explored: genetic myopia; genetic testing as a "quick fix"; and the genetic underclass. Genetic myopia is a condition that results from viewing everything from the perspective of genetics. As a result, genetic reductionism and genetic determinism develop in

28. Kenneth A. Kern, *An Important Message -- Genetic Testing for Breast Cancer in Jewish Women*, HARTFORD JEWISH LEDGER, Nov. 22, 1996, at 13 (advertising that Dr. Kern specializes in "Diseases of the Breast and Tumor Surgery").

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* (emphasis added).

our society.[33] Genetic reductionism results when all traits, health problems, and behaviors become attributable to genes and no attention is paid to other potential factors. Thus, if a gene for cancer is found in an individual, other factors, such as environmental toxins, lifestyle, and diet, will be dismissed as not contributing to the development of the disorder. In a related way, genetic determinism results when an individual believes her future is defined and predicted by genetic makeup and cannot be changed. People may not be motivated to adopt a healthy lifestyle if they believe that their fate is predetermined genetically and therefore, that they cannot prevent disease by reducing other risk factors such as smoking cigarettes. Such attitudes may have significant negative implications for public health and prevention messages. Genetic myopia may, in fact, seriously undermine cancer surveillance and prevention strategies aimed at the population at large.

The genetic "quick fix" theme views genetic testing as an end in and of itself, rather than as a means toward an end that is yet to be defined. By trying to perfect the predictive test, have we failed to concurrently think through what to do once the test result is available? What is the value of the information, its benefits and risks to individuals and their families, its impact on health behavior, and the role of providers in advising about the implications and limitations of test results?

The "genetic underclass" theme describes a future population unable to gain access to genetic testing in the United States. At present, we live in a society where over forty million people have no health insurance and limited or no access to our health care system.[34] Without access to health care, it is unlikely that these individuals would have access to genetic testing or related services. How will resources be allocated to

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33. *See, e.g.*, Abby Lippman, *Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities*, 17 AM. J. L. & MED. 15, 17-18 (1991) (exploring the consequences of prenatal genetic testing and screening on women and their health care needs); Dorothy Nelkin, *The Grandiose Claims of Geneticists*, CHRON. HIGHER EDUC., Mar. 3, 1991, at B1 (suggesting that the rhetoric used by geneticists could foster genetic determinism and be used to justify discrimination).

34. *See Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 1994 Current Population Survey*, SPECIAL REPORT AND ISSUE BRIEF NO. 158 (Employee Benefit Research Institute, Washington, D.C.), Feb. 1995, at 1, 4 (providing summary data on the insured and uninsured as well as discussing changes in health protection).

make sure that in the future, the economic underclass does not also become the genetic underclass?

B. Genetic Accountability and Genetic Identity

Two additional themes emerge in the context of testing for inherited breast cancer in the Jewish community: genetic accountability and genetic identity. These themes are not unique to Jewish women, but provide a useful paradigm for further analysis and for placing genetic testing in context. Historically, pregnant women have been the main targets of genetic testing, and mothers serve as the primary caretakers of those born with genetic disorders. Genetic accountability results when women are deemed responsible for seeking genetic information.[35] Women may believe they have a duty to give birth to the perfect baby free of genetic abnormalities. The expansion of genetic testing may give the impression that we can and should take complete control and responsibility for the results of birth. Although many pregnant women may feel this sense of genetic accountability, certain ethnic groups, including Jewish women, have historically been targeted for testing. Historically, Jewish women have accepted that it is their responsibility to be tested for their carrier status for Tay-Sachs, a "Jewish" genetic disease.[36] Indeed, the Orthodox Jewish community has established a counseling and testing program for couples prior to being matched for marriage,[37] called Dor Yeshorim, that promotes carrier testing for Tay-Sachs and a few other genetic disorders more common among Jews. Testing, however, is only done for recessive genetic disorders which require two carriers for there to be a risk to future offspring. Dor Yeshorim's educational materials include a reprint of a letter from a mother who did not have her daughter tested before the daughter mar-

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35. *See generally* R. Alta Charo & Karen H. Rothenberg, *"The Good Mother": The Limits of Reproductive Accountability and Genetic Choice, in* WOMEN AND PRENATAL TESTING: FACING THE CHALLENGES OF GENETIC TECHNOLOGY 105 (Karen H. Rothenberg & Elizabeth J. Thomson eds., 1994) (discussing the issues surrounding reproductive genetic testing and responses to the increased responsibilities it may create).

36. *See generally id.*

37. *See* COMMISSION FOR PREVENTION OF JEWISH GENETIC DISEASES, DOR YESHORIM, AVOID A TERRIBLE TRAGEDY FOR YOU AND YOUR CHILDREN! (1996).

ried. The daughter subsequently gave birth to a child with Tay-Sachs.[38] The mother writes: "I am guilty, no one but I am guilty of their present tragic state."[39] Thus, genetic accountability in both the preconceptual and the prenatal context has been part of the Jewish culture for many years.

Genetic accountability and genetic identity are now expanding beyond prenatal testing. Jewish women may perceive a "social obligation to do anything they [can] to advance"[40] research on BRCA1 testing. Accordingly, at least one researcher has warned that "those obtaining consent for Jewish women [for BRCA1 testing] should be aware of the 'slippery slope' from perceived social responsibility to coercion."[41] Furthermore, Jewish women feel particularly responsible for seeking information about genetic predisposition to breast cancer, in part for the "sake of one's children."[42] As noted earlier, much of the attention in research, the commercial market place, and the media over the last year has been on the "Jewish genes" for breast cancer. Newspaper headlines sum it all up: "Doctors Launch New Jewish Cancer Test"[43] and "Doc Wants New Study of Jewish Cancer Gene."[44] For Jews, a genetic identity to familial cancer is being legitimized by our drive for the genetic "quick fix."

III. ETHICAL AND LEGAL IMPLICATIONS Of INFORMED CONSENT

With these themes in context, the ethical and legal issues can become more focused. The first issue, with both ethical and legal implications, is informed consent. The informed consent model for genetic (and HIV) testing has altered the traditional paradigm. Rather than focusing on the medical risks

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38. *A Letter Received by Dor Yeshorim with the Request to Publicize it to the Community* (Dor Yeshorim trans.) (Dor Yeshorim, Washington, D.C.) 1995.

39. *Id.*

40. Gail Geller et al., *Informed Consent and BRCA1 Testing,* 11 NATURE GENETICS 364, 364 (1995).

41. *Id.*

42. *Id.*

43. *Doctors Launch New Jewish Cancer Test, supra* note 20, at 5.

44. *Doc Wants New Study of Jewish Cancer Gene: Is Screening Warranted?*, FORWARD, Feb. 9, 1996, at 6 [hereinafter *Doc Wants New Study of Jewish Cancer Gene*] (calling for a study to see whether screening and prevention are necessary).

associated with the procedure, which are minimal, the emphasis is on disclosure of the psychological and societal risks for the individual and family receiving the information.[45] It is important to note, however, that it is very difficult to have a meaningful informed consent process when we still know so very little about the relative risks and benefits of genetic testing.

A number of assumptions have been made about the benefits of predictive testing and the value of predictive information. It has been argued that test results will relieve uncertainty; promote early detection, surveillance, prevention, and intervention strategies; enable us to better plan for the future; influence reproductive decision making; and give us information to share with blood relatives (particularly children), so that they can better assess their risk for cancer.

On the other hand, assumptions are made about the risks as well. These are not the traditional risks associated with an invasive, medical intervention. Rather, as noted earlier, they are social and psychological risks that typically have not been the major focus of the informed consent process. It has been argued that genetic information will increase anxiety; change self-image; alter family relationships; create social and group stigma; impact on privacy and confidentiality; and result in both insurance and employment discrimination.

In fact, we must question the assumptions about both benefits and risks. The reality is that we have very little data. First of all, the value of this predictive information is unknown and it will remain unknown for the near future. Further, it is important to emphasize that whereas genetic information may be predictive, it is not, in and of itself, a definitive diagnosis. Additionally, it is difficult for individuals to evaluate both predictive information and relative risks and how those relate within the context of their lives.[46] Finally, these predictive tests are not perfect and may never be for all population groups. How can such limitations be translated, if at all, for the

45. *See generally* OFFICE FOR PROTECTION FROM RESEARCH RISKS, U.S. DEPT. OF HEALTH & HUM. SERV., PROTECTING HUMAN RESEARCH SUBJECTS, INSTITUTIONAL REVIEW BOARD GUIDEBOOK 5-42 to 5-63 (1993) (addressing ethical issues raised by human genetic research).

46. *See* Elizabeth J. Thomson, *Communicating Complex Genetic Information, in* GENES AND HUMAN SELF-KNOWLEDGE 172 (R.F. Weir et al. eds., 1994).

individual not trained in genetics or risk assessment? How good, in fact, does the genetic information have to be in order to benefit individuals as members of society? In light of the above, it becomes critical for the health care provider to be skilled in risk assessment in order to determine who best can potentially benefit from genetic testing. Thus, the evolving standard of care should not be focused on the provider's duty to offer testing, per se, but rather on the quality of risk assessment and the appropriateness of testing.

Accordingly, we must also question the assumptions made about predictive testing and its potential for a positive impact on cancer surveillance and prevention strategies. What, in fact, do we currently know about baseline health promotion and disease prevention behaviors? Based on what we know about cancer prevention and interventions, what assumptions are reasonable to make with respect to adherence, change of behavior, and access to these strategies in our current health care system? Furthermore, what should people with a positive test be advised? Should they be told to obtain mammograms more often or less often? Should women with BRCA1 mutations be offered chemoprevention and/or prophylactic mastectomies as prevention strategies?[47] Should men with mutations be offered prophylactic prostatectomy? How can we counsel about the benefits and risks of surgical options without any long-term data on the impact of such interventions? We need to formulate a risk/benefit analysis to determine whether the benefits of predictive testing for cancer outweigh the risks with respect to both medical and psychological well-being.

IV. GENETIC INFORMATION AND HEALTH INSURANCE

One societal risk at issue is the discrimination that may result in the health insurance setting.[48] Researchers report that

47. *See* Struewing et al., *supra* note 4, at 198. *See also* Yoshio Miki et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, 266 SCIENCE 66, 66 (1994) (discussing the identification of the BRCA1 gene and how it will facilitate early diagnosis of breast and ovarian cancer susceptibility).

48. *See* Karen H. Rothenberg, *Genetic Information and Health Insurance: State Legislative Approaches*, 23 J. LAW MED. & ETHICS 312, 312 (1995) (detailing state approaches to the

individuals considering enrollment in clinical genetic studies fear that if genetic information is disclosed to third parties, individuals and their families may face discrimination.[49] Until a few years ago, it was rare for legislation to address genetic information in the health insurance context. In the 1970s, North Carolina and Florida passed legislation prohibiting health insurers from refusing to issue insurance or charging higher premiums based on the sickle cell trait. In 1986, Maryland passed legislation (since amended) that covered a number of traits including Tay-Sachs, although insurers could continue to use genetic information to discriminate if there was "actuarial justification."[50]

With the advent of the Human Genome Project, a new generation of state legislation began to evolve with the passage, in 1991, of a Wisconsin law prohibiting health insurers from:

- requiring or requesting an individual or a member of the individual's family to obtain a genetic test;
- requiring or requesting directly or indirectly the results of a genetic test;
- conditioning the provision of insurance coverage or benefits on genetic testing; or
- considering genetic testing in the determination of rates.[51]

This approach attempts to integrate protection against discrimination in insurance practices, coverage, benefits, and rates with some privacy protection for the individual and his/her family. Similar approaches have been incorporated to varying degrees in recent legislation passed in California,[52]

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problem of discrimination by insurance carriers based on genetic information); Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 SCIENCE 391, 391 (1995) (focusing on proposed reforms to protect consumers from health insurance discrimination based on genetic information). *See generally* Ruth R. Faden & Nancy E. Kass, *Genetic Screening Technology: Ethical Issues in Access to Tests by Employers and Health Insurance Companies*, J. SOC. ISSUES, 1993, at 75, 83; Paul R. Billings et al., *Discrimination as a Consequence of Genetic Testing*, 50 AM. J. HUM. GENETICS 476, 476 (1992).

49. *See* Nat'l Inst. of Health, *NIH-Funded Cancer Genetics Studies Consortium Meeting*, Nov. 2, 1995.

50. *See* Rothenberg, *supra* note 48, at 313.

51. WIS. STAT. ANN. § 631.89(2)(a)-(d) (1994).

52. CAL. INS. CODE §§ 10123.2, 10123.3, 10123.31, 10123.35, 10140, 10140.1,1 0140.5, 10147, 10148, 10149, 10149.1, 11512.95, 11512.96, 11512.965 (Deering 1996); CAL. HEALTH & SAFETY CODE § 1374.7, 1374.9 (West 1994 & West 1995); S.B. 1740, 1995-96 Reg. Sess. (Cal. 1996) (enacted).

Colorado,[53] Georgia,[54] Maryland,[55] Minnesota,[56] New Hampshire,[57] Ohio,[58] Oregon,[59] Virginia,[60] and New Jersey.[61] Just within the last year, more than a dozen state legislatures have considered bills addressing genetic discrimination in health insurance.[62]

The development of public policy to address genetic information and health insurance must be analyzed in the context of a complex and inadequate health insurance system, the uncertainty about the future scope and impact of genetic testing and the political realities of a pluralistic society. The current patchwork of state legislation does not provide a comprehensive solution to genetic discrimination and health insurance. State laws focus narrowly on genetic tests, rather than more broadly on genetic information generated by family history, physical examination, or the medical record. Although insurers are prohibited from using the results of a chemical test of DNA, or the protein product of a gene, they can still use other phenotype indicators, patterns of inheritance of genetic characteristics, or requests for genetic testing as the basis for discrimination.[63] Thus, "[m]eaningful protection against genetic discrimination requires that insurers be prohibited from using all information about genes, gene products, or inherited characteristics to deny or limit health insurance coverage."[64]

Further, the federal Employee Retirement Income Security Act (ERISA) exempts self-funded plans from state insurance

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53. COLO. REV. STAT. § 10-3-1104.7 (1996).
54. GA. CODE ANN. § 33-54-1-4 (1996).
55. MD. ANN. CODE Art. 48a, § 223(a)(3) (1996).
56. MINN. STAT. § 72A.139(3) (1995).
57. N.H. REV. STAT. ANN. § 141-H:4 (1995).
58. OHIO REV. CODE ANN. §§ 1742.42, 1742.43, 3901.49, 3901.491, 3901.50, 3901.501 (Anderson 1996).
59. S.B. 276, 68th Or. Leg. Assoc., Reg. Sess. (1995)(enacted).
60. VA. CODE ANN. § 38.2-508.4 (Michie 1996).
61. S.B. 695 & 854, 207th Leg., 1st Ann. Sess. (N.J. 1996) (enacted).
62. *See, e.g.*, H.B. 5705, 1996 Gen. Assembly Reg. Sess. (Conn. 1996) (prohibiting discrimination based on an individual's genetic information in both employment and insurance contexts); H.B. 1200, 109th Leg., 2d Reg. Sess. (Ind. 1996) (prohibiting health insurers from discriminating on the basis of genetic information); H.B. 2943, 89th Gen. Assembly (Ill. 1996) (amending various state acts to prohibit the use of DNA information as a basis for certain insurability decisions).
63. *See* Hudson et al., *supra* note 48, at 392.
64. *Id.*

laws. Nationwide, more than one-third of the non-elderly insured obtain health insurance through self-funded plans.[65] This percentage is expected to increase as more and more employers use self-funded plans to provide health insurance benefits in the future. This Act preempts state law and therefore prevents a statewide approach to regulating the use of genetic information by all plans providing health benefits.[66]

With these policy considerations in mind, the following recommendations were developed by the Working Group on Ethical, Legal, and Social Implications of the Human Genome Project (ELSI)[67] and the National Action Plan on Breast Cancer (NAPBC)[68] for both state and federal policymakers to protect against genetic discrimination:[69]

> 1. Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements.
> 2. Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.
> 3. Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
> 4. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.[70]

The recommendations further provide that genetic information be defined as "information about genes, gene products, or inherited characteristics that may derive from the individual

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65. *Id.*

66. *Id.*

67. The NIH-DOE ELSI Working Group has a "broad and diverse membership including genome scientists; medical geneticists; experts in law, ethics, and philosophy; and consumers, to explore and propose options for the development of sound professional and public policies related to human genome research and its applications." Hudson et al., *supra* note 48, at 392-93.

68. The National Action Plan on Breast Cancer (NAPBC) is a "public-private partnership designed to eradicate breast cancer as a threat to the lives of American women"; and NAPBC "has identified genetic discrimination in health insurance as a high priority." *Id.* at 393.

69. These recommendations have been endorsed by the National Advisory Council on Human Genome Research (NACHGR). *Id.*

70. *Id.*

or a family member."[71] Insurance provider is defined as "an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded."[72]

Based in part on the interest generated by these recommendations and a growing awareness of the issues, particularly among the breast cancer community and women's health advocates, Congress has begun to take notice. The NAPBC/ELSI recommendations have been incorporated in proposed legislation introduced by Representative Louise M. Slaughter[73] and Senators Diane Feinstein,[74] Connie Mack,[75] and Olympia J. Snowe.[76] Further, Senators Mark D. Hatfield[77] and Peter V. Domenici[78] and Representatives Clifford B. Stearns[79] and Joseph P. Kennedy[80] have also introduced bills addressing genetic discrimination in insurance and employment. Although none of these genetic-specific proposals have passed, they have influenced other health insurance legislation. The recently enacted Health Insurance Portability and Accountability Act of 1996[81] specifically prohibits a group health insurance plan from using "genetic information" to establish rules for eligibility or continued eligibility. It also provides that genetic information shall not be treated as a preexisting condition "in the absence

71. *Id.*

72. *Id.* Furthermore, legislation should provide enforcement mechanisms, including civil and criminal liability to assure that insurance entities comply with these provisions. For example, as noted earlier, California provides that negligent and willful disclosure of genetic test results without authorization is subject to civil and criminal liability. CAL. INSUR. CODE §§ 10123.31, 10140.1, 10149.1, 11512.96 (Deering 1996).

73. H.R. 2748, 104th Cong. (proposing a bill entitled "Genetic Information Nondiscrimination in Health Insurance Act of 1995").

74. S. 1600, 104th Cong. (proposing a bill entitled the "Genetic Fairness Act of 1996").

75. *Id.*

76. S. 1694, 104th Cong. (proposing a bill entitled the "Genetic Information Nondiscrimination in Health Insurance Act of 1996").

77. *See* S. 1416, 104th Cong. (1995) (proposing a bill entitled the "Genetic Privacy and Nondiscrimination Act of 1996").

78. *See* S. 1898, 104th Cong. (1996) (proposing a bill entitled "Genetic Privacy and Nondiscrimination Act of 1996").

79. *See* H.R. 2690, 104th Cong. (1995) (proposing a bill entitled "Genetic Privacy and Nondiscrimination Act of 1995).

80. *See* H.R. 3477, 104th Cong. (1996) (proposing an amendment to the Fair Labor Standards Act of 1938 which would restrict employers in obtaining, disclosing, and using genetic information).

81. *See* 104 Pub. L. No. 104-191, § 701, 110 Stat. 1936 (1996).

of a diagnosis of the condition related to such information."[82] Thus, a healthy woman who tests positive for a BRCA1 mutation would not be deemed to have a pre-existing condition related to breast cancer and this genetic information could not be used in the determination of eligibility for a group insurance plan, including self-funded plans. This is a significant first step in the evolution of federal legislation. Genetic information, although not defined in the legislation, is recognized broadly as a "health-status-related factor" in need of specific protection.[83]

Of course, this incremental approach to health care reform does not provide the comprehensive protection outlined in the NAPBC/ELSI recommendations. It does not prohibit insurers from requiring or requesting genetic testing or requiring or requesting the results of genetic testing. Thus, the burden is on the individual to prove that the insurer used genetic information to deny coverage or affect the terms and conditions of insurance. It does not require insurers to obtain authorization before disclosing genetic information. 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.[84] Such applicable terms of a plan may have a disparate impact on individual enrollees and may adversely affect "individuals with serious illnesses."[85] This form of discrimination against women with breast cancer and/or a genetic predisposition to breast cancer, for example, would be permitted as long as plan characteristics are not "directed at individual sick employees or dependents."[86] Absent other contractual and legal protections, plans could specifically exclude, for example, prophylactic surgery. Of course, insurers might also argue that surgery was not medically necessary, was experimental, and/or was not a covered benefit since the insured had only a predisposition to disease, but did not need treatment for cancer.[87]

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82. *Id.* § 701(b)(1)(B).

83. *Id.*

84. *See* H.R. REP. NO. 104-736, at 406 (1996) (noting that a plan may impose restrictions on coverage of conditions and benefits).

85. *Id.* at 406.

86. *Id.* at 406-07.

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

The Act provides even less protection for those not in group plans and provides no coverage for the uninsured. Thus, even if the uninsured had access to genetic testing, the risk of future insurance discrimination would be a reality. In addition, the uninsured would not benefit from genetic information if they could not afford to pay for the related prevention and intervention strategies, including more frequent mammograms and surgical interventions.

V. GENETIC INFORMATION AND THE WORKPLACE

Genetic information in the workplace also poses societal risks that impact on employment possibilities, health insurance, and privacy. Following a conditional offer of employment, employers can require a pre-employment medical exam which may include a physical examination and blood tests (including genetic tests). They may also require a general medical release of an individual's medical records. Courts have held that employers have a legitimate interest in the mental and physical condition of their employees if the conditions impact on one's ability to perform the job, or are otherwise job-related.[88] An employer does not have to hire an employee who refuses to provide a general medical release.[89] Although an employer is prohibited from discriminating based on a disability, it is difficult for the individual to prove that she did not get a job or promotion, for example, based on her disability or other genetic information.[90] There is no specific prohibition on the employer's access to genetic information.[91]

"Insured's breast-ovarian carcinoma syndrome was 'illness,' defined as 'bodily disorder' or 'disease,' within meaning of health insurance policy, notwithstanding insurer's contention that syndrome was merely predisposition to cancer," and as such, prophylactic surgery for removal of ovaries was covered. *Id.* at 645, 652.

88. *See* Mark A. Rothstein, *Genetic Discrimination in Employment and the Americans with Disabilities Act*, 29 HOUS. L. REV. 23, 38, 52-68 (1992) (noting that the only exception to the ADA's prohibition on preemployment inquiries is that an employer may inquire into the applicant's ability to perform job-related functions).

89. *Id.* at 63-64.

90. *See id.* at 52-68 (explaining the problems employees face when employers have access to employee medical and genetic information).

91. *See id.* at 62-68 (describing ways in which the ADA allows employers to gain access to their employee's genetic information).

Employment opportunities and health insurance coverage are clearly intertwined. The employer has a business interest in hiring a healthy work force to limit health insurance claims. At present, employers offering self-funded plans can alter benefits to reduce or eliminate coverage for specific conditions or procedures. Although they cannot directly discriminate against an individual, they could decide, for example, not to cover particular procedures that may affect certain groups of people more than others. Since many employers directly review health insurance claims, as a practical matter, there is no assurance of medical privacy in the workplace.

In order to protect against genetic discrimination in the workplace, in 1995, the U.S. Equal Employment Opportunity Commission issued a guidance in its compliance manual on the definition of disability: the Americans with Disabilities Act (ADA) would protect individuals subjected to discrimination on the "basis of genetic information relating to illness, disease or other disorders."[92] To further clarify their position, they cite as an example an individual with a positive predictive genetic test for colon cancer as being subject to protection under the ADA. However, this provision may not cover carriers of recessive or X-linked disorders. To date, there have been no genetic discrimination complaints filed with the EEOC and the guidelines have yet to be tested in court. There is no federal law that specifically addresses the use, misuse, and access to genetic information in the workplace, although a number of proposals have recently been introduced.[93]

Over the last few years, a number of states, including Wisconsin,[94] Rhode Island,[95] Iowa,[96] New York,[97] New Hampshire,[98] Oregon,[99] and New Jersey[100] have passed

92. 2 EQUAL EMPLOYMENT OPPORTUNITY COMM'N, COMPLIANCE MANUAL, § 902, Order 915.002, 902-45 (1995).

93. *See* S. 1416, 104th Cong. (1995) (prohibiting discrimination by employers based on genetic information); H.R. 2690, 104th Cong. (1995) (proposing the protection of genetic information in the workplace); S. 1898, 104th Cong. § 301 (1996) (regulating the use of genetic information by employers); H.R. 3477, 104th Cong. (1996) (limiting the use of genetic information in determining preexisting conditions).

94. *See* WIS. STAT. ANN. § 111.372 (West 1996).

95. *See* R.I. GEN. LAWS § 28-6.7-1 (1995).

96. *See* IOWA CODE ANN. § 729.6 (West 1996).

97. *See* A.B. 7839, 219th Gen. Assembly, 2d Reg. Sess. (N.Y. 1996) (enacted).

98. *See* N.H. REV. STAT. ANN. § 141-H:3 (1995).

legislation that, to varying degrees, prohibits genetic testing as a condition of employment; prohibits genetic testing without informed consent; prohibits the use of genetic test results to affect the terms, conditions, and privileges of employment; and prohibits payments of benefits to employees in return for taking a genetic test. As with most state legislation addressing health insurance and genetic discrimination, these laws also tend to focus narrowly on the genetic test.[101] These laws do not prohibit employers from requiring a general medical release. At least one state law appears to allow for genetic testing without informed consent where it is shown to be directly related to the occupational environment.[102] Since most employers will continue to have access to genetic information, the burden will be on the employee to prove that the employer used genetic information to discriminate in the workplace.

VI. PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION

The privacy and confidentiality of genetic information is at issue in a number of contexts. Once again, there is no federal law that specifically addresses genetic privacy and confidentiality. There is currently a patchwork of legislative sources that addresses, to varying degrees, genetic privacy and confidentiality. These include medical records confidentiality statutes, public health data bases and registries, public health genetic programs, research regulations, DNA databanks, and antidiscrimination statutes. Most of these statutes provide for exceptions to confidentiality protections for criminal investigations, parentage, and adoption.[103]

Recently enacted state laws to prevent genetic discrimina-

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99. *See* OR. REV. STAT. § 659.036 (1995).

100. *See* S.B. 695, 207th Leg., 1st Ann. Sess. (N.J. 1996) (enacted). This is a comprehensive statute that includes provisions for employment, housing, banking, privacy, health, life, and disability insurance. *Id.*

101. The recently enacted New Jersey statute, in fact, does provide broader protection against the use of genetic information. *Id.*

102. *See, e.g.*, A.B. 7839, 219th Gen. Assembly, 2d. Reg. Sess. § 5 (N.Y. 1996) (enacted).

103. *See* Lawrence O. Gostin, *Genetic Privacy*, 23 J. LAW, MED. & ETHICS 320, 326 (1995) (discussing the genetic information infrastructure and how the privacy of genetic information is addressed in the scientific community and through state statutes).

tion in health insurance integrate some strong privacy protection.[104] As noted earlier, the Wisconsin law established that insurers may not "require or request directly or indirectly any individual to reveal whether the individual or a member of the individual's family has obtained a genetic test or what the results of the test, if obtained by the individual or a member of the individual's family, were."[105] Many of the other state laws and pending bills have also adopted this provision.[106] Ironically, a recent Wisconsin bill that would have expanded the definition of genetic test, deleted this provision.[107] Proponents of the bill believed that as long as state law prohibits the use of genetic information in the underwriting process, there may be legitimate reasons for health insurers to otherwise require or request genetic information.[108] For example, they argued that health maintenance organizations, which are both insurers and health care providers, may need this information to treat the patient and insurers may need access to this information to verify claims.[109]

Other states have further expanded on protecting the disclosure of genetic information. California, for example, prohibits its disclosure of genetic test results to any third party without written authorization.[110] Written authorization is required for each separate disclosure of genetic test results and shall specify the person or entity to whom the disclosure will be made. Negligent and willful disclosure without authorization are subject to both civil and criminal liability.[111] Colorado specifically provides that information obtained from genetic testing

104. *See* Rothenberg, *supra* note 48, at 314-17.

105. WISC. STAT. ANN. § 631.89(2)(b) (West 1996).

106. *See* Rothenberg, *supra* note 48, at 314-16.

107. A.B. 227, 92d Leg., Reg. Sess. § 10 (Wis. 1995) (amending existing Wisconsin law to allow insurers to require or request that an individual or an individual's family member obtain a genetic test or reveal whether such test has been obtained and the results).

108. *See* SPECIAL COMM. ON GENETIC & MED. INFO., WIS. JOINT LEGISLATIVE COUNCIL, LEGISLATION ON GENETIC & MED. INFO., A, B,93-19 (1994) (discussing Assembly Bill 1265 and its listing of circumstances under which patient health care records can be released upon request without informed consent, including release to a health care provider rendering assistance to the patient).

109. *Id.*

110. CAL. INS. CODE § 10149.1 (Deering 1996).

111. *Id.*

shall be "confidential and privileged,"[112] and Oregon and Georgia establish that genetic information is the "property of the individual."[113] Nevertheless, Oregon and Georgia both provide, as do a number of the other states, for specific exceptions in which written authorization is not required for disclosure (i.e., paternity, criminal proceedings, health department protocols). Even when these statutes require informed consent prior to genetic testing, they do not address whether the informed consent process will incorporate a warning that the test results may be disclosed without authorization under certain circumstances.

Additionally, a Florida law passed in 1992 permits DNA analysis to be used in criminal prosecutions, other criminal matters, and paternity determinations without informed consent.[114] Except in these circumstances, the statute declares that the test results are the exclusive property of the person tested, are confidential, and may not be disclosed without consent.[115] Nevertheless, the statute does not prohibit the use of genetic information in determining health insurance coverage and benefits. If DNA test results are used in any decision to grant or deny insurance, the individual must be notified and the analysis must be repeated to verify its accuracy.

Some statutes address privacy issues created by the access to shared insurance databases. The Wisconsin[116] and New Hampshire[117] laws provide that insurers writing life and disability income insurance, in addition to health insurance, cannot use genetic test information when underwriting their health insurance policies. In Minnesota, where a life insurance company may require a genetic test, the statute provides that written informed consent must include information on the uses and limitations of the test, as well as the individual's right to confidential treatment of the information.[118] It is worth noting that

112. COLO. REV. STAT. § 10-3-1104.7(3)(a) (1996).
113. S.B. 276, 68th Or. Leg. Ass., Reg. Sess. (1995) (enacted); GA. CODE ANN. § 33-54-1(1) (1996).
114. FLA. STAT. ANN. § 760.40(2)(a) (West 1995).
115. *Id.*
116. WISC. STAT. ANN. 631.89(3)(b) (West 1996).
117. N.H. REV. STAT. ANN. § 141-H:4, 5 (1995).
118. MINN. STAT. § 72A.139(S) (1995).

the statute specifically provides that "[i]f the individual tested has not given written consent authorizing a physician to receive the test results, the individual must be urged, at the time that the individual is informed of the genetic test results . . . to contact a genetic counselor or other health care professional."[119]

As noted earlier, currently there is no federal law specifically addressing genetic privacy. It is critical that any federal legislation that regulates genetic (and medical) privacy not preempt stricter protections integrated into state anti-discrimination statutes. Furthermore, medical privacy legislation must specifically address protections of genetic information. Currently, federal proposals are pending that vary with respect to how they address these issues.[120]

VII. RIGHTS AND RESPONSIBILITIES WITHIN THE FAMILY

Concerns over privacy and confidentiality extend beyond the employment and insurance context. For many individuals, the primary concern may be for privacy in the context of family, including the extended family. This is an area where it may be inappropriate for the law to have any meaningful role. Mediating roles based primarily on blood, rather than on family relationships, will create new challenges. In the Orthodox Jewish community, there is fear that genetic testing without clear medical benefit will only cause harm to individuals, threaten the privacy of families, and even hamper the prospects of marriage. A Jewish Community Relations Council official queried, "If you know that someone in the family has a specific predisposition to BRCA1, what does this do [to] their possible matches?"[121]

Traditional medical ethics may have to be re-examined to

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119. MINN. STAT. § 72A.139(6) (1995). Similar provisions are included in the California statute. *See* CAL. INS. CODE § 10148(a)-(b) (Deering 1996).

120. *See* S. 1360, 104th Cong. (1995) (proposing a bill entitled the "Medical Records Confidentiality Act of 1995"); S. 1898, 104th Cong. (1996) (proposing a bill entitled the "Genetic Confidentiality and Nondiscrimination Act of 1996"); H.R. 3482, 104th Cong. (1996) (proposing a bill entitled the "Medical Privacy in the Age of Technologies Act of 1996").

121. *Doc Wants New Study of Jewish Cancer Gene*, *supra* note 44, at 6.

accommodate changing rights and responsibilities within the family. The paradigm of individual autonomy in health care supports an individual's right to evaluate the benefits and risks of testing, to decide whether to be tested, and whether to share test results. However, in the context of genetics, what is the responsibility of the individual and the provider to share test results with other family members?[122] Is the patient, in fact, the individual, or the family unit? When sharing information, how many generations should be included? Should a communitarian ethic of sharing be integrated into the ethical paradigm? What responsibilities will there be to obtain and share information about genetic predispositions to cancer? In certain cases, the mutation cannot be found without testing the affected carrier and other blood relatives. What if some relatives want to be tested and some do not? Can family members keep genetic secrets? When should the researcher or physician intervene to encourage family members to participate in testing? Who in the family should contact family members with genetic information? Although there is no ethical consensus or clear legal precedent in genetics,[123] in the context of HIV and communicable diseases, some conclude that one might have an ethical and legal duty to share information about contagious diseases.[124] The rationale, in part, for the duty is to prevent

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122. *See, e.g.*, Madison Powers, *Privacy and the Control of Genetic Information, in* THE GENETIC FRONTIER: ETHICS, LAW, AND POLICY 77, 92-95 (Mark S. Frankel & Albert H. Teich eds., 1994) (discussing when genetic information should be disclosed to third parties in order to protect them from harm); Sonia M. Suter, *Whose Genes are These Anyway? Familial Conflicts Over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1854 (1993) (arguing that courts and legislatures should not follow a presumption against mandating disclosure of a person's genetic information to third parties).

123. *See, e.g.*, Ruth Macklin, *Privacy and Control of Genetic Information, in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 157, 158 (George Annas & Sherman Elias eds., 1992) (discussing the concept of privacy and its implication for the confidentiality of genetic information); Mary Z. Pelias, *Duty to Disclose in Medical Genetics: A Legal Perspective* 39 AM. J. MED. GENETICS 347, 349-52 (1991) (discussing the duty of medical geneticists to disclose medical and genetic information in light of the lack of legal precedent governing a physician's duty to disclose).

124. *See, e.g.*, Kenneth E. Labowitz, *Beyond Tarasoff: AIDS and the Obligation to Breach Confidentiality* 9 ST. LOUISE U. PUB. L. REV. 495, 512 (1990) (discussing the medical profession's standard for third party notification concerning a patient who has a positive HIV status and the mandates of the Public Health Service and Center for Disease Control). *But see, e.g.*, Karen H. Rothenberg & Stephen J. Paskey, *The Risk of Domestic Violence and Women with HIV Infection: Implications for Partner Notification, Public Policy, and the Law*, 85 AM. J. PUB. HEALTH 1569, 1569 (1995) (exploring implications of the partner notification strategy in the fight against AIDS in the context of domestic violence).

the spread of disease. Such an analogy may be premature and/-or ill-advised in the context of predictive genetic testing for cancer.

Two recent cases have considered the physician's duty to warn relatives that they are at risk of developing a genetic disease. In *Pate v. Threlkel*,[125] the Florida Supreme Court analyzed the duty to warn the patient of "genetic transferability" and the role of family members in sharing genetic information.[126] In this case, a patient's adult child brought a medical malpractice action based on the physicians' failure to warn the patient that her condition, medullary thyroid carcinoma, was genetically transferable and that her adult children should be tested for the condition.[127] The court held that expert testimony by physicians would determine the standard of care and thereby whether the physicians had a duty to warn under the circumstances. Obviously, this case demonstrates the importance of risk assessment, an understanding of cancer genetics, and the need for providers to take the lead, rather than the courts, in establishing the standard of care for genetic testing. The court also "emphasized" 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."[128] The court clarified that the physician has no duty to warn various members of the patient's family, reasoning that it would be prohibited by disclosure laws, as well as be impractical, difficult, and "place too heavy a burden on the physician."[129] Rather, the court reasoned that the "patient ordinarily can be expected to pass on the warning"[130] to family members.

More recently, the New Jersey Superior Court, in *Safer v. Pack*,[131] further expanded on the *Pate* opinion. In *Safer*, the plaintiff, who was diagnosed with a form of colon cancer, sued the estate of the physician who had first treated her father for

125. 661 So.2d 278 (Fla. 1995).
126. *Id.* at 280-82.
127. *See id.* at 278-79.
128. *Id.* at 282.
129. *Id.*
130. *Id.*
131. 677 A.2d 1188 (N.J. 1996).

the same disease over forty years earlier. She argued that the physician had a duty to inform the family that they were potentially at risk of developing this genetically transmissible condition. On appeal from the trial court's dismissal of her complaint, the Superior Court held that the physician did have a duty to warn and declined to hold as in *Pate* "that in all circumstances, the duty to warn will be satisfied by informing the patient."[132] It predicted that as the issues develop at trial, the court may have "to resolve a conflict between the physician's broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease."[133] These two cases further highlight our need for better understanding family relationships, privacy and confidentiality concerns, and realistic expectations in the genetics context.

In light of these developments, it may be even more critical to recognize the implications of testing children for cancer susceptibility.[134] When, if at all, do you tell the child of their carrier status? Is it realistic to have a parent withhold such information from a child? If not, when is the right age to share this information? Considering the social and psychological risks associated with testing, it may only be appropriate for the child to make the decision to undergo testing when they reach maturity.[135] If the testing of a child has a medical benefit that cannot be postponed until adulthood, it might be ethical to

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132. *Id.* at 1192.

133. *Id.*

134. *See generally* Board of Directors, Am. Soc'y of Hum. Genetics & Board of Directors, Am. C. of Medic. Genetics, *Points to Consider: Ethical, Legal and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 57 AM. J. HUM. GENETICS 1233, 1234 (1995) (recommending that providers engage families in comprehensive discussions of genetic testing issues and provide them with specific information about testing) [hereinafter Am. Soc'y of Hum. Genetics & Am. C. of Medic. Genetics]; Ellen Wright Clayton, *Removing the Shadow of the Law from the Debate about Genetic Testing of Children*, 57 AM. J. MED. GENETICS 630, 630 (1995) (arguing that tort and constitutional law in the United States have limited impact in the debate over genetic testing of children); Diane E. Hoffmann & Eric A. Wulfsberg, *Testing Children for Genetic Predispositions: Is it in Their Best Interest?*, 23 J. L. MED. & ETHICS 331, 331 (1995) (exploring the psychological impact, burdens, benefits, and other issues associated with testing children for genetic predispositions); Dorothy C. Wertz et al., *Genetic Testing for Children and Adolescents: Who Decides?*, 272 JAMA 875, 875 (1994) (discussing the ethical, legal, and psychological implications of presymptomatic testing of children).

135. *See* Am. Soc'y of Hum. Genetics & Am. C. of Med. Genetics, *supra* note 134, at 1238.

offer testing.[136] Because of concerns for psychological risk, stigma, and discrimination, parental anxiety alone should not be a justification for predictive testing of children.[137] The National Action Plan on Breast Cancer states that "[u]nless a benefit for medical interventions in childhood can be demonstrated, which is currently not the case for heritable breast and ovarian cancer, testing on individuals younger than eighteen years should not be undertaken."[138]

Reproductive decisionmaking in the genetic context also presents new and related challenges. In the near future, preimplantation diagnosis and assisted reproductive technologies may provide the wealthy with the option of the selective implantation of embryos with normal BRCA1 genes. More generally, if genetic testing for cancer susceptibility is marketed to the general population, it may be targeted at pregnant women. A recent article in *Obstetrics and Gynecology*[139] predicted that there would be increasing demand for prenatal testing for mutations in the BRCA1 gene.[140] In fact, most genetic testing is done on pregnant women[141] and predictive testing for cancer may be no exception.

More specifically, it is reasonable to predict that Jewish pregnant women will be the first group targeted since Jews are already being screened for other "Jewish" genetic disorders and are being recruited for 185delAG testing.[142] More generally, with knowledge of the mutation in the parent, prenatal testing using fetal cells will be relatively easy and quick, allowing for pregnancy termination.[143] Will only female fetuses be tested and aborted? Is it ethical to abort for an adult onset disease in which we still understand so little about penetrance and the

136. *See id.* at 1234.

137. *See id.* at 1238.

138. National Action Plan on Breast Cancer, Position Paper, *Commentary on the ASCO Statement on Genetic Testing for Cancer Susceptibility*, 14 J. CLINICAL ONCOLOGY 1738, 1739 (1996).

139. Johnathan 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).

140. *Id.* at 307.

141. *See, e.g.*, WOMEN AND PRENATAL TESTING: FACING THE CHALLENGES OF GENETIC TECHNOLOGY (Karen H. Rothenberg & Elizabeth J. Thomson eds., 1994).

142. *See* Genetics & IVF Institute, *supra* note 24.

143. *See* Lancaster et al., *supra* note 139, at 307.

phenotypic effects of different mutations?[144] Once the test is offered, we cannot place legal limits on termination options. Yet, if a woman decides not to abort, what implications does this have for the child's rights? We are in fact testing minors without their consent. The National Action Plan on Breast Cancer has determined that "[a] host of moral and ethical issues make it inappropriate to offer testing for breast and ovarian cancer susceptibility as part of prenatal diagnosis."[145]

VIII. CONCLUSION: UNANSWERED QUESTIONS

Predictive genetic testing for breast cancer raises a number of complex ethical, legal, and social challenges. Perhaps our greatest public policy challenge will be to determine when, if at all, it will be appropriate to make the transition from predictive testing for high-risk individuals and families in a research context to testing the general population for cancer risk. Will the commercial market promote testing for the general population before we have been able to carry out the benefit/risk analysis even in the high risk population?[146] As the flow of genetic information increases, so too will the risk of its misuse. Should testing be restricted until we enact anti-discrimination

144. *See id.* at 307.

145. *See* National Action Plan on Breast Cancer, *supra* note 138, at 1739.

146. *See generally* American Society of Clinical Oncology, *Statement of the American Society of Clinical Oncology: Genetic Testing for Cancer Susceptibility*, 14 J. CLINICAL ONCOLOGY 1730, 1730-36 (1996) (stating that any physician who offers genetic testing should be aware of, and be able to communicate, the benefits and limits of current testing procedures, and the range of treatment options available to patients and their families); National Action Plan on Breast Cancer, *supra* note 138, at 1739 (stating that testing should only be done under institutional review board approved research studies); Frances M. Visco, National Breast Cancer Coalition, *Commentary on the ASCO Statement on Genetic Testing for Cancer Susceptibility*, 14 J. CLINICAL ONCOLOGY 1737, 1737 (1996) (stating the National Breast Cancer Coalition's concern about the need for more research as well as the lack of legislation prohibiting the misuse of genetic information); National Advisory Council for Human Genome Research, Nat'l. Inst. of Health, *Statement on Use of DNA Testing for Presymptomatic Identification of Cancer Risk*, 271 JAMA 785, 785 (1994) (discussing issues which must be addressed before widespread use of DNA testing for a predisposition to cancer can be recommended); Ad Hoc Committee on Breast and Ovarian Cancer Screening, Am. Soc. of Hum. Genetics, *Statement of the American Society of Human Genetics on Genetic Testing for Breast and Ovarian Cancer Predisposition*, 55 AM. J. HUM. GENETICS i (1994) (identifying characteristics and prerequisites for testing for the BRCA1 cancer gene in high risk and general population groups).

and genetic privacy legislation nationwide? Should the commercial market be regulated? How can we explain relative and absolute risks to the general public? How can we explain the limitations of testing technology? How can we assure quality control over the testing process? What implications will testing have, for example, on cancer surveillance and prevention strategies within our current healthcare system? How will individuals be able to integrate predictive testing results with health behavior, lifestyle, and environmental factors that may significantly contribute to cancer morbidity and mortality? How can the FDA and other regulatory agencies assure the public that predictive genetic testing has clinical and analytical validity?[147] These questions have no simple answers.

Thus, until we have a better understanding of the benefits and risks of genetic testing and our strategies for how best to proceed in order to protect the public, we must strive to resist a genetic "quick fix" mentality that promotes genetic testing in the healthcare market. Obviously, there is no "quick fix" for the ethical, legal, and social challenges.

147. *See Technological Advances in Genetic Testing: Implications for the Future,* 104th Cong. 75-86 (1996) (statement of Karen H. Rothenberg).