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LEGAL IMPLICATIONS OF GENETIC SCREENING AND COUNSELING

by

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When scientific, medical, business, educational, or other disciplines reveal new fields of study and practice, and depending upon their importance, these new fields often come under legal scrutiny. Often these developments raise legal questions of first impression, with little or no analogous precedents to follow. Courts begin to decide these questions on a case by case basis as legal actions are brought by individuals who feel they have gained new rights or their existing rights have been violated. Eventually, such a case will reach a state or nation's higher courts and these decisions will become the basis for determining the liability, standards of care and duties of those involved in these new fields. This is equally true of genetic screening and counseling.

Rapid advances in human genetics, rising concern about family planning, and radical shifts in the public's attitude toward abortion have stimulated a rapid development of genetic screening and counseling services. Through the Human Genome Project, researchers from several nations are attempting to map all forty-six chromosomes.[1] Through this effort, prenatal screening can presently be used to detect 600 of the 3,000 to 4,000 known genetic defects[2] and scientists have identified the genetic abnormalities responsible for 122 different genetic diseases.[3]

Today hundreds of thousands of people and several nations are actively involved in genetic screening and counseling. Services are readily available throughout the United States. In France, Japan, China, India and other nations, genetic screening is regularly used by thousands of people.

Technology in the area of genetics now allows parents to select their child's genetic makeup before implantation of the embryo into the mother. Genetic screening, along with in vitro fertilization techniques, allowed an English couple, who were both carriers of the genetic trait, to eliminate a 25% chance of their child being born with cystic fibrosis. Instead, the parents used genetic screening techniques to guarantee that the child would be born free of this disease.[4]

In China and India genetic screening is frequently being used for sex selection. When couples discover, through genetic screening, that they are carrying a female, they frequently choose abortion, rather than carrying the baby girl to term. Gender ratios are becoming skewed in favor of males. For example, a study of 8,000 abortions in India has revealed that 7,997 involved female fetuses. One Indian government has passed legislation to ban the use of amniocentesis for the determination of the sex of a fetus.[5]

There is less sex-selection desire among Americans for their first born. In one study, less than 2 percent of parents expressing a desire to select the sex of their child were first time parents. Most parents were expressing a desire to have a second child of the opposite sex than that of their first born. In the United States and Europe, women have a more equal status with their male counterparts. If and when it becomes available, Americans are more likely to engage in genetic screening and selection to determine character traits and physical attributes such as intelligence, athletic abilities, artistic or music talents. Given time, such criteria would include eye and hair color, skin tone, height, etc. Parents could potentially go "shopping" for certain characteristics to the exclusion of others. This also could have

detrimental effects on the gene pool and natural selection as certain characteristics are chosen to the exclusion of others.[6]

The increasing use of this new genetic technology necessities an analysis of it's implications. If so many people over such a wide area are involved in this new technology, an understanding of the legal implications is necessary before the technology is too integrated into our society to easily change and regulate.

Such an analysis is important for two reasons. First, genetic counseling activities are expanding rapidly so more members of the public will have the opportunity to use a genetic counselor. These services are becoming more integrated into every day life than ever before. Thus, because the genetic counselor performs such an intimate function, for example in the area of reproductive choices, errors caused by negligence and improper advice hold potential for great harm. Secondly, genetic testing/screening leads to the discovery of some of the most private information about an individual. Not only does this information lead to the opportunity to provide a great service to the individual, but it can also, when used improperly or carelessly, lead to discrimination that can alter the course of an individual's life.

Therefore, the first part of this article will focus on the most common areas where a genetic counselor could face liability (failure to accurately gather and analyze data and failure to properly communicate or advise the patient/client.) The second part will focus on the broader issues of confidentiality and discrimination based on genetic information. Finally, the third part will discuss the necessity for regulation and the attempts at early regulation made by some nations.

I. LIABILITY IN GENETIC COUNSELING

During the next decades there will be a significant increase in the need for and supply of competent genetic counselors. Medical students are now taught the fundamentals of this practice. For certain medical specialists, especially obstetricians and pediatricians, advanced training in human genetics is virtually obligatory.

As a result of this rapid expansion, professional genetic counselors are carefully examining their role. Genetic counseling has been defined as:

> "a communication process which deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family (1) comprehend the medical facts, including diagnosis, the probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder, and risk of recurrence in specified relatives; (3) understand the options for dealing with the risk of recurrence; (4) choose the course of action which seems appropriate to them in view of their risk and their family goals and act in accordance with that decision; and (5) make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.[7]

Genetic Counseling is playing an ever increasing role in today's society and the discipline is continuously advancing. In the United States alone, there are approximately 450 certified genetic counselors and 500 clinical geneticists.[8] Currently, most genetic counselors are master's level (have undergraduate degrees in science or psychology) and are board

certified.[9] Additionally, in the last year, medical genetics received formal recognition as a medical specialty.

The advice of such counselors can have a profound effect on the individual's life. The information and advice provided may be the basis for decisions in the areas of child birth, family counseling, pre-birth screening and abortion, employment, illness diagnosis and treatment, or criminal prosecution and defense, among others.

The term "genetic counselor" includes a general physician, who upon examination of a patient[10] realizes that the patient's circumstances, symptoms, history or test results call for a more thorough genetic study. It also includes a specialist in a specific reproductive chromosome and the likely physical manifestations at birth from abnormalities in the chromosome. Also included is the physician's assistants and laboratory technicians working in a genetic counseling center.

The most frequent counselees are a couple, one of whom has a family history of genetic disorder or both of whom are the parents of a child with such a condition, who are concerned about future pregnancies.[11] The counselor's analysis and advice could determine their procreative decision-making. Erroneous reassurance could lead to the birth of a genetically defective child, such as in the so-called "wrongful life" cases, or the couple may be advised to choose sterilization or abortion where such actions are not warranted, bringing about a medical malpractice action.[12]

In order to determine what legal liability a genetic counselor may incur, it must first be determined what legal obligations the genetic counselor has to his/her patient. All genetic counselors have a legal duty to possess the necessary competence to provide the services

requested. Secondly, genetic counselors are legally obliged to provide health care services in a manner consistent with the standard of reasonable care. Genetic counselors are potentially liable for harms that result from their violation of the duty to act in a reasonable manner, which they owe their patients. (i.e. once a patient is accepted, the counselor is obligated to provide services as a reasonable counselor would in the same or similar circumstances.) In all circumstances, the genetic counselor has a legal obligation to effectively provide the counselee with sufficient, accurate information to allow the counselee to make an informed choice.

A. What Skill Standard Should a Genetic Counselor Be Held To?

As with any expanding field, such as genetics, the standard of care must validate the level of knowledge reasonably prevalent within the professional community. Professions have typically been allowed to regulate themselves and develop the standards applicable to the profession and even to a specific specialty. A general practitioner may not be held to the same standard of care and level of proficiency as a doctor of obstetrics and gynecology or a specialist in detecting and predicting Down's syndrome based upon the parent's genetic makeup. Yet, if the general practitioner attempts to advise a couple on genetic issues prior to pregnancy, he will be required to possess the skill, knowledge and competency to properly do so. The physician, while not having the required expertise, may satisfy his or her duties by consulting with an appropriate specialist.

A revolutionary development or testing procedure may not be known throughout the field. If such is the case, a counselor should not be accused of failing to use it, unless the

procedure has been commonly and widely accepted by many of the practitioners of that field.

It is clear that someone outside the field of genetic counseling cannot create a standard to which genetic counselors should be held. This standard will be created, fortunately or unfortunately, by counselors who fail to meet that standard and litigation that results therefrom. However, we would like to suggest that since genetic counselors include such a wide range of professionals, namely general physicians, specialists in numerous fields, non-physician assistants, laboratory technicians, etc., some generalized standard must be created. It would obviously be confusing and impossible to attempt to impose different standards on each type of professional that undertakes genetic counseling. Regardless of whether the individual is a physician, assistant, etc., if he/she holds himself/herself out as a genetic counselor, he/she must be held to the standard created for a genetic counselor. Obviously a specialist in a particular field of genetic counseling would be held to a higher standard, however, general genetic counselors must be held to the same standard, regardless of their level of education.

Thus, we would suggest that two standards apply to genetic counselors. The first would apply to all individuals, regardless of professional background, who hold themselves out as qualified genetic counselors. The second standard would apply to those individuals who hold themselves out as a specialist in a particular aspect of genetic counseling. Once again, we state that these standards must be created through time and by those in the genetic counseling field. To try to set forth standards through other means would only be to create unrealistic or impracticable standards that would necessitate change over time.

B. Liability for Negligence in Genetic Counseling

Once a standard has been established in the genetic counseling field, it is important to consider the areas of practice in which a genetic counselor can fall below the standard of care and become subject to liability. A genetic counselor can be liable for failure to properly analyze, communicate, or advise about information obtained during the counseling of a couple. When such errors occur, several torts can be brought against the genetic counselor, as discussed below.

As a general rule, all genetic counselors must understand their patient's condition and family history well enough to request the proper testing to be performed, even if the counselor lacks the specialization and expertise required to diagnose, advise and/or treat whatever disorder is revealed. In other words, the physician is still required to recognize the patient's need to see a specialist.

On the other hand, consideration must be given to how readily a genetic abnormality may be detected. In deciding if a physician or other counselor has acted below the standard of care for his or her profession, consideration must be given to how frequently the specific disorder is detected under proper conditions. If a disorder or abnormality is more difficult to detect by its own nature, it is less likely a genetic counselor will be determined to have been negligent for failing to detect it.

The "state of the art" is of central importance to the question of whether a genetic counselor has properly informed and advised a patient prior to his or her decision. Such "state of the art" is concerned with the extent and materiality of information available at the time. Without taking into consideration the consequences of the decision, where certain

material information was not revealed to the patient and had the patient known the additional information, his or her decision would had been different, then the counselor can be held liable for the consequences of that decision. However, the information withheld must have been germane to the decision. If the information was insignificant, a patient will be considered to have been properly informed, even if a different decision would have been made.

The first decisions, in the United States, by any state's highest court to face the issue of professional liability for negligence in providing advice about genetic risks in reproduction were Howard v. Lecher[13] and Becker v. Schwartz.[14] The New York Court of Appeals permitted the parents of genetically impaired children to receive damages for the costs of treatment, however the court did not allow any emotional damages to be awarded. Pennsylvania followed suit in Speck v. Vinegold[15], allowing the parent's claim for economic damages but not for the child's or the parents' emotional suffering claims where a child was born with neurofibromatosis after a failed vasectomy.

More recently, various states in the U.S. have begun to examine the "wrongful life" and "wrongful birth" torts.

1. Wrongful Life/Wrongful Birth

Under the "wrongful life" or "wrongful birth" torts, the genetic counselor can be liable to the parents or the child for the wrongful birth of that child. Liability in these areas can arise from the genetic counselor's failure to accurately analyze data, failure to accurately communicate the results of the data analysis and failure to accurately advise based on the

data analysis. For example, if the genetic counselor's failure to accurately analyze the data collected on a patient/counselee couple results in the birth of a child with severe genetic defects, the parents and child have causes of action against the genetic counselor for that child's wrongful birth/life. The parents can conceivably recover for the expenses of the birth and life (ie. medical, support, education, etc.) of the child. The child can conceivably recover for the pain and suffering associated with living life with the severe genetic defects he/she has. This same result can be reached from the genetic counselor's failure to accurately communicate the information obtained from the research, and from the failure to adequately advise the couple (ie. indicating a lower probability of genetic defects.)

Wrongful life claims, in theory, are made by an infant asserting that recovery should be allowed for injuries which are caused by the defendant's negligence which led to the plaintiff's wrongful existence.[16] At the base of the action there must be a duty on the part of someone either to insure that the infant is not born or that the proper disclosure is made to the parents, so that a decision can be made whether or not to continue the pregnancy to term. The tort claim of "wrongful life"[17] in a genetic counseling context first appeared in the landmark case, Gleitman v. Cosgrove.[18] The defendant physician had not informed Mrs. Gleitman that an attack of rubella (German measles) early in her pregnancy might cause genetic disorders. Jeffrey Gleitman was born deaf, retarded and nearly blind. The New Jersey Supreme Court held that plaintiff Jeffrey could not recover from the physician and, though Jeffrey's parents might have a claim, it "would be precluded by the countervailing public policy supporting the preciousness of human life."[19]

When the Supreme Court legalized abortion in 1973 in Roe v. Wade[20], it provided the opportunity for the court to establish physician liability in genetic counseling situations. Parents could now claim that, given proper information, they would have aborted a fetus affected with a genetic disorder. Therefore, in 1975, the Texas Supreme Court in Jacobs v. Theimer[21] ruled that the defendant physician could be held liable for failing to diagnose and disclose the fact that his patient had contracted rubella early in pregnancy. Then, in 1977, the courts in Becker v. Schwartz[22] and Park v. Chesin[23] rejected the "wrongful life" claim of the plaintiff child but allowed the "wrongful birth" recovery for the parents' economic loss.

Other legislatures have refused to recognize actions for "wrongful life"[24] and other courts have denied claims of medical malpractice for failure to detect genetic abnormalities in unborn children.[25]

Thus, the torts of "wrongful birth" and "wrongful life" causes of action have yet to be ultimately decided. They depend, in large part, on the laws of the state, or nation, making the determination. For example, those states or nations who have legalized abortion in later terms of pregnancy are more likely to recognize the torts. This is because couples in those states or nations have a greater argument that they would have made a different choice, and would have been able to carry out that choice, if they had been fully informed.

2. Unwarranted Sterilization or Abortion

A genetic counselor could also incur liability for the unwarranted sterilization of an individual or unwarranted abortion of a child. Through the same failure to accurately

analyze, communicate or advise, the genetic counselor may have a patient/counselee that either chooses sterilization or abortion. If these choices are made based on actions of the genetic counselor that fell below the standard of care, liability may be incurred.

3. Informed Consent

An individual's medical decisions are based upon a variety of considerations, but primary of these is the advice given by a physician. Coupled with advice, a physician is often requesting the patient's permission to perform a medical procedure, such as treatment by surgery or medication. Because of the importance that information and advice given by a physician plays in the decision making process, patients must be fully informed as to the risks involved and other options available.

The minimum function of the genetic counselor, physician or otherwise, is to educate the patients about their genetic condition and the risks involved. Failure to fulfill this basic function would expose the counselor to liability and damages which could occur where a patient follows the wrong advice or is misinformed or unaware of their true genetic condition on which they are basing their decision.[26]

The primary purpose of the informed consent law is that the decisions made by individuals are informed, intelligent decisions based upon all information available. To do this competently, the genetic counselor must possess the requisite knowledge to recognize the individual's condition, identify the need for additional information and foresee the ramifications of different courses of action. If such results cannot be foreseen, this also must be discussed with the patient.

For example, careful attention has to be paid by the counselor to tests that are still experimental and results that are not completely accurate. Informing the patient that the testing may show a probability for a genetic defect, rather than a certain genetic defect would be imperative to the decision making process.

This discussion is not to say that the genetic counselor must convey each and every scintilla of information remotely related to the individual's condition. To so bombard the individual with such an onslaught of information would certainly work the same result of not informing him/her at all. It is, however, the responsibility of the counselor to consider what information is useful and relevant and separate this from the total body of information available. Before liability can be attached, a counselor's decisions as to what information would be useful to the counselee would be evaluated in light of the information available and the reasonableness of that decision in the eyes of the professional group to which the counselor belonged. A genetic counselor need not inform the counselee about a benign genetic trait, but where the information is questionable, the counselor should share all information the counselee might find material to making his/her decisions.[27]

4. Fear of Liability Means Greater Regulation

One of the benefits of the fear of liability is it's leading to greater regulation of genetic counseling. The fear of liability may lead to more obstetricians referring their patients to genetic counselors. Obstetricians are finding themselves more often subjected to general malpractice liability for: failing to refer a patient to genetic counseling when there is an indication that such might prove helpful, failing to fully inform prospective parents about

the availability of genetic testing, failing to advise of the possible risks of genetic testing, etc.

Therefore, the fear of liability is one of the most profound forces working to transform prenatal genetic screening into a standard component of prenatal care.

II. CONFIDENTIALITY AND DISCRIMINATION

The following is a set of hypotheticals to indicate how confidentiality and discrimination issues develop in the genetic screening/counseling arena.

Hypothetical 1:

Through a study of newborns one cytogenetic researcher found that a newborn had an XYY karyotype. XYY karyotypes have been frequently linked to prisoners and psychological and social problems. Under these circumstances, does the genetic counselor inform the child's parents, family, teachers, etc.? If so, this child may be treated differently throughout life, even though his XYY karyotype status may never affect his "normality."

Hypothetical 2:

Through a study of newborns a genetic counselor finds a girl with XY karyotype and testicular feminization syndrome. In other words, she will develop as a girl, but have no uterus and risk development of a tumor in her abnormal gonads. This information indicates any siblings or immediate relatives may also be at risk. Does the genetic counselor information the family? If not, what if the family asks for

the results of the study? If he should inform the family, who in the family should he consult for release of the information? What about the concern for medical risks in other family members? Do you invade the child's privacy, possibly subjecting the child to lifelong discrimination, to possibly protect other family members?

Hypothetical 3:

Through a study of newborns a genetic counselor finds a child has hemophilia - an infectious, transmissible disease. If the parents refuse disclosure, does the genetic counselor inform other family members who may be carriers? How does the one family's right to privacy compare with the protection of other individuals and the State's right to control transmissible diseases? Could the family sue the genetic counselor for contacting other family members? Could the other family members sue the counselor for not providing them with the information?

Hypothetical 4:

A genetic counselor diagnoses a genetic disorder in a family that has been involved in an adoption. (Either the counselee gave up a child for adoption at some earlier time or the counselee was an adopted child.) Should the counselee parents contact the child they gave up for adoption and inform him/her of the genetic risk? Should the adopted child contact his biological parents and collateral relatives to seek confirmation for a diagnosis or to warn them about their genetic risk?

Hypothetical 5:

A genetic counselor discovers the possibility that a child will develop cancer. However, it is unknown whether the child will ultimately develop cancer or simply be

more readily susceptible to cancer. What happens when the couple decides to carry the child to term and their insurance company discovers this child's predisposed risk of developing cancer? What recourse does the couple have when their insurance company, based on the prenatal genetic testing denies coverage for the child because they consider the cancer a pre-existing condition? Is this type of discrimination allowed?

From just these few examples, we learn that confidentiality and discrimination issues in genetic screening/counseling do not just entail the rights of the individual upon whom testing was done. The issues expand to include immediate family members, more distant relatives, society, government, etc. Who's interests do we protect at possibly the cost of others? How does the genetic counselor determine when to release information and when to keep the information private? How do they determine to whom they are allowed to release the information? What protection does the counselor have if they make the wrong decision? And, what recourse does the individual have when their right to privacy is wrongfully violated, leading to discrimination?

A. Confidentiality

In 1983, the President's Bioethics Commission underlined the importance of confidentiality in genetic screening and counseling by issuing the following recommendations:

1. Genetic information should not be given to unrelated third parties, such as insurers or employers, without the explicit and informed consent of the person screened or a surrogate for that person.

2. Private and governmental agencies that use data banks for genetic-related information should require that stored information be coded whenever that is compatible with the purpose of the data bank.

However, although these recommendations show a recognition of the possible problems, without more, they do not provide a set of guidelines that answer the multitude of questions related to the release of genetic information.

The main protection for informational privacy resides in legislation and the common law. The Federal Privacy Act of 1974 protects citizens from government disclosure of confidential information.[28] The Act however, only applies to hospitals operated by the federal government and private health care or research institutions maintaining records pursuant to government contract. There is limited federal law to govern the uses and misuses of genetic information. Legislation has been proposed which would safeguard individual privacy and protect against misuses of genetic information. The proposed Human Genome Privacy Act would prevent the unauthorized use of genetic information as well as insure that individuals have access to the records kept on them.[29]

State laws provide some protection, however, most state laws only apply to physicians, not other health care professionals, researchers, or health care institutions. Many states have regulated this area, however, because of the federal scheme, there is some diversity between individual states with respect to what genetic counselors may and may not

do. All states have established genetic screening programs to detect genetic diseases in infants, but how else could this information be used or misused?

It is first important to determine what standards control the release of information in the genetic counseling setting. If the genetic counselor operates in a medical setting, particularly in a genetics clinic headed by a physician, he/she may be bound as an agent by the rules governing physicians' conduct.[30]

Common law has recognized that under certain circumstances a physician may betray a confidence to protect other individuals or the general public. However, these exceptions generally arise when there is a threat of communication of a highly contagious disease and there is a great difference between the threat posed by a patient with an infectious disease and that by a patient with a genetic disorder. When warning is not given when an infectious disease is involved, people who are free of disease may become infected. On the other hand, when a genetic disease is involved, relatives of the counselee are either affected or not affected by the genetic condition regardless of the counselee's conduct. The law has traditionally held that people have a duty to avoid intentionally harming others or exposing them to an unreasonable risk of harm, but has refused to recognize the existence of a duty to act when the harm arises from forces outside their control.[31] Nevertheless, while a patient may be under no legal obligation to inform his or her relatives, and hence the counselor would not be justified in remedying a failure to inform them, the fact that the relatives may in ignorance miss an opportunity to prevent the manifestation of a harmful genetic condition suggests the existence of a strong moral obligation to inform.[32] The harm that might occur from nondisclosure to relatives, such as the birth of a genetically impaired child, could be as

immediate and as grave as any risk recognized in one of the "public danger exception" cases, and, if so, could give rise to an obligation to warn the relatives or be liable for the resulting damages.

The most difficult problem is posed by disclosure to relatives solely for their benefit, rather than to benefit the original counselee. Two questions are presented for a genetic counselor with a counselee who will not consent to have his or her relatives contacted. First, would communication by the counselor fall outside the bounds of normal medical confidentiality? And second, if so, would it nevertheless be permissible as an exception to the profession's norm?

Although a patient entering genetic counseling today would probably not contemplate that his or her condition would have to be revealed to anyone, a counselor could avoid the need for overriding the counselee's wishes after-the-fact by informing him or her at the outset of the clinic's policy on contacting relatives at risk. Only those few counselee who would not want relatives contacted would consider declining to go further with the diagnostic procedure. They would have to weigh the risk of revelation against the harm of not getting a needed diagnosis from this counselor and the chances of obtaining help from someone else on other terms.

Various states have or are in the process of passing legislation to prevent misuses of released genetic information. Such legislation places an obligation upon the genetic counselor to maintain the confidence of the patient and exposes the counselor to liability for the failure to do so. An additional advantage is that such legislation also provides counselors

with proper grounds to refuse to release such information unless the individual grants his or her permission.

B. Discrimination

Absent proper confidentiality and regulation, prenatal genetic screening has a vast potential for discrimination by the insurance industry. Imagine the couple, with no history of genetic problems, who wish to under go genetic screening as a preventive measure in anticipation of getting pregnant. Such screening reveals a low percentage potential for a genetic problem in their off spring. After careful consideration, they decide to have a child, who is born with the genetic malady. Second, imagine a second couple, expectant parents, who undergo genetic screening on their developing fetus and an abnormality is diagnosed. The health insurance carriers in both instances could refuse to cover the child's health care costs on the grounds that the condition was preexisting.[33] If allowed, this treatment by the insurance industry would discourage individuals from engaging in genetic screening because of the potential risks of bearing the cost of any genetic abnormality discovered. Likewise, many curable or preventable abnormalities would not be prevented or treated because they were not discovered due to the chilling effect upon a parents' election to undergo prenatal genetic testing. By simple deduction, if a disease is only discovered after a child is born, it cannot be preexisting. The dark side of this logic is that many diseases could be discovered and treated early, sparing the child and others the dangers and harm that ignorance brings.

Individuals who have participated in genetic screening may be discriminated against by employers or insurance companies who obtain certain information during background

investigations. They could be turned down for jobs or health care. Genetic counselors in responding to requests from the potential employer, insurer or health care provider could expose themselves to liability from the discriminated individual for the release of such information.

Prospective parents may be denied insurance coverage because they are carriers of a genetic trait, even though there is no risk to the parent's health and little risk that the trait will be passed on to their children.[34]

There is also the simple concern that society will discriminate against what it considers to be an inferior individual. Even though a genetic deviation may have no impact upon the individual, he or she could be considered inferior or suspect as a carrier of a genetic disease which may never manifest itself.

Confidentiality is also important for offspring. Existence of a genetic problem in a parent does not determine that his or her children will also have it. Yet, discrimination has occurred in such cases. For example, a twenty-eight year old lawyer was denied insurance coverage because her father was incorrectly diagnosed with Huntington's disease.[35]

Due to the potential for misuse of genetic information by insurance companies and employers, Congress has considered passing the Human Genome Privacy Act.[36] Additionally, some states have also enacted or are considering enacting laws to prevent discrimination by employers or insurance companies based on genetic information.[37]

III. NEED FOR REGULATION OF GENETIC SCREENING AND COUNSELING

What is evident from our admittedly limited analysis of the issues created by genetic screening and counseling, is the need for regulation. Without specific requirements or regulations, public policy will not be furthered, standards will not be established and individuals will end up hurt by improper use of the technology. One of the greatest dangers comes from a lack of regulation of researchers who may not be conscious of the large scale impact of their work.[38]

Currently, only 10 states in the United States have specific requirements for the licensing of clinical laboratories providing and analyzing genetic tests.[39] On the federal level, the United States Congress enacted the Fertility Clinic Success Rate and Certification Act of 1992.[40] This law establishes a certification program for fertility clinics and prohibits misleading claims of pregnancy success rates. Genetic counselors who make false or misleading claims about their pregnancy success rates can endanger their certification and expose themselves to civil liabilities.

Regulation is important, because without proper regulation there is the very real threat that genetic tests will be interpreted by primary care physicians, instead of genetic specialists, leading to inaccurate results and decisions based on those results.

Several nations have begun to regulate this rapidly advancing technology. England, for example, set up a national commission to debate issues such as genetic privacy and reproductive technology.[41] France is currently enacting broad legislation that will cover prenatal genetic screening and other biomedical advances. The purpose of France's

legislation is to ensure that public policy decisions resulting from the advances of biomedical science are subject to public scrutiny rather than being decided on a case-by-case basis.[42] The proposed legislation calls for the creation of a National Consultative Commission on Ethics for Life Sciences and Medicine. This commission would render advice and publish opinions regarding ethical problems raised by research and practice in the fields of biology, medicine, and health.[43] The legislation even includes penal and administrative sanctions to ensure compliance.[44]

IV. CONCLUSION

One of the benefits of litigation is that the results are far reaching and felt by the public at large. In fact, the public as a whole is benefited, whether because of improved medical procedures or increased protection of individual privacy. As individual cases are brought before the courts, the professional discipline is shaped and a clear definition of what is acceptable, what is expected and what constitutes negligence or malpractice emerges. These are in turn brought to the attention of other practitioners or members of a state's legislature. A standard of care and a course of conduct is established. New laws are established based upon situations brought to light by individual events and decisions made by the courts as to whether a counselor acted correctly or not.

Although we cannot set forth all of the standards, rules and laws that should be enacted with respect to genetic screening and counseling, we have attempted to bring to light some areas that must be considered. As the profession of genetic counseling continues to

grow, additional standards of care for the profession will be established and what is acceptable will become clearer.

NOTES

1. The Human Genome Project was initiated by United States Congress in 1989. However, work on deciphering the human genome is also being conducted in other countries, such as those coordinated by the Human Genome Organization in Europe.
2. Benjamin P. Sachs & Bruce Korf, The Human Genome Project: Implications for the Practicing Obstetrician, 81 Ob. & Gyn. 458 (1993), Kimberly Nobles, Birthright or Life Sentence: Controlling the Threat of Genetic Testing, 65 S. Cal. L. Rev. 2081 (1992).
3. Kate Thomas, Marriage in the Works for Biology, Electronics, Hous. Post, Apr. 14, 1993, at B1, Assessing Genetic Risks: Implications for Health and Social Policy ch. 2 at 1-5 (Lori B. Andrews et al. eds., 1995.
4. Larry Thompson, Cell Test Before Implant helps Ensure Healthy "Test Tube" Baby. Washington Post, April 27, 1992, at A3; Alan H Handyside, et al, Birth of a Normal Girl After In Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis, 327 New Eng. J. Med. 905 (1992).
5. Vicki G. Norton, Comment: Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation, 41 U.C.L.A. Law Review 1581, 1600, (1994).
6. Id. at 1600.
7. Fraser, Genetic Counseling, 26 Am. J. Human Genetics 636, 637 (1974).
8. Benjamin P. Sachs & Bruce Korf, The Human Genome Project: Implications for the Practicing Obstetrician, 81 Ob. & Gyn. 458 (1993).

9. Until approximately mid 1994 board certification for master's level genetic counselor's was conducted by the American Board of Medical Genetics. Board certification is now conducted by the American Board of Genetic Counselors.

10. The terms "patient" and "counselee" will be used interchangeably throughout. The term "patient" merely reflects that the specific facts or situation discussed arises from a medical setting.

11. Counselees are not limited to those prospective parents with a history of genetic disorders. As genetic counseling grows in acceptance, more couples are being tested prior to conceiving children as a general precaution, not because of a known problem in their genetic history. Also, most states now have mandatory genetic testing for certain diseases.

12. See Stewart v. Long Island College Hosp., 58 Misc. 2d 432, 296 N.Y.S.2d 41,48 (Tr. T. 1968), modified, 35 App. Div. 585, 313 N.Y.S.2d 502 (1970), aff'd 30 N.Y.2d 695, 283 N.E.2d 616, 332 N.Y.S.2d 640 (1972).

13. 42 N.Y.2d 109, 366 N.E.2d 64, 397 N.Y.S.2d 363 (1977).

14. 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978).

15. 48 U.S.L.W. 2112 (Penn Super. 1979).

16. See Comment, "A Cause of Action for 'Wrongful Life,'" 55 Minn. L. Rev. 58 (1970). See also Ploscowe, "An Action for 'Wrongful Life,'" 38 N.Y.U.L. Rev. 1078 (1963).

17. The term "wrongful life" was a play on the statutory tort of "wrongful death." It designates the complaint of the child born with genetic disorders against the physician, as opposed to "wrongful birth," which is the complaint of the parents of

the child. See P. Reilly, Genetics, Law, and Social Policy. See also Comment, Wrongful Life: A Misconceived Tort, 15 U.C.D. L. Rev. 447, 449-51 (1981).

18. 49 N.J. 22, 227 A.2d 689 (1967).

19. Id. at 31, 227 A.2d at 693.

20. 410 U.S. 113 (1973).

21. 519 S.W.2d 846 (Tex. 1975).

22. 60 A.D.2d 587, 400 N.Y.S.2d 119 (1977), modified, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978).

23. 60 A.D.2d 580, 400 N.Y.S.2d 110 (1977), modified, N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978).

24. Campbell v. United States, 962 F.2d 1579, 6 Fla. Law W. Fed. C. 689, (1992).

25. Mackey v. United States, 8 F.3d 826, 303 U.S. App. D.C. 422 (1993).

26. Capron, Tort Liability in Genetic Counseling, Columbia Law Review, 1979, Vol 79:618, 628.

27. See also P. Kelly, Dealing with Dilemma: A Manual for Genetic Counselors (1977).

28. 5 USC §552a (1988)

29. Norton, 41 U.C.L.A. 1581, 1584. (1994)

30. Restatement (Second) of Agency §214 (1958).

31. 79 Columbia Law Review 618, fn. 94.

32. See R. Veatch, Case Studies in Medical Ethics 129-31 (1977); Bohlen, The Moral Duty to Aid Others as a Basis of Tort Liability, 56 U. Pa. L. Rev. 217 (1908). But see L. Fuller, The Morality of Law 9 (rev. ed. 1969) (law ought not convert aspirations for excellence into binding duties.)

33. Michael J. Malinowski, Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening, 45 Hastings Law Journal 1435, 1508, n. 218, (1994).

34. Beth Healy, Genetic Testing has Attention of Insurers, Boston Bus. J., Oct 11, 1994, at 4.

35. Vicki Quade, Protecting the Essence of Being, Barrister, Summer 1993, at 9.

36. H. R. 2045, 102nd Congress, 1st Session (1991).

37. Several states have enacted laws prohibiting an employer from requiring an employee to take a genetic test or from discriminating against an employee who has taken a genetic test. Iowa Code §729.6(2) enacted in 1993, R.I. Gen. Laws §28-6.7-1 (1993), Wis. Stat. §111.372 (1993).

38. For example, at the 1991 Human Genome conference in San Francisco, the issue was raised as to whether Japan is playing unfairly by claiming they have made discoveries before they actually have. This has led to the United States claiming that perhaps Japan should e cut out of any international information exchange on the genome. George J. Annas, Mapping the Human Genome and the Meaning of Monster Mythology, 39 Emory L.J. 629 (1990).

39. Assessing Genetic Risks: Implications for Health and Social Policy, ch. 3 at 2, (Lori B. Andrews, et al, eds, 1995 (prepublication copy dated Nov. 4, 1993).

40. 42 U.S.C.A. §263a, et seq. (1993).

41. The Warnock Commission helped enact legislation in 1990 in the United Kingdom.

42. Richard Saltus, Law on the Biomedical Frontier, Boston Globe, Oct. 22, 1993 at 18.

43. Bill Adopted by the National Assembly, No. 67, 1st Reg. Sess. (1992-1993).

44. Id. art. 13 (to be codified at VI Pub. H. code tit. III, ch. 2, art. L 682-9.)