LESSONS LEARNED

Risk Management Issues in Genetic Counseling

Susan Schmerler

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Susan Schmerler, M.S., J.D.

Children's Hospital of St. Joseph's Regional Medical Center, Paterson, New Jersey

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Susan Schmerler
St. Joseph's Hospital and Medical Center,
Paterson, NJ, USA
Email: schmerler@sjhmc.org

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For my F1 and F2 generations

Preface

I was sitting at the dining room table, eating brownies and brainstorming about my future with my sister, when the old, familiar question came up: What do you want to be when you grow up? That is not an easy question for a 20-something-year-old with two children to answer. Darwin's finches and speciation were my favorite subjects in graduate school. I had done laboratory work, and decided that it wasn't for me. The options for someone with a Master's degree to work in genetics outside the laboratory in the 1960s were limited. Go to medical school was one suggestion I heard. As I finished cleaning my plate, I thought about it. Medical school was a big commitment of time and energy, and then what could I do once I finished? That was about the time that the *New York Times* published an article highlighting the new Sarah Lawrence College training program in human genetics. I could teach at that program if I had a medical degree. Wow! A light bulb went on in my brain. I won't teach those students; I'll be one of them! My future was sealed.

In the context of medical care specialty professions, genetic counseling is the newcomer at the table. Dr. Melissa Richter created the role and directed the first training program at Sarah Lawrence College in 1969.[1] The profession of genetic counseling was conceived as a method for delivering genetic counseling and testing services more efficiently to patients with genetic disorders. The field of human genetics was beginning to identify and understand a growing number of disorders. The role of a patient advocate, that of helping people understand the medical and genetic information being provided, was seen as a needed addition to the medical genetics team. I came to genetic counseling relatively early, having seen that article in the newspaper. I graduated from Sarah Lawrence College in 1974.

In 1975, the *ad hoc* Committee on Genetic Counseling of the American Society of Human Genetics (ASHG) defined genetic counseling 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 to (1) comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; (3) understand the options for dealing with the risk of recurrence; (4) choose the course of action which seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and (5) make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.[2]

This is the statement that defined our profession until relatively recently, when an updated definition was published by a Workgroup of the National Society of Genetic Counselors (NSGC).[3]

Training programs for genetic counselors are at the Master's Degree level in human genetics and/or genetic counseling. Since the first training program began at Sarah Lawrence, the number of programs in the United States and Canada had expanded to 30 in 2006.[4]

Practitioners usually turn to colleagues for support when professional issues or questions arise. Genetic counselors practicing in the 1970s felt the need for an organized way to address these common issues. A professional society was considered the best way to meet these needs, to enhance communication among genetic counselors and to promote the profession.

A group of counselors met at Sarah Lawrence College to discuss forming such a professional organization. One of our first challenges was to choose the title for our work and decide how we would address ourselves. Various titles were being used at the time: genetic associate, genetic assistant, genetic counselor. The process of defining ourselves was not as painless as it may sound. We had long discussions among ourselves and with our medical colleagues. We finally agreed to call ourselves genetic counselors. The name of our future organization was to be the National Society of Genetic Counselors, and the *ad hoc* Committee to Form the National Society of Genetic Counselors (NSGC) was established. As a member of that first committee, I worked on the by-laws and membership guidelines. I consider myself a founding mother of the NSGC, which was incorporated in 1978.

As the fields of medical genetics and genetic counseling continued to mature, the need to establish standards for practitioners and for their training was recognized by members of the genetics community. Certification and accreditation processes were developed. Medical geneticists, clinical geneticists and genetic counselors were included in the certification process that was established by the American Board of Medical Genetics (ABMG).

The first group of candidates sat for the board certification examinations in the winter of 1981. As is still the case, everyone took the same general genetics examination, and then sat for a second examination in a specialty field. Genetic counselors sat for a specialty examination in genetic counseling. There was no grandfathering of practitioners for experience or longevity. No one was exempt from the certification examinations. It was strange to sit in the same room, taking the same examination, as the men and women who had written the genetics books we all had to study.

Over time it became clear to the ABMG that recognition by the AMA as a specialty board would enhance the status of medical genetics. In order to meet the requirements, the ABMG would no longer be able to certify anyone who did not have a doctoral degree. The ABMG had to withdraw from certifying genetic counselors, and the American Board of Genetic Counseling (ABGC) was formed in 1993. The ABGC now has the sole responsibility of certifying genetic counselors and for accrediting graduate genetic counseling training programs. As the genetic counseling profession has continued to mature and grow, so have the visibility, responsibility and liability of genetic counselors.

During the early years when genetic counseling was establishing itself as a recognized profession, the legal profession was using the tort liability system as a means to aid the consumer. Tort law, of course, has been available to individuals for centuries. It was transformed, however, by a number of legal theorists who believed that consumers were unaware of the risks they took and were settling for less safety from products and healthcare than they should. The costs of preventing accidents and of paying for those accidents that do occur, these theorists suggested, should come from the manufacturers of goods and the providers of health care. Their intended goal was to deter substandard manufacturing and medical practice by requiring that compensation be paid to individuals harmed by faulty products and to patients wrongfully injured by healthcare providers.[5]

Prior to the early 1960s, malpractice litigation was very rare. The number of tort litigation rates rose dramatically in the 1970s. Figure 1 illustrates the rising numbers of lawsuits and claims against physicians since 1970. Not only has the number of cases filed increased since that time, but the damages awarded in those cases have increased as well.[6]

Figure 2 illustrates the increased amount of jury awards and settlements between 1993 and 2000. As can be seen in the figure, the median size of the damages awarded to plaintiffs more than doubled over the years. Total payouts reported by members of an insurance trade association can be seen in Figure 3. Payments of $1 million or more increased from 3% to 8% of the total claims paid. One of the outcomes of this system has been an increase in price of some goods and a decline in the availability of some services. The question has now become how a system that was developed to increase safety and deter dangerous practices could result in a burden on those who work to help others.

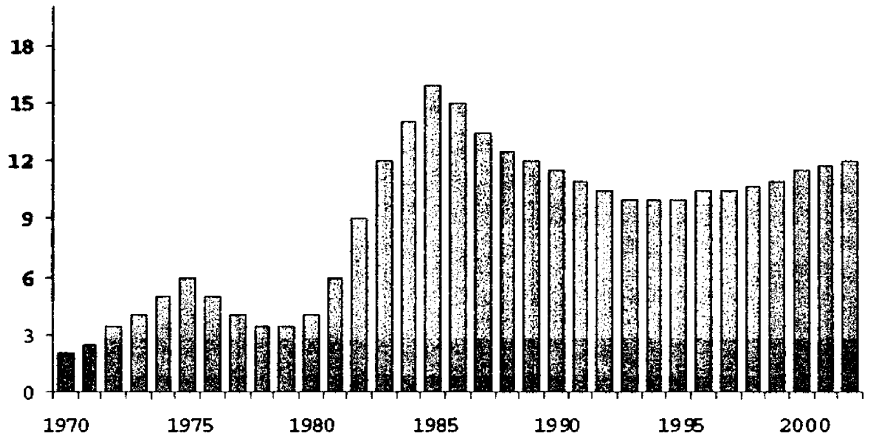

Fig. 1 Conceptual trend in the number of lawsuits and claims against physicians synthesized from the AMA data and other resources.
Source: From: Bovbjerg, R.R., and Bartow, A. (2003). *Understanding Pennsylvania's Medical Malpractice Crisis: Facts About Liability and Insurance, the Legal System, and Health Care in Pennsylvania*. Pew Project on Medical Liability.

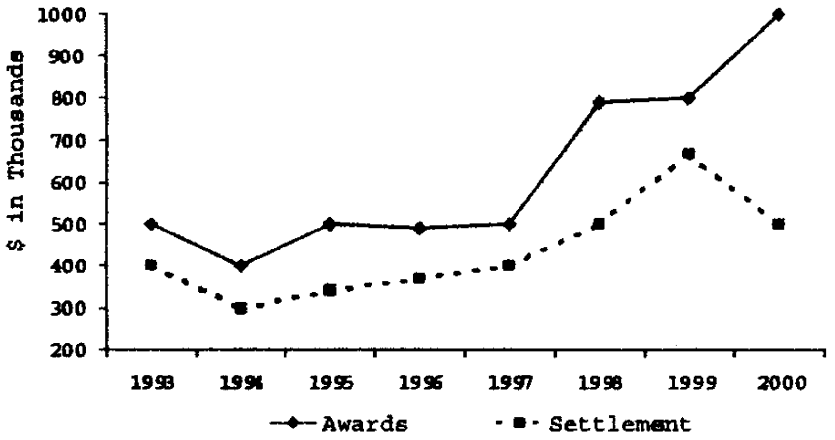

Fig. 2 Reported U.S. median medical liability awards and settlements.
Source: From: Bovbjerg, R.R., and Bartow, A. (2003). *Understanding Pennsylvania's Medical Malpractice Crisis: Facts About Liability and Insurance, the Legal System, and Health Care in Pennsylvania.* Pew Project on Medical Liability.

A comprehensive research study on medical error and malpractice litigation done in 1990 by the Harvard Medical Practice Study demonstrated a lack of agreement between the occurrence of actual medical negligence and the initiation or resolution of legal claims. One out of eight occurrences of negligence (as judged by the study team) led to malpractice lawsuits. Half of the plaintiffs in those lawsuits received damages. For every valid claim filed, about six were filed over non-negligent care.[7]

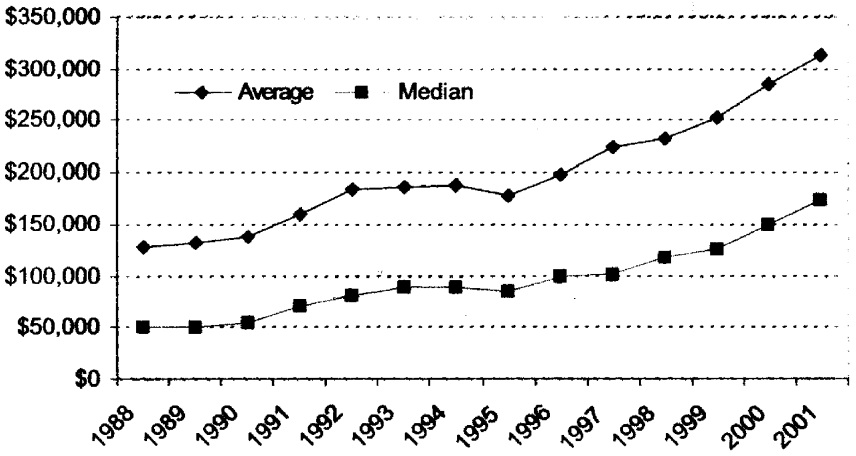

Fig. 3 Amount of money paid out to plaintiffs between 1988 and 2001.
Source: From: Bovbjerg, R.R., and Bartow, A. (2003). *Understanding Pennsylvania's Medical Malpractice Crisis: Facts About Liability and Insurance, the Legal System, and Health Care in Pennsylvania.* Pew Project on Medical Liability.

There is no evidence that malpractice suits are a reliable indication of bad medical practice or inadequate providers. Litigation outcomes correlate more with the extent of the patient's injury rather than the fact of medical negligence. In comparing claims in obstetrics and nonobstetric cases, for example, Ross[8] reports that obstetric anesthesiology claims contain a significantly higher proportion of what might be considered "minor" injuries, such as headache, back pain, pain during anesthesia, and emotional distress. The incidence of claims of "major events" (such as nerve damage, aspiration, death) was similar in the two groups of patients. The number and amount of paid claims are only weakly predictive of future litigation for any one individual professional.[9] In any given year, 2% of the claims filed are responsible for about 50% of the damages paid to plaintiffs. Lawsuits are very costly to defend, averaging about $23,000.[10]

I personally found this situation very alarming. In order to better understand the process and obtain insight into the medical negligence situation in greater detail, I decided to learn more about the legal system. It was a long haul, and I had major support from my family and colleagues over the four years going to law school took. It became clear to me that the best way a practitioner has to protect herself is to understand the risks of practicing her profession. This understanding would help her avoid as many risks as possible. Since I passed the bar in 1995, I have been teaching and lecturing genetic counseling professionals about risk management issues and techniques. One step in avoiding liability is to understand risk management. The present book is the result of my understanding of the legal system and the ways in which genetic counselors can negotiate the "potholes" in our day-to-day practices.

In the material that follows, the feminine pronoun is used in the manner of the practice of the legal literature. Some of the points raised may seem obvious, but they need to be said. Some issues may seem to be common sense, but they are not always taken as seriously as they should be. The content of this book has been prepared for educational and information purposes only. It is not to be considered or used as legal advice or a legal opinion on any specific matter. Any specific or personal questions you may have about your practice should be discussed with your attorney or risk manager.

Acknowledgements

I always wondered why authors had such a long list of "most grateful to," "was invaluable in," and "owe a debt of gratitude to." Now I know. Unless you live on an isolated island in the middle of nowhere, a project like this one does not get completed without a lot of support. So, here are my deep appreciations:

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Kenneth M. Morris, Jr., drew the cartoons. He is a medical illustrator and graphic designer, with work published in numerous medical books, magazines and journals. Mr. Morris has a BFA degree in Medical Illustration from the Cleveland Institute of Art in partnership with Case Western Reserve University, an MA degree from Montclair State University, and an MHA degree from Seton Hall University. He is an Adjunct Professor of Art at William Paterson University.

Contents

"I'm your genetic counselor, and this is my attorney."

Chapter 1
Introduction

One day many years ago, when the risk manager from my hospital knocked on my door asking for a patient's chart, I experienced palpitations. The case involved a patient who had been seen because she had a child with a chromosome abnormality. She wanted and had an amniocentesis. When the laboratory reported an elevated amniotic fluid alpha-fetoprotein level, I had arranged for a targeted ultrasound scan at another institution. The level of ultrasound scan needed was only offered by a few experienced centers at that time.

Instead of keeping the scheduled ultrasound scan appointment, the patient went for an abortion. The patient planned to sue the institution, and me, for malpractice. What had I said to her? What did she misunderstand? Could I have handled the situation in a way that would have resulted in a different outcome? I did not understand it then and am not sure even now why she had the abortion or why she thought there had been malpractice. It was an unpleasant several weeks for everyone involved.

No one likes to be sued. A lawsuit is an assault on one's self-image and reputation. It is physically and financially draining. We do not, however, want to spend our professional lives looking over our shoulders. In the following pages, we will look at the day-to-day practices of genetic counselors and try to identify areas in which possible sources of liability can be found. We will discuss how a genetic counselor can change her behavior and possibly minimize her exposure to lawsuits. No one is exempt from the experience. Although there are no assurances that you or I as individuals or as members of a team will never be named in a lawsuit, we want to heighten our awareness so that we can say with conviction that nothing we have done has left us vulnerable to being sued.

One formal purpose of a medical malpractice lawsuit is to encourage practitioners to avoid injuring patients by refining and reshaping their practices. Everyone benefits from the prevention effect of such lawsuits. A medical malpractice lawsuit is also supposed to provide compensation for injuries, although very few people actually receive compensation. Finally, these lawsuits are meant to uphold the traditional values of justice and responsibility, which hold people accountable for their actions. The process of litigation is available to determine the existence or absence of liability when there is a dispute between parties.

A healthcare provider gets sued because a patient/client thinks she has been harmed in some way. Her issues can be expressed through a number of different

legal actions, such as breach of contract or negligence. The profession of genetic counseling has developed as a specialty within the general field of medicine. The majority of genetic counselors work in a medical setting, so that a medical model usually applies to how we practice. We expect, for example, that a formal complaint by a patient about a genetic counselor for what has been done or not done will come under the laws that apply to medicine as opposed to business. Most commonly, complaints take the form of a lawsuit that claims malpractice or negligence.

The medical malpractice system works to discourage or minimize injury to patients, and to keep any injuries to a socially acceptable level. There is an underlying assumption that individually oriented financial liability will work as a deterrent, and will prevent future patient injuries. The failures and limitations of this type of system are beyond the scope of our discussion here. We are going to look at a general negligence lawsuit and consider how it would concern a genetic counselor. In that way we can identify and get to know where the potholes may be, and plan how we may avoid them in the first place. We will also look at specific lawsuits that have been heard by the courts. These can be used as the basis of our lessons learned.

The outcome of lawsuits with similar claims and facts is not always predictable or consistent among the states. In *Becker* v. *Schwarz*,[11] the parents of a child with Down syndrome were suing for a failure to counsel on the increased risk of advanced maternal age and the failure to refer for genetic counseling. The New York court allowed the parents to recover damages for the cost of the treatment for their child. One year later in New Jersey, in *Berman* v. *Allan*,[12] the New Jersey court ruled that the parents of a child with Down syndrome born to a woman who was over 35 years of age could recover for emotional, but not economic, harm.

Lawsuits do not always go away. A good example is the case of *Moscatello et al.* v. *University of Medicine and Dentistry of New Jersey et al.*[13] In that case, the parents of a child born in 1982 with an unbalanced chromosome 14/18 translocation settled a wrongful birth suit against the geneticist who counseled the family and who had ordered the mother's chromosome analysis. A wrongful birth suit is a lawsuit brought by parents of a child born with a defect or a disease that they allege was caused by some act of negligence.

The settlement in the original *Moscatello* case was for emotional harm and the cost of extraordinary medical expenses. Fourteen years later, the family again brought a wrongful birth claim seeking more money. The family also brought a wrongful life claim in the name of the child. A child who is born with a defect or a disease alleges in a wrongful birth case that he or she should have been born without the problems at issue. The *Moscatello* wrongful life claim was for extraordinary medical expenses. Although the wrongful birth claim was barred by the previous settlement, the court allowed the wrongful life suit to go forward. Having a case brought up a second time imposes an emotional and financial toll on the provider who had thought the case was settled and over.

Medical malpractice case law does not always relate specifically to the area of genetics or to the profession of genetic counseling per se. In the following discussion, we will be looking mostly at cases that address medical issues that could, and may, be applied to genetics and genetic counseling. Some of the cases that will be discussed are very old. They are important for the lessons we learn from them. Some

cases have historic value, some have set precedence, and decisions in some are still valid. The cases we will refer to or talk about do not represent all those that have been filed. I have chosen those that I thought are good illustrations of a point of law or an area of practice. They may not all have references to legal catalogs, since some have been settled prior to being presented to a jury.

Keep in mind that when you read "genetic counselor" or "genetic counseling" in a case discussion, it may refer to a wide range of providers (M.D., Ph.D. or M.S. geneticist) and services (clinical, laboratory, research). The genetic counseling and genetic centers referred to in some cases may not necessarily be what we know of as genetic services today. The principles raised by these cases, however, still apply.

Chapter 2
Sources of Liability

2.1 Forms of Legal Complaints

You get sued because someone (the plaintiff) thinks you (the defendant) have harmed her in some way. The plaintiff's issues can take different forms. Below is a brief introduction to some of the causes of action or forms these lawsuits can take. We will discuss some of these later in more detail as they apply to our day-to-day practice.

2.1.1 Tort Law

One of my neighbors drove a truck across my lawn so that he could trim the trees on his own property. My grass was torn up and the ground was left with deep ruts. My neighbor had knowingly damaged my property.

A tort is a civil wrong or injury for which the law provides a remedy. The wrong can involve individuals or a company, as opposed to an individual and some level of the government. The injury may be a wrong committed against a person, such as a bad faith breach of contract, or against a person's property, such as my lawn. It may be either a direct invasion of some legal right of an individual, an infraction of a public duty, or the violation of some private obligation. The wrong or injury has to be one that is recognized by the law and for which a court will provide a remedy (damages).

The remedy for the injury, the damages paid, is the compensation of the plaintiff. Damages are generally intended not so much to punish the tortfeasor, the negligent defendant, but to restore the injured person as nearly as possible to the position she would have been in had the wrong not occurred. The fundamental policies of tort law are (1) to compensate the victim, (2) to deter negligence, and (3) to encourage due care. One basic purpose of tort law is to keep the peace between people with issues by providing a mechanism for finding fault for wrongdoing and preventing individuals from seeking vengeance. In my case, my neighbor had to resod my lawn.

A number of forms of torts are applicable to health care and are reviewed below.

2.1.1.1 Malpractice

Negligence is the failure to comply with the standard of care to protect a person from harm. It may result from the performance of an act, which is an error of commission, such as removing the healthy kidney from a person with a multicystic, displastic kidney. It can also result from a failure to act, which is an error of omission, such as not obtaining an allergy history for a patient before administering penicillin.

The determination of whether a person was negligent requires a comparison of her conduct to a standard of care. If that conduct is found to have fallen below the accepted standard of care, then that person was negligent. Malpractice applies to all professions, and is called professional negligence. Negligence in medical practice is called medical malpractice.

An individual who thinks she has been injured by the malpractice of a health-care provider may bring an action against that provider for compensation. The time period within which a person has the opportunity to bring a malpractice action is set by state statute (statute of limitations). In the past, the statute of limitations for malpractice actions was often considered to begin at the time the treatment was rendered. That would be the time of the surgery during which the wrong kidney was removed.

Not everyone realizes, however, that she has been injured within that time frame. To avoid precluding justified claims for injuries that were not discovered until after that time period had elapsed, many states have rewritten their statutes of limitations. The revised statutes allow the time period to begin when the patient discovers the fact that medical malpractice has occurred. A woman whose Pap smear was misread would not necessarily know that at the time the test was performed. She would find out or discover that fact at the time she was diagnosed with advanced cervical cancer three years later. Under a revised statute of limitations, the time period for bringing a malpractice action would begin with the discovery of the error, not when the laboratory actually incorrectly read the preparation. Many of the negligence cases mentioned here were foreclosed by the statute of limitations in existence at the time of the case.[14]

Everyone wants and expects a normal, healthy child. We often meet people in our practices who do not realize that 2%–3% of all children are born with a major problem. As we have also experienced sometime in our careers, families look for someone (the mother, the doctor) or some thing (the bug spray, the evil eye) to blame when it is their baby who has been born with problems. Some birth defects or diseases could have been anticipated through counseling or testing. Others could have been avoided through alternative pregnancy management. Sometimes the problems that babies are born with can, with certainty, be attributed to malpractice.

A. Wrongful Birth

Wrongful birth suits can be brought by the parents of an unwanted child (these are also called wrongful pregnancy suits) or the parents of a child born with a disease or

defects. A wrongful pregnancy suit usually involves a failed sterilization, with the birth of an unplanned, unwanted, but healthy child.[15]

Some wrongful pregnancy suits involve the unplanned pregnancy and birth of a child with a genetic disorder or birth defect. For example, following failed sterilization of either the man or the woman, a child has been born with alpha-1 antitrypsin deficiency (*Weethee* v. *Holzer Clinic*, *Inc*.),[16] albinism (*Pitre* v.*Opelousas General Hospital)*,[17] neurofibromatosis (*Speck* v. *Finegold*)[18] and a congenital heart defect (*Simmerer* v. *Dabbas*).[19]

We will be looking mainly at those lawsuits brought by families affected by the birth of children with defects or diseases.

Prior to *Roe* v. *Wade*,[20] wrongful birth suits alleged that the physician's negligence, that is, her failure to act appropriately, was the proximate cause of the child's birth. After *Roe* v. *Wade*, the legal harm claimed in the majority of wrongful birth actions was not necessarily the birth of the child but the parents' lost opportunity to decide for themselves whether to continue the pregnancy of an affected fetus.

The parents' interest in self-determination has become the basis of these suits. Courts have found that a physician who negligently or intentionally withholds information about or misdiagnoses a disorder affecting a fetus has "impermissibly" deprived the pregnant woman and her partner of the opportunity to exercise the constitutionally protected right to make reproductive decisions. It also deprives these parents of the "opportunity to cushion the blow, mute the hurt, or prepare themselves as parents for the birth" of a seriously impaired child.[21] The duty considered to be owed to the parents of the child is based on the public policy of promoting family unity in making decisions. It is also based on the recognition that when such a duty is breached, both parents share the emotional and financial burdens of a child's care. The first recognized successful wrongful birth case was in 1975, *Jacobs* v. *Theimer.*[22] It involved a woman who contracted rubella during her pregnancy and was not warned of the possible consequences to the fetus.

Genetic counseling has become a more visible part of healthcare as it has been integrated into medical services in a variety of subspecialties. Errors in obstetrics and gynecology, family practice and internal medicine, for example, can impact the outcome of a pregnancy. In a case of negligent genetic counseling, the plaintiff would have a number of actions she could pursue. She could allege that the genetic specialist, or other healthcare professional offering genetic services, has failed to inform her that she was at an increased risk of having an affected child based on the fact that that there was a genetic disorder in the family or on the basis of her ethnic background. She could claim that there were tests that were available but not offered that could have determined whether a disease or birth defect was present, or that the testing that was done was improperly interpreted. She could claim that tests were done but the results were not communicated to her. Birth defects could be attributed to medication used during pregnancy that was/may have been harmful to the fetus.

Park v. *Chessin*[23] is a good example of a negligent genetic counseling case. The Parks were parents of a child who died at 5 hours of age with polycystic kidney dis-

ease (PKD). They were told the recurrence risk for PKD was "practically nil." The parents accepted that risk, relied on the information provided and had a second child. The second child was also affected and she died at age 2 years. A second example of negligent genetic counseling is *Lininger* v. *Eisenbaum.*[24] The physicians in this case failed to diagnose the first child's blindness as Leber's congenital amaurosis before a second affected child was born.

These cases illustrate the expansion by the courts of the definition of breach of duty to include the deprivation of the parents' right of choice through the absence of or negligent provision of genetic counseling. Parents were found to have the right to recover for that tort of deprivation of their rights. We will be discussing other cases of negligent genetic counseling as they relate to aspects of our practice.

The plaintiff in a wrongful birth action does not need to prove that the doctor's negligence caused the defect or disease. She must prove that her emotional and economic injuries were proximately caused by the negligence that deprived her of the opportunity to decide whether or not to continue the pregnancy.

B. Wrongful Life

Have you ever pondered the question of why you were born, or how you came to be you? These are philosophical questions that courts of law rarely address. More concrete claims concerning having been born, however, have come under consideration by the courts.

Wrongful life suits are brought by children born with birth defects or disease who claim they should not have been born at all, or having been born, should have been born whole (free of disease or defects). The infant or child does not claim that the physician caused her disease or her birth defects. Her claim is that the physician's negligence failed to identify the problems, thus allowing her to be born into a life of suffering. The child claims she was harmed by being born impaired.

There have been very few successful wrongful life suits. They are almost uniformly rejected by state courts. In *Phillips* v. *United States*[25] and *Speck* v. *Finegold*,[26] the parents' claims were recognized, but the affected children's claims were not. A major exception was the 1980 case of *Curlender* v. *Bio-Science Laboratories.*[27] The plaintiffs claimed that the laboratory did not properly perform Tay–Sachs disease carrier testing and misinterpreted the test results. They were not identified as a carrier couple. The parents had a child with Tay–Sachs disease. That court found that a child born with Tay–Sachs disease has the right to recover for the pain and suffering she would have to endure during her lifetime.

The New Jersey Supreme Court, in the case of *Gleitman* v. *Cosgrove,*[28] is quoted most frequently by other courts when explaining why wrongful life cases should not be recognized. The New Jersey court rejected the child's cause of action for wrongful life because it thought that damages in such a situation were impossible to ascertain. Remember, the definition of a tort is a cause of action

for which damages can be awarded. The court in *Gleitman* refused to weigh the value of life with impairments against nonexistence. In the court's view, nothing the defendants in a wrongful life lawsuit could have done would have given the child plaintiff an unimpaired life. That is, if the defendant had performed her job properly—for example, interpreted the parents' test results correctly—the child would not have been born unimpaired; instead, she would not have been born at all.

In contrast is the interesting "Perruche judgment" in France. This judgment established the right not to be born in a case of misdiagnosis of rubella during pregnancy. Public opinion was so strong against the decision that the outcry caused the judgment to be overruled by a majority of the National Assembly of the French Parliament.[29] More recently, wrongful life claims have been recognized for extraordinary medical expenses (see *Moscatello*).[30]

Claims by or on behalf of children are typically tolled. That means that the statute of limitations that would ordinarily apply to the cause of action is suspended. It does not begin to run during the child's minority. Traditionally, injured children can bring claims up until they are 23 years old—once the child becomes 21 years old plus the typical two-year statute of limitations for malpractice actions. These claims can be brought by the child only if no action has been brought on her behalf by her parent or guardian.

2.1.1.2 Unauthorized Disclosure of Confidential Information

An acquaintance of mine received a telephone call from a friend who worked as a hospital clerk. My acquaintance's brother was a patient in that hospital. This individual thought my acquaintance would want to know that her brother had HIV/AIDs. There was no signed release, the brother is an adult, and the clerk had no authority to access his medical records. My acquaintance has not shared with her brother the fact that she has this knowledge.

The causes of action that may be brought for the unauthorized disclosure of confidential information include breach of privacy, breach of confidentiality, breach of loyalty, breach of contract (discussed in more detail below) and breaches listed in some state statutes.[31] A communication that is confidential is one that has been shared with the intention of keeping it secret. A person seeking medical attention has an expectation of confidentiality based on the physician–patient relationship.

Violation of privacy was claimed in *Bazemore* v. *Savannah Hospital*)[32] for the unauthorized production and publication of photographs of the plaintiff's child, who was stillborn with malformations. Breach of fiduciary duty was claimed in *MacDonald* v. *Clinger,*[33] when a patient's psychiatrist disclosed to the patient's wife some personal information that was learned in the course of treatment. Such a disclosure may have been justified if there had been a danger to the patient, his spouse or another person, but since these conditions did not exist, the psychiatrist was found to be liable for breach of fiduciary duty.

The physician–patient relationship has also been privileged, and thus protected, by state laws. As a rule of evidence, it gives the patient the right to exclude from evidence communications made by her to her doctor. Violation of this privilege is a statutory breach. The confidentiality of a patient's medical records would be waived only if a malpractice suit was filed (see below).

2.1.1.3 Informed Consent

When I had genetic testing myself many years ago, I had to sign a consent form. Careful reading of that form revealed that the confidentiality of my test results was actually not well protected. I wanted the test and no other laboratories offered the analysis. I signed the consent form anyway. I have since been informed that my sample has been used for research purposes.

When a patient has a genetic test, the results can be straightforward or they can be unusual. We often see this, for example, with testing results for breast cancer genes and for cystic fibrosis mutations. Amniocentesis, when done for any reason, can reveal chromosomal abnormalities that are not common and are not common knowledge. More than one of my patients has been referred for counseling when her amniocentesis results were not normal, although I had not seen her prior to her testing. Sometimes I find that the patient does not know what a normal chromosome is, let alone what a chromosomal abnormality means. It makes me wonder how, with such a lack of understanding and information, she could have given informed consent for a procedure that is designed to count and look at chromosomes.

A claim based on the doctrine of informed consent is predicated on the patient's right to self-determination—the right to make personal decisions. The doctrine of informed consent is rooted in the premise that every adult with a sound mind has a right to determine what will be done with her own body.[34] As we will discuss in greater detail later, a healthcare provider has a duty to disclose information to a patient that will enable that patient to make decisions about the options, risks and treatment involved in her care. The standard applied is what information a reasonable patient would want to know in order to make those decisions. The patient has to prove that there is a connection between the risk that was not disclosed to her and the harm that she ultimately experienced.

Informed consent actions are similar to wrongful birth causes of action in that they are based on a patient's right to determine for herself the course of her care. There are important differences, however. In an informed consent case, the plaintiff must show proximate cause by proving that the risk that was not disclosed actually occurred and was caused by the treatment. In a wrongful birth case, the plaintiff does not have to prove that the negligence was the medical cause of the birth defect or disease, only that the risk to the fetus that was not disclosed was material to her decision, that it occurred, that it was reasonably foreseeable, and that if she had known of the risk, she would have terminated her pregnancy.

2.1.1.4 Emotional Distress

We all worry about the emotional response of a patient when we offer presymptomatic testing. The protocols for Huntington disease testing have taken into consideration and have prepared for some of the expected emotional responses to positive and negative test results.[35] Not all practitioners realize that harms or injuries are not all physical. Mishandling a case or a test result can lead to outcomes for patients that cause great emotional harm. An award of damages for emotional distress has been recognized as one of the few avenues of compensation for tortuous conduct in wrongful birth cases (see *Berman*).[36]

The courts do recognize that the death or serious injury of a family member may often produce emotional distress, sometimes quite severe, in another member of the family. Early claims for emotional distress were not found to be compensable unless there was an accompanying physical manifestation, such as agitation or sleep disturbance. Courts have come to recognize that mental distress and emotional distress are just as real as physical pain. They also realize that placing a financial value on emotional distress is no more difficult than placing a financial value on physical pain (see *Berman* v. *Allan,*[37] *Schroeder* v. *Perkel*[38]).

In some situations, emotional distress can be anticipated. Every time a physician (or anyone for that matter) injures a child, it is foreseeable that the parents will suffer emotional distress. The physical and emotional ties between a mother and a fetus unite the two in such a way that a physician should anticipate that any malpractice that adversely affects the fetus will cause emotional distress to the mother. The father's interests have been found to be no less deserving of protection than the mother's. The physician's duty to the father is similar to that owed to the mother, as long as the father is sufficiently involved in the care of the pregnancy.

There have been attempts to extend wrongful birth claims to include members of the family other than the parents of an affected child. The grandfather of a child born with Tay–Sachs disease sued for emotional distress. The court pointed out that a grandparent does not have a physician–patient relationship with either the parents' or the child's healthcare provider. Although he may have been impacted by the claimed breach of duty, the grandfather has no legal basis on which to act regarding the information that resulted in the claim.

Grandparents have not been included along with the parents of an affected child as individuals who may recover for pain and suffering (*Michelman* v. *Erlich*).[39] Siblings have also attempted to bring wrongful birth lawsuits, but have been unsuccessful.[40] The duty of the healthcare provider is owed to the parents and the child with birth defects or disease, and at this time to no one else.

2.1.2 Fraud

The false representation of a material fact is fraud. In the nineteenth century, many medicines were marketed as panaceas or miracle cures. The ingredients were usually kept secret, unidentified or mischaracterized and mostly ineffective. The men who

touted these cure-alls, AKA snake oil peddlers, used exaggerated marketing as part of an elaborate and fraudulent scheme.

Fraud is the intentional distortion of the truth or deception through an act, omission or concealment in order to induce someone to give up a thing of value, such as money. It can be a single act or a combination of circumstances. The difference between fraud and negligence is that fraud is always intentional.

Fraudulent statements or intentional misrepresentation of results can, for example, include claims about what can be expected from a particular treatment, such as snake oil. The disappointed patient—the plaintiff claiming fraud—has to prove that the statements of reassurance were made with malice and were knowingly false. That can be based on an obvious existence of clinical findings, such as diabetes, which clearly indicate both before or after treatment that less-than-desirable results were inevitable.

2.1.3 Contract Law

A contract involves at least two parties, one who makes an offer of something, a product or a service (such as a consultation), and one who accepts the offer for a consideration or payment of a fee (such as a chicken). Contracts can be implied or express.

The relationship between a healthcare provider (physician, genetic counselor) and a patient (client) can be considered to be based on a contract in which there is an implied promise by the physician to the patient that the physician will function within the accepted standard of care. An express contract is created if the provider promises to cure the patient or to produce a specific result: "When we're done, you'll look like a movie star." Not making good on an express promise may be a breach of express contract or breach of warranty. Of course, not everything a provider says becomes a contract.

Healthcare professionals can find themselves subject to a contract if specific promises are made ("You'll be better than before."). Overzealous assurances to a patient by a healthcare provider can be construed by that patient as a guarantee of a cure or a good result. These assurances can be as mild as, "You will be fine," "You will return to normal," "You will improve considerably." Patients may transform such statements into firm promises in their own minds. An expressed guarantee of a stated result can create a contract (*Murray* v. *University of Pennsylvania Hospital).*[41]

In *Hammonds* v. *Aetna Casualty & Surety Co.,*[42] the claim was interference with contractual relations. The plaintiff threatened to file a malpractice suit, prompting his insurance company to induce the physician to disclose information without authorization. The insurance company was found to be liable for inducing breach of confidentiality. This breach of confidentiality lawsuit claimed that the promise of secrecy is as much an express warranty on the part of the healthcare provider as a commercial advertisement. Actions for breach of warranty are usually against the manufacturer of a product. *Horne* v. *Patton*[43] claimed breach of contract as well as breach of confidentiality when the physician released personal medical information about an employee to his employer.

	Statute of Limitations	Level of Proof	Damages
Negligence			Higher
Breach of Contract	Longer	Easier	

Fig. 2.1 Comparison of actions for negligence and breach of contract

2.1.3.1 Abandonment

In general, a provider does not have to provide care to anyone who requests it. Once a person is accepted as a patient, however, there is a duty to provide continuity of care. A suit claiming abandonment may be based on the contractual obligation to attend to the patient properly and continuously until care in the particular illness is no longer needed. Abandonment is the total neglect of a patient, or the failure to give any care or attention to a patient for an extended period of time. A physician may not unilaterally discontinue the care of a patient without proper notice to the patient and the opportunity for the patient to reasonably secure other medical care.

Malpractice suits are not often brought under contract law. Most courts think that negligence is the only type of lawsuit that applies to the physician–patient contract because malpractice constitutes a breach of duty to the patient by the physician. There are advantages to claiming breach of contract rather than negligence. Many personal injury actions against physicians for breach of contract are recognized as thinly disguised attempts to avoid the unfavorable aspects of tort actions that would apply for negligent medical care. Proof and procedural rules are easier for the plaintiff to comply with in a breach of contract lawsuit than in a negligence suit. The statute of limitations is longer for breach of contract than for tort actions. In breach of contract actions, a medical standard of care does not have to be shown and allegations of fault are irrelevant. The plaintiff only has to prove (1) that a promise was made and relied on, (2) that the promise was not kept, and (3) that damages resulted. A limitation of breach of contract suits is that only out-of-pocket losses can be awarded. Damages for emotional distress and punitive damages for breach of contract are more limited than for negligence. Suing for negligence has the potential for large general damages for pain, suffering and mental anguish.

Figure 2.1 presents a comparison of actions for negligence and breach of contract.

2.2 Legal Initiatives

There is legislation on both the state and federal levels that addresses issues that are of interest to genetic counselors. Although these laws may not directly influence our day-to-day decisions, they do impact the lives of our clients. They were enacted in part to address the fears of the public and professionals of unfair use of genetic

information and discrimination against those with positive presymptomatic genetic test results. On a public policy basis, they also encourage the participation of people in genetic testing for purposes of treatment, prevention and research. The following is an introduction to some of these laws.

2.2.1 Federal Regulations

2.2.1.1 Disability Discrimination Legislation

Disability discrimination legislation has been enacted on the federal and state levels to protect individuals from employment and/or insurance discrimination. The Federal Rehabilitation Act of 1973[44] protects individuals with physical or mental impairment who are otherwise qualified from being excluded from participation in any program or activity receiving federal financial assistance solely on the basis of their impairment.

This act was intended to prevent employers from not hiring an individual who they may think may increase the costs of healthcare within the company or who may not be able to work on a regular basis. A person who (1) has an impairment that substantially limits one or more major life activity, (2) has a record of such an impairment, or (3) is regarded as having such an impairment is protected by this Act. For our patients, this might include someone, for example, with a known gene mutation.

The Americans with Disabilities Act (ADA) of 1990[45] broadened the scope of the protection afforded by the Rehabilitation Act by including private employment in companies that have 15 or more employees. The U.S. Supreme Court, however, has held that the ADA requires proof under the first part that the limitation on a person's major life activity by the impairment be substantial.[46]

The ADA requires that people who may have a genetic disorder not be treated in any way that is different from others in all aspects of employment (Title I), public access to services (Title II) and facilities (Title III). Under the ADA, an employer is not compelled to prefer an applicant with disabilities. The employer is restricted from rejecting the applicant on the basis of the disability or on the need to make reasonable accommodations for the individual. The ADA prevents the use of genetic tests or medical examinations to discriminate against a job applicant. Once a job is offered, the employer may then require a medical examination. For further illustrations of the application of the ADA to individuals with genetic conditions, Alper and Natowicz (1993)[47] offer some interesting hypothetical cases.

An employer is required to keep any medical information about an employee confidential and separate from the employee's general personnel records. The ADA has been interpreted by the Equal Employment Opportunity Commission (EEOC) to include genetic information. EEOC policy is not law. It only offers guidance in applying the law. The first case brought to the EEOC alleging job discrimination was filed by a woman from North Carolina who was fired when she began

treatment for alpha-1 antitrypsin deficiency. Terri Seargent was tested following the diagnosis of her brother, who died about 18 months later. Ms. Seargent was employed by an insurance broker who was self-insured. Even with good performance evaluations she was fired. The EEOC supported Ms. Seargent's claim of genetic discrimination.[48]

In 1995, the EEOC issued a statement supporting the view that having a gene mutation creates the perception of disability in Title I (employment) cases. This means that discrimination against asymptomatic individuals by employers on the basis of a genetic predisposition falls under the ADA, because those individuals meet the third part of the definition of impairment when they are regarded as having a disability.[49] A woman who loses a job because she has a breast cancer gene mutation, although she is presently healthy and cancer-free, would be protected under the ADA.

The Civil Rights Act (CRA) of 1964[50] is a comprehensive civil rights law. As amended, it addresses discrimination on the basis of race, nationality and gender, among other classifications. These are considered "immutable characteristics," that is, characteristics with which an individual has been born. Title VII of the CRA addresses equal employment opportunities and broadly prohibits discrimination in employment. Classification of employees on the basis of race, for example, is not permissible, whether a particular practice has a discriminatory purpose to begin with or a disparate impact on any one race. It has been suggested that Title VII could also be used to protect individuals with genetic disorders or traits that are found in a specific race or sex from discrimination in employment. Discrimination against a person with sickle cell anemia, for example, because hemoglobin S is found more often in the black population, might conceivably be interpreted as prohibited under Title VII.

2.2.1.2 Privacy Legislation

The Privacy Act of 1974[51] protects personal information that has been gathered and is maintained by the government. It prohibits federal hospitals and agencies, among others, from disclosing any information that is in patient medical records without a written consent.

The Privacy Act lists the practices that the government must follow when collecting, using or disclosing personal records. These "fair information" practices also include, besides the requirement of a written consent, the opportunity for individuals to review and correct the personal information in their records. The government allows public access to records maintained by federal agencies within the executive branch of the government through the Freedom of Information Act (FOIA).[52] Exceptions to the FOIA include personal information that would be used for commercial purposes, and personnel and medical files, that is, those files that might result in an invasion of privacy if released.

Both the Privacy Act and the FOIA have limitations. They only protect federal records, and do not, most importantly, extend to the records kept by state governments or in the private sector. Under these acts, federal agencies retain

the ability and discretion to disclose some data without the consent of the individuals involved. Also, the judiciary is empowered to require federal agencies to disclose healthcare records if they are necessary for the administration of justice.

Medical records no longer exist only in paper form. Congress recognized the need for a comprehensive law that would address the confidentiality of patients' electronically maintained medical records. One goal of any legislation was to maintain the public trust in the healthcare provider–patient relationship without undermining the efficiency of the modern healthcare delivery system.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996[53] set national standards for protecting the privacy of a patient's health care information and medical records that are transmitted or maintained. Paper records and oral statements are included under HIPAA. It protects healthcare information that would, or might, identify a particular patient.

Congress was given a time limit within which to pass privacy legislation. When no new legislation was passed, the U.S. Department of Health and Human Services (DHHS) Secretary had the responsibility to develop the rules and regulations for HIPAA. These rules are based on principles outlined by then DHHS Secretary Donna Shalala. She wanted boundaries that prevented healthcare information from being used for purposes other than healthcare.

Information needs to be secure in the absence of the patient's approval for distribution. Consumer control over the content of and access to records, as well as the accountability of those who disclose that information, were recommended. Public health research and safety were recognized as exceptions.[54] The final regulations had to be fully implemented by April 14, 2003 (April 14, 2004 for small health plans).

HIPAA was not the first privacy law enacted, but it is a broad law that sets a minimum level required for the protection of patient confidentiality and medical privacy. Some states may have stricter rules than HIPAA, and those rules apply in that particular state.[55] HIPAA applies to what are called "covered entities." These include health plans, healthcare clearing houses, healthcare providers and any person or organization that furnishes, bills or is paid for healthcare in the normal course of business.

For purposes of HIPAA compliance, "covered entities" includes the workforce of that entity. If you work in any setting that is within the definition of a covered entity, you must comply with HIPAA regulations. For private practitioners, any licensed or certified professional is considered a covered entity. HIPAA regulations will apply to the electronic transmission and storage of the patient's medical records. Although there are no differences made among the types of information covered by HIPAA, genetic information, test results and family histories contained in a patient's record would be included in the definition of personal information. You must have reasonable safeguards in place to protect, limit the use or disclosure of your patient's information to the minimum necessary.

Glaring violations of HIPAA carry federal criminal consequences including fines as high as $250,000 and ten years in prison. HIPAA regulations impact many differ-

ent aspects of healthcare. We will return to them in our discussion as and when they affect our practice.

2.2.2 State Regulations

2.2.2.1 Nondiscrimination

Many states have genetic privacy acts. These acts define what constitutes a genetic test, what protections need to be in place to protect the patient's privacy, and what points need to be included in the written consent for genetic testing. There are regulations that address discrimination in employment and in health insurance. There does not seem to be agreement among the states as to what constitutes genetic information. The first state to address genetic discrimination was North Carolina in 1975. It prohibited discrimination in employment on the basis of sickle trait. Wisconsin became the first state (1991) to enact a comprehensive law prohibiting discrimination on the basis of the results of genetic tests.[56] Each person should be familiar with the regulations in his or her state.[57]

Both federal and state agencies also prosecute fraud in healthcare. In healthcare, fraud has been found[58] in billing for services, supplies, or prescriptions not provided; in billing for a procedure that is more expensive than the one provided; in the use of treatments that are not required; and in taking payment in the form of rebates and referral fees. Knowingly making false and fraudulent claims under the Medicaid and Medicare programs is a felony. Using the U.S. Postal Service to commit such fraud adds penalties. Criminal prosecutions can involve going to jail, paying high fines, and losing your private property.

2.2.2.2 Licensure Boards

Licenses to practice certain professions are provided under state regulation. To protect the public's health and welfare, a state has the right to exclude any incompetent practitioner, as well as to evaluate professional practice on a continuing basis. Licensed professionals are obligated to act within the parameters set out by their licensing act. Medical practice acts create and define the composition of a state medical board with the authority to license candidates. Medical boards receive and investigate complaints of unprofessional medical conduct. Revocation of a license is the most severe consequence of medical discipline.

Genetic counselors are not licensed in all states. As of July 2006, the five states listed in Table 2.1 have enacted licensing requirements for genetic counselors.[59] In those states, a mechanism for receiving and investigating such complaints has been established. In Utah,[60] for example, the Commerce Department, Division of Occupational and Professional Licensing oversees the licensing of genetic counselors. An appointed Genetic Counselors Licensing Board assists and advises the division with the review and investigation of complaints.

Table 2.1 States with licensing requirements for genetic counselors (as of July 2006)

California (2000)
Illinois (2004)
Massachusetts (2006)
Oklahoma (2006)
Utah (2001)

Master's-trained genetic counselors are not physicians. The line between what a medical geneticist may do for a patient and what a genetic counselor may do must be kept clear. Licensing boards define what a licensed medical practitioner is permitted to do as far as concerns procedures, actions and processes. Usually, these are limited to what the individual has been taught and trained to do, and what she has demonstrated competency in. Professional organizations can also develop a scope of practice for their members. A Scope of Practice for genetic counselors has been approved by the Board of Directors of the NSGC.[61] Patients should not leave your office with the impression you are a physician. People need to be corrected when they call you "doctor."

2.2.3 Criminal Complaints

Some cases of negligence are so extreme that civil liability is considered insufficient to address them. These rare cases almost always involve charges of either reckless (a perceived risk has been disregarded) or intentional gross deviation from the accepted standard of care. A state can begin criminal procedures against a physician for an action that was a gross deviation from the professional standard care. The state must prove beyond a reasonable doubt that there was reckless disregard of a patient's safety. This is a higher standard than the standard that applies for medical malpractice (Table 2.2).[62]

The following case represents a good example of intentional gross deviation from standard of care. In 1969, a chiropractor discouraged the parents of a child with cancer of the eye from seeking the traditional, known treatment. He was convicted of second-degree murder when the child died despite his attempts at faith healing.[63]

The American Medical Association has issued a position statement that opposes the criminal treatment of medial negligence,[64] unless the physician's conduct is found to be reckless, or an injury to a patient is the result of willful and intentional behavior. In *People* v. *Klvana*[65] the physician was charged with nine counts

Table 2.2 Standard of proof required

Medical Malpractice: Proof of a breach of duty resulting in harm to the patient by preponderance of the evidence.
Criminal Prosecutions: Reckless or intentional gross deviation from the accepted standard of care beyond a reasonable doubt.

of second-degree murder. The counts all involved the deaths of fetuses around the time of delivery.

Practicing outside the scope of your practice as defined by your licensing act or your professional scope of practice might be a source of liability. Practicing medicine without a license has been found to be a criminal activity. Anyone who practices as a physician when not qualified to do so can be prosecuted. The definition of what constitutes practicing medicine can be found in the scope of practice included in each state medical licensing act. People who have had medical licenses revoked but continue to provide medical services, and healthcare providers who misrepresent their credentials, are included in this category.

There are several defenses that can be used to try to excuse criminal responsibility:

- *Infancy*: Children under 7 are usually presumed to be incapable of committing a crime. This presumption changes as a child gets older, with increasing responsibility through age 18, the usual age of majority. For medical negligence crimes, this defense would not be useful. The training requirements for physicians and for genetic counselors would preclude an individual attaining the skills and knowledge for practice before the age of 18 years. An individual can theoretically graduate from high school at 15 years old, complete college in two years and do her graduate training in one year. She would still be more than 18 years old at the completion of her education. In reality, a genetic counseling graduate student could be 17 years old at the start of her training. Because she would want to become a certified genetic counselor, she would choose to attend an ABGC-accredited training program. The guidelines for ABGC accreditation of training programs include a minimum amount of academic and clinical hours that is recommended to extend over a minimum of 21 months.[66]
- *Mental illness* as a defense to criminal charges presumes an inability to hold the defendant morally responsible for her conduct if she lacks the capacity to appreciate the criminality of her conduct or to conform to the requirements of law. A genetic counselor who is experiencing difficulty maintaining her emotional balance hopefully would feel comfortable asking for help or be identified as needing help by her colleagues. The NSGC Code of Ethics reminds us that our relationship with colleagues is based mutual respect, caring and support.[67] This would include helping colleagues in emotional distress.
- *Intoxication* may result in the impaired ability of an individual to appreciate the significance of her conduct. Genetic counselors do not typically work in isolation, although there are a growing number of genetic counseling private practitioners, we would not expect them to be totally isolated from other healthcare providers. A counselor who is working while intoxicated, whether on drugs and/or alcohol, will eventually reveal her limited abilities to her colleagues. This is not a defense, but an excuse, and would add an additional count to any criminal complaint.
- *Mistake of law* is an unusual excuse, as there are very few exceptions to the rule that ignorance of the law is no excuse. It is also not a real defense. I often hear people discuss legal questions with great authority despite any understanding or knowledge of the law. If there is a legal issue that may impact how you han-

dle a case, the best course of action for you is to consult with your attorney or risk manager. Institutions have legal counsel available for just that purpose. For private practitioners, it would be wise to have an attorney with whom you can consult. The long-term savings are worth the short-term costs.

- *Entrapment* excuses the commission of a crime if a law enforcement office or agency has actually instigated or induced an otherwise innocent person to commit the crime in question. This is an unlikely, although not impossible, scenario for genetic counselors. I have had telephone calls inquiring as to my professional position regarding pregnancy termination and amniocentesis as a path to abortion. If I put on my conspiracy-theory hat, I can imagine those calls being made by a government agency. It is not too far-fetched to imagine a future in which *Roe* v. *Wade*[68] has been overturned and the government attempts to identify those who may be still providing termination services by setting up appointments, for example. Think back to the government activities that occurred during the Prohibition era.
- *Duress* occurs when a person commits a crime under the threat of personal danger (death or great bodily harm) by someone else. I cannot stretch my imagination enough to conceive of a genetic counseling situation that would include doing genetic counseling under duress.

2.2.4 Organizational Requirements

Institutions are not immune to lawsuits. If a hospital, for example, has failed to act to protect the interests of the patients admitted to its facility when it has had notice of the negligence of a physician, liability can be imposed on it through vicarious liability.[69] Organizations, institutions and corporations have written policies regarding many aspects of the services provided under their auspices in part in order to avoid such circumstances.

Codes of conduct are often included in written policy manuals, as are procedures for test, medical and personnel record confidentiality, storage and retention. Conflict of interest concerns inform the policies on gifts from clients and from industry contacts, on honoraria for various professional activities, on relationships with suppliers, and on either concurrent or subsequent outside employment. Policy manuals that present these organizational requirements are available to the public.[70] Organizations employ clinical professionals directly or indirectly through contractual relationships with them.

Management decisions and policies may affect the way your job is performed. Dilemmas can arise when you are expected to perform your duties in a manner that may be contrary to your professional ethos. I know a genetic counselor who was directed to present testing options to her clients in such a way that they would opt for one particular procedure. There was an institutional need to provide a new physician with a large number of patients. I had a similar experience when I was instructed by my organization to "Never use the 'A' word." All the many ways to say abortion were

included, such as termination of pregnancy, voluntary interruption of pregnancy, change of pregnancy management plans. My Code of Ethics, however, says "Clarify alternatives" (II.4), and my Scope of Practice says "Discuss available options" (I.7). This put me in a very difficult position, both personally and professionally.

Everyone agrees that patients' questions always have to be answered honestly. In my particular case, I found that, although this organizational policy seemed to put me in a bind, I did not need to initiate that discussion very often. If the situation required such a discussion, though, I felt that I had to put the patient's needs first. Patients have a need and a right to know all of their options, whether or not they can access them at that institution. The organization changed its policy over time to one of inclusion. I was, of course, happy to comply with the new policy. If you find yourself caught in the position of having to decide between conflicting organizational requirements and professional expectations, you can seek advice from your organization's ethics committee and/or the ethics committee of the NSGC.

There are corporation compliance programs at institutions that emphasize the ways in which employees can conform to the laws and regulations that apply to healthcare. It is the responsibility of the compliance officers in those organizations to develop a program that raises the awareness of the employees with the aim of keeping them from violating any rules or regulations, either knowingly or unknowingly.

A campaign to stop employees from talking about patients in elevators is one such program designed to protect patient privacy. It is the individual provider/employee's responsibility to acquaint herself with the legal regulations and policy standards and restrictions that apply to her own assigned duties and responsibilities, and to conduct herself accordingly. In an adolescent clinic, for example, you would need to know and understand when and how a minor becomes emancipated. You would also need to know the rules about when and what you may discuss with an emancipated minor's guardian. We will discuss this, and other rules and regulations that impact genetic counseling practice, throughout this book.

2.3 Private Practice

The provision of genetic counseling is not limited to institutions. It is also offered within the private sector. A useful guide to practical strategies and recommendations for those contemplating going into private practice is available on the NSGC website.[71] Many of the concerns raised for genetic counselors employed by an institution, such as the issues of privacy and confidentiality, are the same as for those in private practice. The NSGC Code of Ethics is relevant to all genetic counselors, regardless of the specific employment environment. Section II is not specific to any one genetic counseling role, but addresses the relationship with clients in general.[72] The Scope of Practice for genetic counselors applies to those providing clinical services, regardless of the employment environment, private practice or employed by an organization.[73]

HIPAA rules apply to genetic counselors in private practice. A genetic counselor can be considered a covered entity if (1) as a professional you are certified or licensed, (2) you provide, bill or are paid for healthcare services in the normal course of your business, and (3) you transmit any health information electronically.

Patients who come to your office for the first time must be given a notice of privacy practices that is written in plain language.[74] Over time, you have to be prepared to give a patient an accounting of any disclosures of personal health information you have made in the last 6 years. This includes the date, name of the person to whom you gave the information, the data that was disclosed and the purpose of the disclosure. This is all information you would want to have in the client's chart. You may also want to keep Title III of the ADA in mind when setting up your office. You want to make your office accessible to people with disabilities if it is easily accomplished.

The Security Rule of HIPAA may also apply to genetic counselors who contract with a covered entity, such as a hospital or medical group. As a business associate, you must safeguard the confidentiality, integrity and availability of the electronic health information you create, keep or transmit. Complying with HIPAA's Privacy Rule will help you satisfy the Security Rule standards.

There are some areas of concern that may apply in private practice that do not overlap with the genetic counseling practice of those employed by an institution due to the nature of private practice.

2.3.1 Partnerships

You may decide not to practice alone, but to form or join a partnership. You need to be aware of your liability. *Common partnerships* are formed when two or more individuals or co-owners (general partners) provide a business for profit. There is full personal liability for the debts of the partnership which may be unlimited. Your share in the profits will be consistent with the partnership agreement. A *limited partnership* is formed with at least one general partner and one or more limited partners. Limited partners contribute to the partnership and obtain an interest from it, but may not be co-owners. The liability for partnership debts for limited partners is only to the extent of their contribution. As an individual or as a partnership you may employ someone who provides genetic counseling services for you. Employers could be found responsible for the negligent acts of their employee counselor through indirect liability.

2.3.2 Billing

Fees for services provided by an institutional employee are usually set by the institution. As a private practitioner, you decide what services you will provide, you set your own fees, and you locate your office where you want to see clients. You may

find yourself in competition with other private practitioners and with institutions offering genetic counseling services. You should be aware of some potholes that may involve people in business. Although not strictly a billing issue, federal and state laws prohibit a physician from referring a Medicare or Medicaid client to a healthcare service in which she has a personal financial interest. The federal laws[75] regarding self-referral are complex and have a long list of exceptions.

Another issue is the manipulation of the market. One form of competition can be eliminated by fixing your fee at a level that can control the market. Price-fixing can be avoided by not agreeing with any of your competing providers on any term of price, quantity or quality. When competitors agree to divide geographic markets or customers, the outcome is called market allocation. This can even take the form of agreeing where to locate your office.

Payments from others or from third parties should be easily justified. If you receive payments in the form of rebates and referral fees that are used as business inducements, these qualify as kickbacks. Most kickbacks are illegal. As a private practitioner, you will most likely do your own billing. Knowingly filing a false or fraudulent claim for payments from Medicaid, Medicare or other third-party payers is prohibited by state and federal laws. If you offer group counseling sessions, you cannot bill each participant for an individual consultation.

Institutions and physicians have been charged with, for example: performing surgeries that were not necessary, billing for additional services and add-ons that were not provided, billing out-patient services as if they were provided to an in-patient, double billing, physician billing for services provided by interns, forging physician or patient signatures, and billing for cancer treatments that were covered by research grants.

After finding in 1995 that the University of Pennsylvania Health System had fraudulently billed the Medicare program, the DHHS instituted a nationwide audit program of attending physicians and physician groups at other institutions. Thomas Jefferson University in Philadelphia was the subject of the first audit and paid a $12 million settlement. More recently, St. Barnabas Health Care System in New Jersey agreed to pay $265 million to settle a False Claims Act lawsuit for overcharging Medicare.[76]

2.4 Industry/Technology

Industry, as we use the term, refers to the production and sale of medical devices, tests, and pharmaceuticals. Genetic counselors work in industry in a number of capacities, such as clinical coordinators or educators. Many are guided by the role definition of the industry. The issues for genetic counselors working in industry encompass client privacy/confidentiality as well as truth-telling and conflict of interest. There are also potholes at the boundaries of those roles and services, with the possibility of crossing over into a clinical role.

Clients can experience injuries that are caused by a medial device or a drug. People who are injured by a device or a technology can sue a company under product

Table 2.3 Example of warning created to protect manufacturer

Caution: Using this medication alone, with other medicines or with alcohol may lessen your ability to drive or to perform other potentially dangerous tasks. Do not drive, operate machinery or do anything else that could be dangerous until you know how you react to this medicine.

liability laws for defective products. A product is considered defective if it is not "reasonably" safe. This standard can also be applied to pharmaceutical products. A drug is considered to be defective if the foreseeable risk from using the drug was so great in relationship to its benefits that no reasonable physician would ever prescribe it for any patients. Needless to say, this is very difficult to prove.[77]

The Food and Drug Administration (FDA) does not usually require suppliers of medical technologies to communicate risk information directly to patients. Drug manufacturers provide warnings and instructions to the physician. These warnings create an intervening level of protection for the companies (Table 2.3).

Prescription drug inserts serve to reinforce and augment the information given by a doctor to the patient.[78] Providers, however, are expected to fulfill a separate duty to exercise good judgment particularly when applying new technologies and procedures (*Jones* v. *Karrker).*[79] In a case in which a woman used Accutane in the first trimester,[80] the court ruled that the manufacturer's warnings about the dangers of Accutane therapy were adequate. The company had developed a Pregnancy Prevention Program for physicians to use which included patient information and a consent form that patients signed. The defendants were shown to have complied with the prevention program protocol.

2.5 Reproductive Technology

People have many technological options available to them for family planning. The legal requirements for such technologies begin with the duty to exercise good judgment when applying new technology or procedures.[81] Organizations offering preimplantation genetic diagnosis (PGD) have been sued for failure to perform proper testing.[82] Efforts to plan technologically assisted reproduction involve the law of contracts, which has threatened to supplant family law in determinations of parentage. When couples divorce, property, contract and family law have all been brought into the conflict over what to do with stored frozen embryos.[83]

2.6 Research

Genetic counselors fill many different roles in research. Some are the principle investigators, while others act as project coordinators. Some of us have participated as subjects. As a graduate student, I was a subject in a project that looked at the

levels of hexosaminadase A over a defined period of time. Because of questions that came up in the course of the testing process, both my parents were conscripted to be tested!

There are controls on the research community from different sources. For genetic counselors participating as coordinators or investigators in research projects, the institution that sponsors the work will have oversight responsibilities about which you need to be aware. There are also federal regulations that may apply. The boundaries between medical research and clinical practice or accepted therapy are not always clear.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a report that addressed this subject. Known as the Belmont Report,[84] it defines "practice" to include interventions that are designed to improve the well-being of an individual patient and that have reasonable expectations of success. "Research" is considered an activity that is designed to test a hypothesis, permit conclusions to be drawn, and to develop or contribute to universal knowledge. Formal protocols describe the objective of the research and the procedures that will be used.

2.6.1 Human Subjects

Research with human subjects is invaluable when it results in benefits that can be applied to the understanding and treatment of disease. History has taught us, however, that the abuse and misuse of human subjects, both adults and children, has been more common than we would like to think. Plutonium exposure studies were conducted in the 1940s on men, women and children who were thought to be terminally ill. The subjects were not told what the substance was with which they were injected. They were not told that they were be given 2 to14 times the dose that was the standard at the time.

In the 1950s, women were given diethylstilbestrol (DES) during pregnancy as part of a research protocol without having been told and without having given consent to participate in the project (*Miller* v. *University of Chicago).*[85] In *Ahern* v. *Veterans Administration*,[86] the patient received doses of radiation to treat his cancer that were much higher than the dose that was the accepted standard of care at the time. The court in that case ruled that a patient must always be fully informed of the experimental nature of a treatment.

The foundation of the guidelines for research with human subjects is the Nuremberg Code.[87] The ten-point Code begins with the need for the informed consent of the participant: The voluntary consent of the human subject is absolutely essential. The Code serves as the core of all the standards that have been written since, including the Belmont Report. The Belmont Report was a response to the ethical problems in research projects such as those cases mentioned above. It developed basic ethical principles to govern research with human subjects.

Consent is required in all cases in which an investigational drug is administered for either scientific knowledge or to patients who are receiving medical treatment.

Federal regulatory agencies, such as the FDA and the DHHS, mandate extensive disclosures to subjects who are enrolled in clinical trials. Consent forms that are employed should use words that make the project understandable.

Some people argue that the standards for consent should be higher in research than in regular medical care. Their reasons include the greater uncertainty about the therapeutic benefit, the heightened concerns about conflict of interest, and greater uncertainties about the risks of the interventions.[88] Although some courts recognize a duty to simply reveal the experimental status of a treatment to the patient, others impose heightened requirements. In nontherapeutic research, that is, research that involves healthy volunteers or studies on patients that are not designed to test potential treatment, some courts have required higher requirements for informed consent.[89] This consent may include information about whether a drug used for treatment had FDA approval. An informed consent to research participation does not preclude lawsuits based on perceived poor outcomes.

In *Ande* v. *Rock*,[90] parents of a child with cystic fibrosis sued for failure to timely disclose the results of cystic fibrosis testing, claiming the child suffered health consequences due to a two-year delay in treatment. The child had been in the control group of a research project, and the parents claimed that they were not told that she was tested for and had cystic fibrosis. A second child was born with cystic fibrosis during the time period of the research.

If a court finds that the decision to continue a patient in a test group was negligent, serious questions may arise about the validity of exposing such groups of patients to potentially dangerous agents or environments. Monetary or other inducements to encourage enrollment in clinical trials could bias the sample or coerce continued participation, and is usually considered inappropriate.

2.6.2 Gene Transfer

Clinical trials of human gene transfer, a cutting-edge biotechnology, involve the therapeutic or experimental administration of genetic material to human beings. Gene transfer raises concerns that are different from those raised in conventional drug research. These include the threshold toxic effects, hazards of viral recombination and accidental gene transfer to personnel, poorly characterized risks of insertional mutagenesis, and the possibility of inadvertently affecting the germline of trial participants.

Human gene transfer therapy may need special safety and ethics reviews. Problems that arise can have life-threatening consequences. Recently, three cases of children who had undergone treatment for adenosine deaminase–severe combined immunodeficiency and who had developed leukemia were reported.[91] The Recombinant DNA Advisory Committee recommended the continuation of retroviral human gene transfer studies, because of the lack of data to warrant stopping them.[92] The case of *Gelsinger* v. *University of Pennsylvania* (Pa. 1999), which settled out of

court, raised questions of informed consent, conflict of interest, and ethics violations in the gene therapy phase one safety clinical trial for ornithine transcarbamylase (OTC) treatment.

2.6.3 Clinical Testing on Research Samples

DNA is commonly stored in the laboratory in the form of blood, saliva, and tissues removed during surgery, or is extracted from these samples. Informed consent for testing to be done on samples taken for research should be obtained prior to acquiring samples. The consent needs to be detailed and include the patient's permission to contact her if clinical information comes to light. Pathology samples, newborn screening samples, and DNA collected as part of medical care can be sources of samples for research.

The federal oversight is largely limited to economic regulation and done through government regulations that apply to funded projects. Scientific misconduct by researchers may lead to sanctions that can be administrative, such as restrictions on specific activities or expenditures or ineligibility for government grants and contracts. There can possibly be criminal sanctions for false statements and false claims that violate federal prohibitions.

Compensation from research sponsors to healthcare providers for their participation in clinical research is prohibited by federal kickback laws if it is intended to induce the purchase of drugs or services paid for by federal funds. Scientific misconduct is defined as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."[93] Because institutions are typically the recipients of federal funding for research, the responsibility for oversight of the projects is also part of the institution's purview.[94]

2.6.4 Institutional Review Boards

As a result of earlier abuse of human subjects in research projects, we now have safeguards in place to monitor research protocols. The federal government requires all institutions that receive federal funds for research with human subjects to establish institutional review boards (IRBs) and obtain voluntary informed consent from participants.[95] The federal policy that formalizes and enforces the protection of human subjects in federal agencies and departments is known as the "Common Rule."

Research protocols and consent forms are reviewed by IRBs. These committees are charged with responsibility for reviewing and approving prospective research protocols. They enforce regulations and oversee the protection of research subjects. Not all research projects need to be reviewed and approved by an IRB. Research

done with anonymous data (see Section 2.6.5 for an explanation of anonymous data), or studies involving the use of questionnaires or interviews may not need to be submitted to an IRB.

Before you start such a research project, it would be helpful to touch base with the Chair of the IRB at your institution and ascertain which guidelines your institution follows. Federal rules do not preempt state tort laws, and institutions and IRBs may face liability for injuries suffered by the subjects of a research project. Research that is not federally funded or regulated by a federal agency does not require the approval or oversight of an IRB. Commercially funded research conducted with no government funding is not subject to IRB procedures. HIPAA's Privacy Rule does not override the Common Rule or the FDA's regulations governing the use of human subjects.[96]

2.6.5 Epidemiology

Epidemiological studies track and compare large groups of individuals over an extended period of time. It is a research method used to describe the occurrence of disease in populations and to identify the causes of disease. The study group may include an entire population, or it may involve randomly selected members of the population selected on the basis of special characteristics. Research projects may be retrospective or prospective.

Confidentiality and privacy play important roles in epidemiological studies, and are ensured by the use of anonymous identifiers. Personal health information can be used for epidemiological studies under HIPAA rules. The information must be created in a form that is not individually identifiable by "de-identifying" it. This can be done by removing 18 specific identifiers. The list of identifiers includes the following: name; street address; city; county; precinct; ZIP code; Social Security number; date of birth (except year alone); admission and discharge dates (except year); age over 89 (including date of birth and year of birth alone); telephone, fax, medical record, insurance and account numbers; e-mail address; certificate/license number; vehicle identifiers and serial number (including license plates); device identification and serial numbers; URLs and Internet Protocol address number; biometric identification (including finger and voice prints); full face and profile photographs; and any other unique identifying number, characteristic or code.

2.7 Trainees

Many genetic counselors participate in the clinical component of genetic counseling training programs. When I was a trainee, there was very little I was expected to do in my clinic placements. The role of genetic counseling interns has been better defined and is now more participatory.

As a supervisor, I have worked with trainees of all levels of capability. Some

need close supervision, while others have the skills needed to conduct a counseling session independently. Some trainees have no confidence, while for others it is possible to anticipate a future successful professional career. Before delegating responsibilities to others, you need to be sure that the individual is competent to handle them. As a supervisor of a student or trainee, you are responsible for what is said and done in a consultation.

Courts have found that a supervisor is responsible for any negligence committed by a student while that student is acting on the supervisor's behalf. The liability that is derived from your role as supervisor is called "vicarious liability". Your responsibility and potential liability for mistakes and possible harm from the care given by supervisees is proportional to the degree of your control over the trainee's actions and your knowledge of those actions. You may well be responsible for any negligent care you instruct the student to give, and for the negligent supervision of the student.

You are considered to still be practicing your specialty even while you are supervising a trainee.[97] At this time, most supervision is direct, or face-to-face. However, it is possible that some supervision can be done by telephone or written communications. The same expectations, responsibilities and standards apply to the supervisory relationship, regardless of the mode of communication you use.

“I know you’ll be facinated by my family’s story.”

Chapter 3
Duty as an Element of a Lawsuit:

Obligations and Responsibilities

The profession of genetic counseling has developed within the field of medicine. The majority of genetic counselors work with patients in a medical or private practice setting. Thus, we expect that a formal complaint by a patient about a genetic counselor, or what she has done, will come under the laws that have been applied in medicine. Whether a case is called wrongful birth or wrongful life, the title is a way to provide a shorthand description of the kinds of facts that are being asserted by the plaintiff (the person who brings the lawsuit).

Most commonly, such cases are decided by the analysis that is used in a malpractice lawsuit that claims negligence. Studies suggest that there are two major reasons why people file malpractice suits: (1) they want to be compensated for their economic losses, and (2) they are angry because they feel their harms were not addressed candidly or in a compassionate manner.[98] Malpractice does not imply a general lack of competence. It refers to any professional action or inaction that encompasses an unreasonable lack of skill or knowledge in carrying out one's professional duties.

In this chapter, we look at the general principles of a negligence suit so that we can apply them to the particulars of our practices. As we get to know where the possible problem areas or potholes may be, we will be better able to avoid them. When we refer to the physician–patient or provider–patient relationship in the following discussion, we intend to also include the genetic counselor–client (or patient) relationship, even if it is not explicitly stated.

There are four elements to a negligence malpractice lawsuit. The person who brings the suit (the plaintiff) has to prove each element. These elements are (i) *duty* (you had some responsibility to someone); (ii) *breach of duty* (you did not fulfill this responsibility), (iii) *causation* (your failure to fulfill your responsibility resulted in some harm for which you should pay), that is, (iv) *damages*. The first two elements, duty and breach, include the areas over which we have the most control, so we will focus on them.

3.1 Duty Element

A duty is an obligation that is owed by an individual to someone who has a corresponding right. When a professional–patient relationship is formed, a duty on the part of the provider is created. This duty requires that the provider possess that

degree of knowledge, skill and care exercised by a reasonable and prudent similar provider under similar circumstances. The scope of the duty generally depends on whether the consequences of a negligent act are easily foreseen. It is limited, however, by policy considerations and concerns for fairness. The existence of a relationship is a matter of fact that will be determined by a jury.

In a lawsuit, the plaintiff (for purposes of illustration, we will call her Ms. P.) first has to show that (a) a professional relationship existed between the provider (let's say you) and herself. She then has to show that (b) because of that relationship, you owed or had a duty to her. The first defense to the duty element is: There was no duty because there was no relationship.

3.2 Establishing a Professional Relationship

How is a counselor–client relationship established? A professional relationship can be established in many different ways. In a medical or private practice setting, we prefer the formal procedure. In this method, a person schedules an appointment to see you in your office, and you accept her as a client. There are, however, informal ways in which a professional relationship can be formed.

Example 1. Ms. P. says to you at a party: "I hear you are a genetic counselor and I know you'll be interested in my family story." She then regales you with her husband's mother's health problems, as well as the similar problems her sister-in-law is experiencing. Ms. P. continues by telling you how worried she is about her husband and children. She then asks you what she should do.

You have to consider very carefully what to say to her. The response you give her may lead her to think you have given her professional advice. This is not something you want to do is such a social situation. Politely sidestepping her questions may take some fancy footwork. Some people, however, are very persistent. It may be hard not to get caught up in her story, especially when she is correct in thinking her family history is interesting. If the family history is typical of an autosomal dominant condition, for example, it will be difficult not to tell her that at her husband's age he is most likely unaffected and therefore her children are not at risk for the disorder. For this family, it may also be difficult to suggest that her obviously affected sister-in-law needs specific testing. In this scenario, a professional relationship can be established, even if you do not intend it.

Example 2. Following the party, Ms. P. calls you at home. She got your phone number from a mutual friend who said you were very knowledgeable about family issues. She only wants to ask you a few questions. These may include: What is genetic counseling all about? Does she need it, given the family history she shared with you at the party. A general statement such as, "In my opinion everyone can benefit in some way from genetic counseling" may satisfy her. Letting Ms. P. know that genetic diagnosis is not made without medical corroboration and/or testing, and that risk analysis involves a formal pedigree, may also be helpful in this situation. The specifics of how you answer Ms. P. can result in a professional relationship.

Example 3. When she finally gets the gist of your message, that you do not provide genetic counseling on an informal basis, Ms. P. calls you at your office and wants to speak directly with you. She is pushing for answers on the phone: "Just tell me this one thing."

What do you say to her? A professional relationship can be established by telephone. If a patient calls to make an appointment, for example, it is possible that you may indicate to the patient that you have agreed to provide care for her problem, by the way you answer. She then may reasonably assume that since the care will be provided, she does not need to pursue other plans for obtaining care for that problem. She has relied on that assumption.

In this situation, a relationship, and therefore a duty, can be shown to have been formed. I received a telephone call from a friend asking for a referral to an adult metabolic specialist. Because I told her I would look into it for her, she did not ask anyone else for names of providers. If I had not gotten back to her one way or another and her health had deteriorated because of lack of care, I could have been considered in breach of my duty to her on the basis of the professional relationship I formed with her when I agreed to help.

If during a telephone conversation you have agreed to counsel the patient, and the content of your conversation includes your making some evaluation as to the problem so that the patient goes ahead and relies on that evaluation, a jury can easily find that a relationship has been established.

Example 4. One further example needs to be mentioned. Your cousin calls you from out-of-state. One of her prenatal screening tests is positive. She wants you to interpret the test for her and tell her what to do next. No matter how close you are to your family, you cannot assume that you will not be sued by a relative if there is a poor outcome. Be supportive as a relative, but make your role clear. Advise her to seek, or refer her to, a professional in her area. You are not obligated to give free advice to either family or to colleagues.

I was approached by a psychologist whose maternal serum marker screen was abnormal. She refused to come in to talk face-to-face, insisting that I counsel her on the telephone. When I asked her if she would provide counseling over the telephone to someone who was not her client, she was shocked at the suggestion. She did not, however, apply her standards to my services. Not everyone wants to circumvent proper procedures. You may be approached by an attendee following a talk you give. Often what you have said touches people very personally. They may share their stories rather than look for free advice. You have to use your judgment is assessing such situations.

In a lawsuit, you first want to argue against the claim that a professional relationship had been established. An important question is how you handle Ms. P. in the above example situations. Even when you are approached informally, either in person, on the telephone, or by e-mail, a professional relationship can be formed. If you feel you did not establish, or you do not want to establish, a relationship with a particular individual, that has to be made very clear to her. An effective way to do that is say something along the lines of: "This subject is too important not to give it my full attention and the time it deserves." You can also say: "This is not my area of

expertise. Ask your primary physician for an appropriate referral." These are ways of saying you are not going to establish a professional relationship with Ms. P. at this time or in this manner. You can always give her your card and ask her to call you at the office in the morning.

Keep in mind that there is no such thing as giving advice "unofficially" or "off the record." The setting of the conversation is not as important as the impression you give Ms. P. that you are a professional offering your expertise. The important point is how you present yourself. Putting on your professional hat by giving an opinion or offering a diagnosis can lead a person to think that there is a professional relationship between you. Having given advice to someone who may rely on it, you may owe her a professional duty. You should be careful what you say and how you say it to avoid establishing a relationship when you do not intend to do so.

3.2.1 Abandonment

Practitioners often feel that they have to see any patient who desires or needs their services. In general, you are not obligated to see every person who asks to make an appointment with you. That refusal does not constitute abandonment. Abandonment is the unilateral ending of a professional relationship without giving advanced notice or time to locate another qualified professional. You cannot abandon a person with whom you have no professional relationship. If you are the only provider within a large geographic area, and travel to other genetic counselors is very onerous, you may have to see whoever knocks on the door. That will be determined by the circumstances and the laws in your area.

3.3 Obligations and Duties

If Ms. P. makes an appointment to see you at your office and you have accepted her as a client, then it is clear that a professional relationship has been established. That relationship is a fiduciary one. This is the highest legal degree of obligation or duty. It is based on good faith and trust. She has come to you for your expertise. You have something she needs, your knowledge and skills. The relationship is uneven. Your obligations and duties are defined by your role within that relationship. They are based on trust and confidence. A duty has been established whether you see the patient once or see her on a continuing basis.

You are responsible for what you say and do, as well as what you don't say and don't do. One of the tools you learn in genetic counseling training is how to

Table 3.1 Definition of a fiduciary relationship

A fiduciary relationship is . . .
• Unequal
• on trust
• Requires good faith and fairness

contract with the patient at the beginning of the first session. This is very important from a risk management perspective, because it is a good way of establishing the parameters or limits of the relationship you have begun. That is, you will know what questions Ms. P. is asking (e.g., her concerns regarding her husband, her children, her pregnancy), and she will know what you can and cannot do for her (e.g., pedigree analysis, testing explanations, referrals, treatment).

In medicine, within the provider–patient relationship, you are obligated to do all you can within your role for the benefit of the patient. Ms. P. should know what she can expect from you in your professional role. My friend knows the limits of my offer of assistance. I have told her I will get her a list of adult metabolic specialists. She does not expect me to arrange treatment for her disorder. Your duty defines the standard of care that the patient has a right to expect.

3.3.1 Standard of Care

What your duty to your client entails is defined by the practice of the profession. The general definition of a standard of care is that it is a broad guideline that helps define the minimum level of quality of care. Every healthcare provider is expected to exercise that degree of skill that is ordinarily used under similar circumstances by the members of that profession. Using reasonable care and diligence, along with your best judgment in the application of that skill, is an implicit part of the definition.

Historically, courts have applied the "locality rule" to medical practice in defining the proper standard of care. That is, "under similar circumstances" was defined in terms of a local area. This was based on the idea that to hold a local general practitioner in a small or rural community to the same standard as a doctor in a teaching, research center in a major city was unreasonable. Over time, the local area became a similar community or locale. The community has been expanded to general neighborhood by some states, and to the entire state in others. The trend, however, has been towards a uniform, or national, standard, especially when applied to specialists.[99] The locality rule, for example, was found not to apply to a pediatrician, who was expected to know that testing for PKU was used throughout the country at that time.[100]

In today's world, with the availability of telemedicine techniques, the rationale for the locality rule no longer fits present-day medical malpractice cases. The new geographically broader, national standard that can be applied reads: The standard of care, or good practice, is defined by what is the customary and usual practice in the field.

The standard of care can be expressed in a variety of ways, but in essence it requires the professional to engage in good practice, and good practice is defined as what is customary and usual in that profession. The professional has a duty to have and apply the skill and knowledge commonly possessed by members of the profession who are in good standing. If a professional fails to recognize the limits of her professional knowledge, skills and experience, she can be found liable. A physician who failed to consider a 23-year-old patient's positive family history of Down syndrome was found liable when the patient had a child with Down syndrome.[101]

3.3.2 Specialty Practitioners

A specialist in a field of medicine represents to the public that she has and will use not only the knowledge and skills of a generalist, but that she also has and will use the knowledge and skills normally possessed and used by the average specialist in that field.

The standard of care for practicing genetic counselors rendering services in the recognized specialty field of genetic counseling includes the exercise of that degree of skills and knowledge ordinarily employed under similar circumstances by members of that specialty. We need to add to this definition the qualifying phrase, "in good standing." We also need to add the phrase "the use of reasonable care and diligence along with the best judgment in applying that skill."

The court in S*hilkret* v. *Annapolis Emergency Hospital Association*[102] recognized that various specialties had established uniform standards for certification. Because the medical profession itself recognizes national standards for specialists, the court said that the law should follow suit and hold the specialist to the standard of care applicable to that specialty. A corollary to this is, if the provider knows or should know that she does not possess the required knowledge or skill to properly treat a patient, an appropriate referral should be made.[103]

Keep in mind, however, that standard of care is not a fixed concept that can be relied on indefinitely. The standard in genetic counseling must evolve to accommodate advances in genetics and changes in societal concerns. The standard is determined at any point in time based on consensus: a professional consensus and a legal consensus.

3.3.3 Good Practice

An integral part of the definition of what is the standard of care is good practice. Good practice is established by professional consensus. It would be helpful to look more closely at what constitutes good practice by using the needs of a prenatal patient as a reference. We need to ask ourselves: When we offer a maternal serum marker screening, how many analytes should be measured? Should we be including fragile-X DNA mutation analysis or connexin 26 to the package offered to all prenatal patients?

Our example is Ms. F., a 31-year-old G1P0 woman of Jewish (Ashkenazi) descent. Ms. F. is clearly a candidate for some prenatal screening. How do we determine the range of screening tests that are appropriate for her? How do we know whether the testing we offer her is enough? To answer these questions, we will consider which tests (a) we *must offer*, that is, those we have an obligation or requirement, or that are necessary, to do; (b) which tests we *may offer*, that is, those that are most likely, or probably will be offered; and (c) which tests we *might offer*, that is, which we may offer but are not obligated to do.

Although in this example we confine our discussion to testing options, the logic used to think through this situation can be applied to any kind of services that genetic

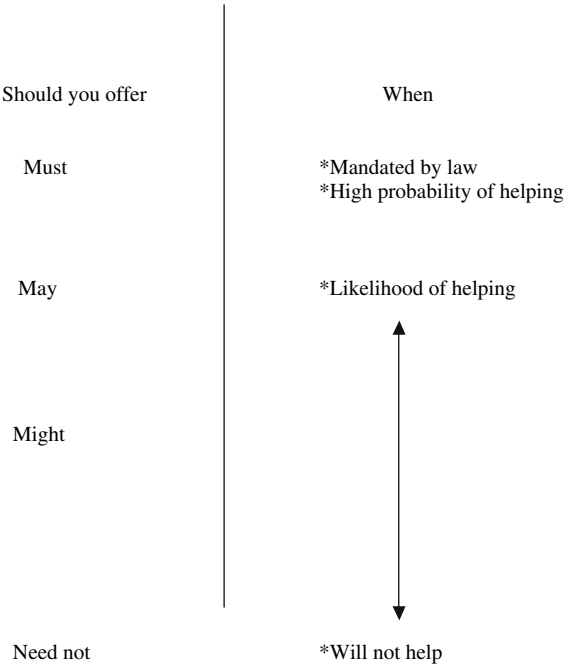


Fig. 3.1 Continuum of Good Practice in Testing

counselors can offer. What constitutes good genetic counseling practice and how the genetic counselor can recognize what is within the standard of care and what falls below the standard of care will become clearer as we continue.

When we look at the range of all tests available, we can place them on a continuum with those we must offer at one end and those we need not offer at the other. Figure 3.1 illustrates the continuum of choices. The *must offer* category is relatively straightforward. It always includes those tests that are required, or are mandated by law. It also includes those tests that will definitely help the patient or at least have the highest probability of doing so. Tests are legislatively mandated based on considerations of the common good, benefits vs. harms analysis, and the efficacy of the testing, so there is an overlap with the high probability of helping category.

Although the list of mandated tests is not necessarily carved in stone, for our purposes we will consider all mandated testing as "musts." Although there are no mandated tests for Ms. F., there are an ever-increasing number for her newborn. The testing we would consider definitely helpful for Ms. F, and therefore would become "musts" in her case, include at least a heritage panel[104] and maternal serum marker screening.

The category at the other end of our continuum, *need not offer*, includes tests that will not help this individual patient. We certainly do not, from the information at hand, have to offer Ms. F. a fetal echocardiogram. The court in *Munroe* v. *Regents of the University of California*[105] found no duty for genetic counselors to test or advise regarding Tay–Sachs, for example, when the parents are not suspected of

carrying the gene, that is, they are not in a high-risk population and have no family history of the disease.

The *may offer* category is also reasonably straightforward. The testing in this category is based on our pedigree analysis, the reason for the referral, and in general an evaluation of the patient's needs. If Ms. F. has a parent with familial adenomatous polyposis, the genetic testing that has a good likelihood to be helpful for her moves into the *must* category.

It is the *might offer* category that gives us pause, because here is where the boundaries are not clear and where the standard of care will have a strong influence. In thinking through the question of testing for Ms. F., we have to balance our definition of appropriate tests (i.e., those with benefits for Ms. F.) with the possibility of overlooking a needed test (i.e., which may result in a harm for Ms. F.). If we do not offer an unnecessary test, Ms. F. is not harmed, and we have not acted below the standard of care. Put another way, it is not malpractice to not do an unnecessary test. But if we do not offer a test that will be helpful, we have not performed within the standard of care. Most of the time no injury ensues from bad practice, but if injury to the patient does result, we are liable for malpractice.

We listed a heritage panel and maternal serum screening for Ms. F. as *musts*. Our screening difficulty with the *mights* category is illustrated very well by the heritage panel. We have to ask ourselves how many disease genes can we include. Are five enough? Are eleven too many? One question is whether the standard for the heritage panel is set by what is offered at a major research and treatment institution or by a majority of centers offering such testing across the country. How do we know what the standard is for the heritage panel?

One method for establishing any standard in general, and for the heritage panel in particular, is to poll centers or institutions offering the heritage panel to assess what the majority include in their panels before deciding what you should offer to Ms. F. The results of such a poll might look like those suggested in Fig. 3.2. The survey may, for example, find that six centers include 8 disease genes, four include 9 diseases, one offers 10, and one has an expanded panel of 11. Based on these results, it will be clear that you should not offer Ms. F. a panel with less than 8 disease genes, because no institution offers fewer than 8. That would not be the standard of care. And you probably do not have to offer a 10 or 11 disease panel, because what a single practitioner does is not sufficient to establish the standard of care at that time. Whether you offer a panel of 8 or 9 disease genes can be argued.

A professional consensus can also be identified by looking at published research and data, at shared clinical experience such as professional practice guidelines, and

Number of Disease Genes Tested	Number of Centers
8	6
9	4
10	1
11	1
12	0

Fig. 3.2 Hypothetical poll of 12 genetic centers offering screening for Jewish genetic diseases

in an assessment of the patient's best interest. The use of maternal serum marker screening for Down syndrome illustrates very well how this consensus evolves. In 1984, Merkatz[106] published the association of low maternal serum alpha-fetoprotein (MSAFP) and increased incidence of chromosomal abnormalities. The next year, the American College of Obstetrics and Gynecology (ACOG) sent all its members a liability alert suggesting that they become familiar with and use AFP kits.[107] The alert represented a professional consensus and standard in obstetrics at that time.

The genetics community through the American Society of Human Genetics (ASHG) published laboratory and testing policies regarding maternal serum markers in 1987.[108] Then Wald[109] suggested the use of triple markers, followed a few years later by Crossley's[110] proposed sufficiency of two markers. The debate that ensued illustrated a lack of professional consensus. The American College of Medical Genetics (ACMG) published a policy in 1994 that stated that the use of AFP alone was not acceptable, and that either the double or triple screens were acceptable. A new standard was set. In 1996, a similar announcement was made by ACOG, and the use of MSAFP alone slipped below the minimum standard of care for obstetrics and genetics professionals.

This appears to be an ever-evolving area of practice, with the introduction in about 2003 of combined screening.[111] ACOG has published a *Practice Bulletin*[112] that discusses the first and second trimester screening options available to patients for the risk evaluation for fetal chromosome abnormalities. The recommendations presented are based on the scientific evidence and the determination of the detection rate and false positive rate. The use of maternal age of 35 years alone as a cut-off for offering invasive testing is no longer the standard of care. The maternal serum marker screening saga goes on.

These are some of the questions to consider for the *might offer* category. What we do or do not do will reflect the changing standard of care in the use of these tests, as well as what is current at the time of the testing.

The second source of consensus used in identifying a standard of care, besides the standards defined by a profession for itself, is a legal consensus. That is because until such time that an injury occurs to a patient from the tests you did not offer, no one other than you will question your choices. An example of such an injury might be a baby born with mucolipidosis type IV (MLIV), for example, after you have offered her parents a heritage panel that did not include MLIV. When there is a dispute over whether or not your performance was within the standard of care, the legal system becomes involved. The courts define when services are necessary and place the boundary between necessary and unnecessary care, between the *might* category and *need not* category, and establish the limits of permissibility for not providing services.

There are two aspects that go into the legal consideration of whether services *should* have been provided (not how well they were provided). The first is an objective, scientific component. It is established by professionals and includes issues such as what services would benefit a patient in a given situation, and the degree to which the services would benefit the patient (which is an analysis of harms to the patients). These are based on scientific studies or consensus from experiences of professionals. This is the profession's definition of the standard of care.

Sources of evidence used by the courts and the plaintiff to ascertain this standard include expert testimony, textbooks, professional articles, practice guidelines, and professional codes of ethics[113]. The conclusions of professionals are usually, but not always, determinative for this component.[114]

There is a value judgment component that is taken into account in the legal consideration made in light of the knowledge of the benefits or likely benefits, which involves normative social judgment about the amount of care and resources that should be expended on an individual patient. This judgment is made by the court, and is based in part on the obligation that is derived from the professional–patient relationship "to do all one can do for the benefit of the individual patient." It is not based on what is in the best interests of someone else or of society as a whole. This has nothing to do with rationing. Rationing is not the equivalent of necessity. It is a limitation of access to necessary care because of insufficiency of resources. When courts expressly consider the costs of using existing resources, it is mostly to justify why services should have been provided rather than as a reason why it is justifiable to not provide services. Fortunately, because professionals and courts are all part of the same society and mostly share similar values, the professionals' value judgments are, more times than not, consistent with those of the court.

The legal concept of what is a necessary test involves both objective science and value judgments. There is no rule of law that assigns a weight to these factors and no universal cut-off. Keep in mind, though, that courts tend to favor providing services to patients if there is a reasonable possibility they may help the patient. The boundary line on a not necessary/necessary continuum may be closer to not necessary than you would think.

In *Hellig* v. *Carey and Laughlin*[115] the court disregarded the standard of care set by the ophthalmology profession regarding the age at which to begin testing patients for glaucoma, and compelled the use of a diagnostic procedure in young patients.

You must present the patient with the appropriate testing options. In *Howard* v. *Lecher*,[116] the family claimed their ethnic background was not evaluated and that they were not offered carrier testing for Tay–Sachs disease. The physician had not referred them for appropriate testing. Parents of a child with Down syndrome claimed they were not offered maternal serum marker screening and were therefore deprived of the opportunity to make an informed decision regarding their pregnancy (*Blair* v. *Hutzel Hospital*[117]). Following the birth of a child with spina bifida, a patient who cancelled her ultrasound scan appointment made a claim for failure to notify her of the time-sensitive nature of a test ordered, and failure to offer maternal serum marker screen for open neural tube defects (*Lodato* v. *Kappy*[118]). A case claiming failure to retake a maternal serum marker screen following an ultrasound scan that showed incorrect dating was settled out of court when a child with spina bifida was born.[119] A child with Down syndrome was born to a woman of advanced maternal age who claimed she was not advised of the availability of genetic counseling and amniocentesis (*Azzolino* v. *Dingfelder*[120]). Similar claims were made by women who were over the age of 35 years in *Karlsons* v. *Guerinot*[121] and in *Keel* v. *Banach*.[122] A woman with a family history of hemophilia was tested for factor VIII deficiency and told her risk of being a carrier was low. No testing for factor

IX deficiency was performed and a child with hemophilia was born (*Siemieniec* v. *Lutheran General Hospital*[123]).

Good practice standards apply to providing testing services. When testing is offered by a practitioner or by a laboratory, it needs to be performed correctly. The interpretation of test results must be correct. The complexity of genetic test results may lead to misinterpretation by providers who are not well trained in medical genetics. Improper testing has resulted in a number of lawsuits naming physicians, institutions, laboratories and government providers.

In *Gildiner* v. *Thomas Jefferson University Hospital*[124] the family claimed that the incorrect interpretation of an amniocentesis sample by the university's laboratory, as well as the representation that the interpretation was guaranteed to be correct, prevented them from exercising their right to make pregnancy management decisions. Although *Curlender* v. *Bio-Science Laboratories*[125] was a wrongful life claim that was eventually overruled, the family claimed improper testing and interpretation of Tay–Sachs tests.

The California State Department of Health was named in a suit for failing to timely diagnose an infant's congenital hypothyroidism when the newborn screening was read as normal (*Creason* v. *State Department of Health Services*).[126] A child with Down syndrome was born following the misinterpretation as normal of the mother's maternal serum marker screen by the physician (*Thornhill* v. *Midwest Physician Center of Orland Park*[127]).

When we consider the implications of testing errors, we should not limit our thinking to those tests done in laboratories. Testing services can include imaging procedures such as ultrasonography. The parents of a child born with femur–fibula–ulna syndrome that was not diagnosed by ultrasound claimed failure to perform their ultrasound scan properly (*Taylor* v. *Kurapati*[128]).

Not only must testing be offered appropriately and done correctly, but any abnormal test results must also be communicated in a timely fashion. The provider is obligated to report any abnormal test results to the referring healthcare provider and to the patient. In *Bader* v. *Johnson*,[129] the couple had already had one child with hydrocephaly. Although the specialist had recommended genetic counseling, she did not advise the patient or the referring obstetrician of the abnormalities that had been seen on ultrasound scan. A second child with hydrocephaly was born. The physician in *Campano* v. *Delahunty*[130] failed to discuss the finding of a thick nuchal fold on ultrasound scan with parents who then had a child with Down syndrome. The duty to convey results of tests showing fetal abnormalities was reinforced in *Hester* v. *Dwivedi*,[131] when the results of tests showing spina bifida were said not to have been shared with the plaintiff.

The duty to discuss results of screening tests includes informing a patient of the consequences of test results, such as hemoglobin (Hgb) S carrier status (*Dorlin* v. *Providence Hospital*[132]) or Hgb O and Hgb Arab carrier status (*McAllister* v. *Ha*[133]). When screening tests are done for children, the duty to convey the results extends to the child's parents. When providing parents with their child's test results, as discussed above, these results must be correct. The parents of a child whose newborn screening test was misrepresented as normal, although the child was a carrier

Table 3.2 Issues that have been brought to court regarding genetic testing

Failure to refer when indicated
Failure to inform of availability of tests
Failure to order screening test
Failure to disclose test results
Failure to perform additional tests
Failure to follow up testing that was done
Unauthorized disclosure
Negligently performing test
Negligent interpretation of test

of Hgb S, had another child who was affected with sickle-beta thalassemia.[134] Table 3.2 summarizes some of the issues brought to court involving genetic testing.

3.3.4 Nongeneticists Providing Genetic Services

In 1968, I asked my obstetrician about carrier testing for Tay–Sachs disease. He told me he could perform that testing for me, and he tied a tourniquet around my arm. As we both sat there watching my arm turn blue I asked him in alarm what was going on. "I'm testing you for Tay–Sachs," was his answer. He most likely did not know what Tay–Sachs disease was. If he did, however, he certainly did not know that the status of testing at that time was nonexistent.

The physician–patient relationship requires that the provider conform to a standard of care that is usually defined by the profession. A nonspecialist has the duty to make appropriate referrals when they are indicated.[135] In 1982, the American Medical Association (AMA)[136] published a list of reasons for referring a patient for genetic counseling:

1. genetic or congenital anomaly in a family member,
2. family history of an inherited disorder,
3. abnormal somatic or behavioral development in a child,
4. mental retardation of unknown etiology in a child born previously,
5. pregnancy in an older (> 35 years) woman,
6. specific ethnic background that may suggest a high rate of genetic abnormality,
7. drug use or long-term exposure to possible teratogens or mutagens,
8. three or more spontaneous abortions, early infant deaths, or both,
9. infertility.

When a provider decides to provide counseling services to her own patients in general, she could be negligent for not doing the counseling for genetic indications. If a healthcare provider asserts she does genetic counseling, then she has to offer it appropriately. In *Howard* v. *Lecher*,[137] *Geler* v. *Akawie*,[139] and *Goldberg* v. *Ruskin*,[139] the plaintiff in each lawsuit claimed that the obstetrician failed to identify the need for and to provide genetic counseling, among other services, regarding the

risk for Tay–Sachs disease. Failure to inform of the recurrence risks for autosomal recessive polycystic kidney disease was part of the claim in *Park* v. *Chessin*.[140] A companion case to *Park* was *Becker* v. *Schwartz*,[141] in which a 37-year-old woman claimed to have not been counseled regarding advanced maternal age.

Those professionals who do provide genetic counseling must meet the standard of care for genetic professionals. It was pointed out by the court in *Park* that there is a pre-existing duty for a physician not to speak without good sense or due care when she has a duty to speak, when she knows the other party intends to rely on what is said, and then does rely on what is said to her detriment.

In *Gallagher* v. *Duke University*,[142] the cause of action was for negligent genetic counseling. Negligent genetic counseling was also an issue in *Hester* v. *Dwivedi*[143] (spina bifida) and in *Siemieniec* v. *Lutheran General Hospital*[144] (Factor IX deficiency). Providing genetic counseling services that do not meet the standard of care established by the genetic counseling profession is the basis of a claim of negligent genetic counseling.

A physician should be aware of her own limitations and refer the patient to the appropriate specialist when she knows, or should know, that a patient's problems are beyond her professional skills and competence. She has an affirmative duty to refer (*Larsen* v. *Yelle*[145]).

A physician who did not consider a 23-year-old patient's positive family history of Down syndrome was sued following the birth of a child with Down syndrome for the failure to recognize the limits of her professional knowledge, skills and experience in *Phillips* v. *United States*.[146] A general duty for obstetricians to refer patients to specialists in the field of genetic counseling was recognized in 1968 in *Morgan* v. *Engles*.[147]

If you take a family history, it should be done according to published guidelines. The failure to properly evaluate the family history and to refer the patient to a genetic counselor was part of *Donadio* v. *Crouse-Irving Memorial Hospital, Inc*[148]. Referrals, however, cannot be without thought. The court in *Estate of Tranor* v. *The Bloomsburg Hospital*[149] recognized a cause of action in a general practitioner's negligent referral of a patient to an incompetent specialist, and negligent failure to recognize during follow-up treatment that deficiencies in the specialist's care resulted in harm to the patient. The general practitioner was not found to be required to provide follow-up care after referring a patient to a specialist. If she does, however, she must exercise reasonable care, which includes recognizing deficient care provided by the specialist.

Most nongenetic healthcare professionals are inadequately trained to deal with genetics.[150] There is recognition of and concern about this situation by many professionals.[151] Some physicians with training other than in medical genetics may think they can and do provide genetic counseling.[152] When their actions do not meet the standard of care for geneticists, the courts have found them liable.

The failure to diagnose a genetic disorder, or the making of an incorrect diagnosis, has led to many lawsuits over the years. A few of these cases include the failure to diagnose: phenylketonuria (*Lewis* v. *Owen*),[153] Leber's congenital amaurosis (*Lininger* v. *Eisenbaum*),[154] Duchene muscular dystrophy (*Nelson* v. *Krusen*),[155] autosomal recessive polycystic kidney disease (*Park* v. *Chessin*),[156] cystic fibrosis

(*Schroeder* v. *Perkel*),[157] neurofibromatosis (*Speck* v. *Finegold*),[158] and hereditary deafness (*Turpin* v. *Sortini*).[159]

Increasingly, genetic services are being provided by primary care providers. The National Coalition for Health Professional Education in Genetics (NCHPEG) has assembled core competencies in genetics that are recommended for all medical professionals. The competencies make it clear that nongenetic healthcare professionals are not expected to provide comprehensive clinical genetic services. They are, instead, expected to work with genetic specialists. The core competencies have set a groundwork for the standard of care for all nongeneticist health professionals.[160] The difference between the duty owed by a specialist and that owed by a nonspecialist is not the degree of care required but the amount of skill and knowledge that is required.

"Say, ah."

Chapter 4
Duty as an Element of a Lawsuit:

Sources of Standards

4.1 Test for a Standard

Standards are not static. They evolve to accommodate advances in medicine and genetics. A good example of the shifting nature of standards is the question of a duty to share genetic information with third-party relatives. As the ethical principle of justice influences how we approach patient autonomy, family-based genetics has been given more weight. Professions also evolve and develop, and societal opinions and concerns change over time.

The role of parents in testing children for adult onset disorders has changed from one of being primary, with total control, to one limited by recommended restrictions on testing children for adult onset disorders. Now we have available direct-to-consumer testing for many genetic conditions.

Usually, the standard that is applied in a particular case is that which existed at the time of the alleged breach. The New Jersey case of *Safer* v. *Estate of Pack*[161] stands out. The court applied the standard of care of the 1990s, which was a time during which we saw the development of a duty to warn third parties. The tort in the case occurred in the 1960s, which was a time when physicians not only did not share a patient's diagnosis with the family, they also did not always even tell the patient. Not using the standard of practice that applied at the time of the tort does not make sense. The decision in this case has not yet been challenged.

4.2 Sources for Standards

Standards of practice are established by various means. The legal system looks to a profession to set its own standards of practice (S*hilkret* v. *Annapolis Emergency Hospital Association).*[162] The injured party, Ms. P., will have many different sources available to her that demonstrate and document what the standard of care was at the time you provided her services. The following are some of the first sources that the plaintiff will turn to for information.

4.2.1 Scope of Practice[163]

A patient walks into your office and asks you to look at her rash, identify it for her and tell her how she should treat it. Is this an appropriate request to make of a genetic counselor?

The activities in which a genetic counselor engages while carrying out her clinical professional role have been structured and described by the profession. The Scope of Practice for genetic counselors includes critical thinking, psychosocial and analytic skills. It has been published, and is available to any interested party. There are also other sources that have an influence on what we think of as the scope of genetic counseling practice. There are required criteria for graduate training programs in genetic counseling which are online and also available to the public.

In the Preamble to its accreditation requirements, the ABGC discusses what it considers to be a genetic counselor and how a genetic counselor communicates with patients. A list of competencies for genetic counseling includes communication skills, critical thinking skills, and interpersonal, counseling and psychosocial assessment skills.[164] The scope of practice of a professional can also be found in a state's licensing act. How a genetic counselor may practice in a particular state would be shaped by that state's licensing act.[165]

4.2.2 Code of Ethics[166]

Your prenatal patient has a maternal serum quadruple marker screen with a uE3 level of 0.15 MoMs. Do you ignore this result because when you last looked at the literature two years ago there were no published papers addressing the implications of low levels of uE3?

A published code of ethics is a valuable and major source of information regarding professional standards, particularly for the reason that the profession writes the code for itself. If a person was interested in knowing what to expect from a genetic counselor or the level of skills and knowledge a practicing genetic counselor is expected to maintain, the NSGC Code of Ethics (COE) would provide some guidance.

Section II of the COE addresses the counselor's relationship with the client, and provides a framework of expectations of counselors by clients. The client will know that you will not tell her what she must do ("enable their clients to make informed decisions, free of coercion . . .": Section II-4), and that you will maintain the confidentiality of the information she shares with you ("maintain information received from clients as confidential, unless released by the client or disclosure is required by law": Section II-6).

Section I-1 states that genetic counselors will strive to "seek out and acquire sufficient and relevant information required for any given situation." This statement suggests that genetic counselors consider researching the literature and keeping current regarding scientific knowledge are part of the definition of competent genetic counseling practice. The NSGC COE also states in Section I.3 that "genetic counselors keep abreast of current standards of practice." The goal of keeping current

is not unique to genetic counseling practice. Medical practitioners in general are required to keep abreast of the times and to practice according to approved methods and means of treatment.[167]

Based on the two statements from the NSGC COE, as well as the general medical practice, Ms. P. can expect that the information she receives will be scientifically and professionally current. You will know which tests should follow the finding of a low-level maternal serum uE3. There are several pathways available to us as we strive to keep current, maintain our knowledge and skills and to continue to work within the scope of practice.

4.2.3 Professional Organizations

We look to professional organizations such as the NSGC and the American College of Medical Genetics (ACMG) to provide opportunities for us to continue to learn, including educational programs and conferences. National and regional meetings, as well as conferences offered by specialty organizations or interests that are continuing education credit providers, offer a faculty that presents material that must meet learning standards that have been established by an authorizing organization.

Documentation of attendance at such meetings demonstrates that you are indeed keeping your knowledge current. Communication among practitioners, through a professional newsletter (e.g., *Perspectives in Genetic Counseling*) or a discussion group (e.g., the NSGC member ListServ) allows for an exchange of ideas, clarification of issues, and notification of findings and research. These are opportunities to not only continue your education and training and meet the goals of the NSGC COE Sections I.2 and I.3, but also to have input into the changing professional thinking, and to keep your knowledge and standards of practice current.

4.2.4 Professional Literature

The professional literature not only provides a way for you to keep up with the changing information and changing professional perspectives in genetics, it also serves as a source of standards for the plaintiff. Textbooks written by genetic counselors are valuable sources of professional standards. Written from the point of view of the genetic counseling practitioner and educator, what is expected and what are the parameters of practice can often be found in these publications.

You also need to look at the professional literature (e.g. *Journal of Genetic Counseling*) to keep abreast of current knowledge. Books and journals are valuable resources, although there is a time lag between the time of writing and publication of textbooks that impairs the timeliness of the information. Until recently, there has also been an issue with time lag in the publication of journals. Online access to articles as they are accepted for publication, even prior to the assignment of a journal volume, has made the information in articles much more current. The editorial comments and review articles available in journals offer great value in providing a perspective on a particular theme.

In a profession where access to the most current information is an everyday concern, print materials are no longer sufficient as the only research tools used. There are resources available online: On-line Mendelian Inheritance in Man (OMIM), Medline, Reprotox, Teris, Sheppard's, Possum, GeneTests, among others. Online research probably will not replace print sources altogether, but it is necessary to enhance print research. Practitioners will be expected to know and use those resources. Possible liability may attach for failing to enhance your knowledge and skills by accessing easily obtained medical information (*Harbeson* v. *Parke-Davis, Inc*.).[168]

Patients often search the Internet for medical information. They come to your office with stacks of printouts of information from a variety of websites. They may find helpful information or they may misdiagnose their own symptoms. It is helpful to be familiar with some of the sources of information favored by patients. You must be aware that some sources of online information may not be correct or current, especially if you use material from lay organizations or private sources. We will discuss this in more detail in Section 8.4.

4.2.5 Professional Guidelines

Professional clinical guidelines and/or recommendations are systematically developed statements written by the profession to assist the practitioner and the patient in making decisions about what the appropriate healthcare would be for a specific clinical circumstance.[169] Following the Institute of Medicine criteria proposed for good practice guidelines, genetic counseling practice recommendations have been developed by the NSGC.[170] These address a growing number of areas of practice, such as consanguinity, Fabry disease, and Fragile-X syndrome. They are available to the practitioners and to the public through the organization's publications[171] and website.[172]

4.2.6 Credentials

Professional credentials represent, and are also a source of, the standards of the profession.

4.2.6.1 Certification

Certification is a voluntary process for determining whether an individual meets the professional standards that have been established within her specialty. It assures the public that the specialist has successfully completed the approved education and evaluation process that was designed to assess the knowledge, skills and experience that are essential to providing high-quality patient care in that specialty.

Attaining professional recognition can go a long way toward providing evidence of a defined level of training and experience. National certification standardizes a minimum acceptable level of knowledge and skills across state boundaries. Having national certification demonstrates that you have attained that level. As a practitioner, your conduct is compared to others in the profession who are in good standing. This is best demonstrated by meeting certification and recertification criteria established by the profession. The courts look first to the standards that are set by a profession for its practitioners.

Certification standards indicate what constitutes appropriate standard of care in that field.[173] For a genetic counselor who took and passed the certification examinations prior to the establishment of a time limit on certification, recertification is a voluntary procedure. Although many may consider those genetic counselors to have been "grandfathered" regarding recertification, this term does not actually apply. Those genetic counselors achieved certification under a different set of rules. The 10-year limitation on certification cannot apply retrospectively to include them. Voluntary recertification does not change the certification status of those genetic counselors. It does, however, provide a mechanism for demonstrating the continued maintenance of their skills and knowledge. A current list of certified genetic counselors is available to the public.[174]

4.2.6.2 Accreditation

Minimum standards of quality have also been established by the profession of genetic counseling and applied to the education of genetic counselors. Accreditation represents the professional judgment about what constitutes the quality of an educational program. At this time, the training of genetic counselors is at the Master's degree level. The standards of quality for educational programs in genetic counseling are published by the American Board of Genetic Counseling (ABGC). Those training programs that meet the standards are recognized through accreditation and reaccreditation. A list of accredited programs is also available to the public at the ABGC website.

I have often been addressed by patients as "doctor." It feels awkward to interrupt the flow of your conversation to correct that impression. But it should be done before the client leaves the office. Representing your credentials accurately is essential. You do not want to create liability by being considered to be practicing medicine. Also, Section I.5 of the NSGC COE states that genetic counselors strive to "accurately represent their experience, competence and credentials, including training and academic degrees."

4.2.6.3 Licensing

Licenses are credentials that are established and regulated by the individual states. They grant a practitioner the right by law to practice, and may protect both the title of genetic counselor and the practice of genetic counseling. A license also protects

the public's right to be served by qualified practitioners. A license defines the scope of practice and standards of care for practitioners in that state for the protection of the residents of the state.

Requirements may vary and not be uniform from state to state. Although genetic counselors are not licensed in every state at this time, there is a strong movement to establish licenses for genetic counselors. In the not so distant future, another source of standards will be licensing acts and the rules and regulations that define those licensing acts in all states. State medical and/or genetic counseling boards will enforce those rules and regulations. As a licensed genetic counselor, you will be held accountable for your practice by your state. Complaints may be made to a practice review board. This is another legal recourse for patients who believe they have been injured by a breach of the state's genetic counseling standard of care.

4.2.6.4 Maintaining Credentials Through Continuing Education

Our professional competence is acquired through education, training and experience. Professional incompetence can be the result of a lack of proper training, but more often it is related to a failure to keep abreast of the times. Continuing education is the third phase of a genetic counselor's education, after graduate school and board certification. It reflects a commitment to lifelong learning, and keeps you apprised of new developments and changes in the field. This has been a standard in the medical field since 1898.[175] Whether for recertification, maintenance of a license, or keeping up with the knowledge and skills of the profession, continuing education units (CEUs) document that you are maintaining the standard of care (Table 4.1).

4.2.7 Expert Testimony

When a genetic counselor is named in a lawsuit, the defense attorney will look for someone with experience and expertise to testify as an expert as to the practice of genetic counseling.

An expert is a person presented to the court who has demonstrated a high level of knowledge about a subject. This is based on the person's knowledge, skill, experience, training, and education, or on a combination of these factors. The testimony regarding what the standard of care is and what members of the profession would do in a given situation becomes a big part of the basis of a jury's judgment. An expert

Table 4.1 Opportunities for continuing education can include:

- Employer in-house programs (e.g., Grand Rounds)
- Professional meetings
- Professional journals
- Academic courses

witness may be cross-examined, and professional "learned materials" (written publications) may be used in that process.

Being an expert witness is an art and a science. Van Brunt and Strider[176] offer the following recommendations for a prospective expert witness. Whether you are the expert or have hired the expert, these are important areas of which you need to be aware. Expert testimony can be written, in the form of deposition, and/or oral, as trial testimony. A conflict of interest should be avoided in order to maintain your credibility. Credibility can be safeguarded by maintaining an objective professional opinion. The need for confidentiality applies to the expert witness and to the materials available for forming an opinion. As a consulting expert, your communication with the attorney should be frequent as your review of the facts progresses. Your fee should be fair, and you should make every effort to avoid inefficiencies. As always, you should document the work that is done. Only what is necessary to assist in the preparation of a report or testimony should be written down.

Keep in mind that all written statements prepared by an expert are "discoverable." You will want to discard copies or drafts of any work that is updated. As an expert, you will want to have a thorough understanding of all the facts necessary to reach an opinion. You should not only review all the materials, you should also be familiar with the standards that apply to the case.

Court rules often govern the form and the content of an expert's report. When you write your report, it should be in language that is understandable by the court. Preparation is the key to being an effective expert. For trial testimony, your effectiveness begins before you take the witness stand. How professional you appear, as well as your demeanor in the courtroom, are observed by the jury. Your responses to questions should be accurate, succinct and without jargon. The questions asked during cross-examination should be considered thoroughly before answering. Genetic counselors are the appropriate expert witnesses for other genetic counselors. Carefully consider any request to appear as an expert.

"Ignorance of the standard is no excuse!"

Chapter 5
Duty as an Element of a Lawsuit:

Procedural Requirements

Up until now, we have been discussing the claim of a breach of duty that involves not having met the standard of care because of a lack of achievement of the level of skill and knowledge defined by the various sources available to our plaintiff, Ms. P. Our standard of care also includes some procedural issues, such as informed consent, as well as procedures defined by the institutions at which we work. The following discussion is about procedural requirements that come from several sources and apply to many aspects of our practice.

5.1 Medical Records

Writing a note in a patient's chart or summarizing a counseling session in a letter to the referring physician may seem very straightforward. When you review an infant's chart in the nursery and see a copy of your prenatal report attached to it, just how significant what you have said and how you have said it is impressed on you. Because this is such an important area of practice, we are going to look at it in detail.

Documentation is one of the most important areas in medical risk management. This cannot be emphasized strongly enough. A properly written medical record can support you during a lawsuit and serve as a witness to what you have done. An improperly kept record can undermine your position. Good documentation is the best way to demonstrate that the standard of care has been met. Remember the old saw: if it isn't written down, it didn't happen.

The patient medical record has several purposes.[177] It represents a means of communicating with others, both other professionals and the patient, in order to ensure a continuity of care. It furnishes evidence of the patient's evaluation, treatment and change in condition, assists in protecting the legal interests of all parties involved (patient, healthcare provider and institution), and can provide data for use in continuing education and research. The purpose of medical records is the same, whether they are hospital records or a healthcare provider's own private office record. There are recognized standards for recordkeeping. Keep in mind that under HIPAA the

patient has a right to inspect and copy her own records. The patient also has the right to request an amendment of her health information.

5.1.1 Chart Contents

Charts usually include a variety of pieces of information. We will go through this list, although it may seem obvious to you. Over the years I have reviewed charts and found many that do not follow these straightforward guidelines and are impossible to use in the care of the patient or in research projects. The patient's medical and social history, with notes taken by the health professional, should include the reason for referral. The history should include what has already been done, and the results of a physical examination. If the patient is seen more than once, progress notes for each visit need to be included with the date of each visit. Copies of the patient's records, any diagnostic test results, consultant reports, and any consent forms signed for treatment or for the release of information should be in the chart as part of the record. What has been said to the patient, including any patient education, the patient's responses, correspondence with the patient or others about the patient, are included. Notes concerning lack of patient cooperation, failure to follow advice or to keep appointments, as well as phone calls, are all very important. Financial records will include bills submitted for care and treatment. Keep a copy in the chart of any research you have done, especially if you have used it to form your opinion.

5.1.1.1 Documentation

The following discussion is written with a paper medical record in mind. Most of these recommendations will apply to electronic medical records as well. Hospital records may be admissible as evidence in a lawsuit. Medical records often contain errors. No medical record is perfect. Many errors can be explained to a jury. It is in your best interest, however, to avoid making obvious mistakes. Therefore, proper documentation needs to be done carefully. You do not want to give the impression that you do not know what you are doing and/or that you are disorganized.

A. Some Basic "Do's"

Keep in mind that medical records must be *accurate*. The medical record needs to reflect what actually occurred in the care of the patient. This is important if the record is to provide the basis for planning a course of treatment for a patient, for example. In order to accurately represent the care of the patient, the chart must also be *detailed* enough to show that you have met the standard of care.

A statement such as, "the patient was counseled," is inadequate. It is too broad. It does not tell the reader what the patient was told in regard to her healthcare or what she understood. Your notes should be *complete*. They should include everything

that was said or done for the patient. Gaps and omissions make it difficult to know what happened during your care and to reconstruct what happened in the event of an injury. A patient who was referred to you for advanced maternal age, for example, may have taken a medication that she was concerned about. Even if the medication was one aspirin, any discussion about it should be included in your notes.

Your notes should also be *contemporaneous*. They should be written when the patient is seen or soon after, not weeks or months later. I have known genetic counselors who were months behind in writing their reports. Notes written weeks after the patient had been seen have less credibility than those made at the time of the visit. Your institution may have regulations that require records to be completed within a prescribed period of time. Charts should be *neat* so they are easily read. Scraps of paper can easily be lost and should not be left in a chart. If information is important enough to be retained, it should be written out in a proper note, with a date and signature.

Each page in a chart should have the patient's name, a date, and be signed. The signature should include at least the initial of your first name, your full last name, and if you are writing in a hospital chart, usually your professional designation (see Fig. 5.1).

We all know the reputation of physician handwriting. Legibility and clarity are very important, so that the record can be understood by everyone taking care of the patient. It is important to write *clearly* and *objectively*. The use of abbreviations saves time. However, the use of ambiguous abbreviations can lead to misinterpretation. Within genetic counseling practice, AMA means "advanced maternal age." A genetic counselor would not read AMA and think it meant "against medical advice," which it does in another context. As used in genetic counseling practice, AMA is a term of art with an accepted use in the field. Not all abbreviations meet this criterion. Several years ago there was an online discussion about IP. To my mind IP stands for incontinentia pigmenti. When the information began not to make sense, a member of the discussion group asked for the author's definition of IP. It turned out to have meant intermittent porphyria, which was different from what many of the participants thought it meant. Write out what you have to say if there could be more than one reasonable interpretation of your abbreviation. Your institution may have a list of approved medical abbreviations.

Table 5.1 Some basic "Do's" for patient charts:

Accurate
Detailed
Complete
Contemporaneous
Neat
Signed

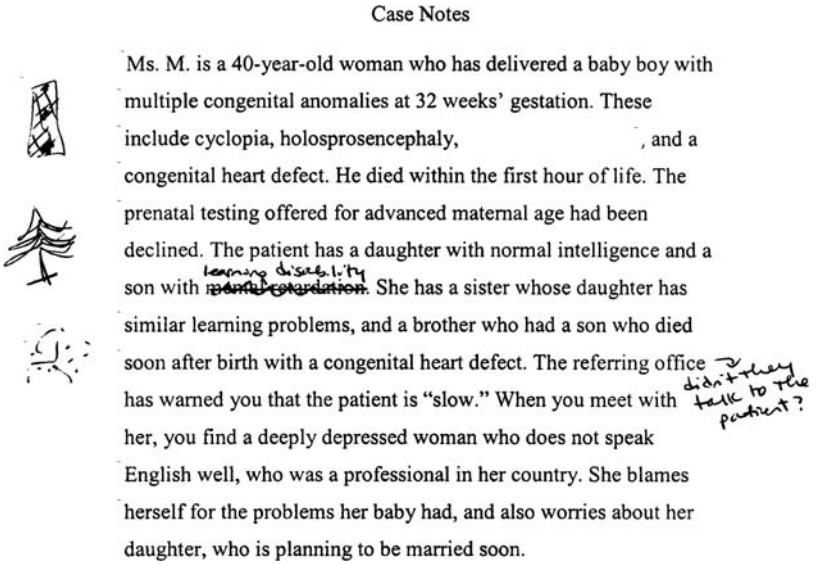
Fig. 5.1 Signing a patient's chart

B. Some Practices That Are "Don'ts"

The patient's chart is available to and read by those providers involved in the patient's care. It is no place for *editorializing*. None of your opinions about other professionals, colleagues, or the patient belong in the chart or in any letter you write. Sarcasm or derogatory statements are inappropriate and have no place in the patient's chart. As we have already noted, the chart should be clean and should therefore not include any *doodling*.

You can avoid the need to make corrections in the chart by planning what you are going to write prior to making an entry. If you do make a *mistake*, it should be clearly labeled as such. You should draw a line through the incorrect word or phrase so that the original wording can still be read. The necessary change can then be made. You should initial the change. *Erasures* and *obliterations*(by scribbling or using whiteout) look like attempts to alter the record. They can give the impression that you have something to hide. Patients have the right to request that changes or amendments be made to their medical records. Any such amendments made at the patient's request must be an attachment to the record, and not made by erasures or obliterations. You may not, however, amend information that was not created or received by you. Figure 5.2 is an example of what a page in your patient's chart should **not** look like!

Deliberate *falsification* or tampering with medical records can result in civil or criminal liability and malpractice awards even when there has been no negligence. The destruction of medical records that are needed for a lawsuit is called "spoilation of evidence." This is very serious and can be considered an obstruction of justice, which is a criminal offense. Nothing should ever be added, deleted, substituted or removed from a record without the proper authorization and documentation.


Case Notes

Ms. M. is a 40-year-old woman who has delivered a baby boy with multiple congenital anomalies at 32 weeks' gestation. These include cyclopia, holosprosencephaly, , and a congenital heart defect. He died within the first hour of life. The prenatal testing offered for advanced maternal age had been declined. The patient has a daughter with normal intelligence and a son with ~~mental retardation~~ learning disability. She has a sister whose daughter has similar learning problems, and a brother who had a son who died soon after birth with a congenital heart defect. The referring office has warned you that the patient is "slow." When you meet with her, you find a deeply depressed woman who does not speak English well, who was a professional in her country. She blames herself for the problems her baby had, and also worries about her daughter, who is planning to be married soon.

didn't they talk to the patient?

Fig. 5.2 Examples of what **not** to do in a patient chart

5.1.2 Ownership

The ownership of patient medical records has been addressed by the courts and by state legislatures. The actual record, that is, the physical document and its contents, belongs to the healthcare provider. The information in the medical record is the property of the patient. The rules that apply to the patient's right to inspect or copy her own records are determined by HIPAA and by each state, and may vary from complete access to only a summary or report being allowed. The refusal to make records available to someone who is entitled to them can be looked at as fraudulent concealment. If you have any questions about the parameters of a release of information for your practice, your risk manager or attorney should be contacted.

5.1.3 Storage of Medical Records

If you are in private practice, you are responsible for the proper maintenance and storage of your patients' records. If you are employed by an institution, the responsibility is the institutions'. A statute of limitations is the length of time within which a proper lawsuit can be brought, or the time period during which you are vulnerable to a lawsuit. It also defines the length of time you must maintain the client's medical record. This period of time is determined by state statute. You should be aware of the specific time limits in your state, since they will dictate your retention policies.

You may need a patient's complete and accurate medical record to defend yourself against a lawsuit. A general guideline is to expect to maintain the complete medical records for at least 7 years after the first time an adult is seen by the healthcare provider. In the case of a patient who is a minor, the medical record should be kept for a minimum of 10 years or until the patient reaches the age of majority, plus the statute of limitations that applies, whichever is longer.

Table 5.2 illustrates the timing for some patients. Records can be stored at a commercial facility or transferred to microfilm. Loss of all or part of a patient's record creates the appearance that it was intentional. Spoilation of evidence involves the destruction of evidence that may include the patient's medical records. It can be seen as deliberate, intentional or negligent. You must be able to adequately explain any loss of material from a patient chart so as to show there was no deliberate violation of your duty to maintain that chart.

Table 5.2 An illustration of length of time necessary to maintain the medical record of a client who is a minor

Age at last visit	No. years to age 21	Statute of limitations	Total years
2 months	21	2	23
8 years	13	2	12
17 years	4	2	10

5.1.4 Shadow Charts

Concern about the misuse of genetic testing information, and the possibility of insurance discrimination against a patient based on that information, has led some healthcare providers to store the results of genetic tests in charts that are not part of the patient's medical record. These have been called "shadow charts." Many healthcare providers use shadow charts[178] to store what they think of as information that is more sensitive than other laboratory test results.

Genetic exceptionalism, or the question of whether or not genetic information should have greater protection than other confidential patient information, is a discussion that is beyond the scope of this book. You should understand that the use of a second, or shadow, chart does not afford greater protection to the information that is in that chart if you receive a proper release of information or a court order requesting the patient's medical records. Unless there is some specific privilege that applies to the materials that have been requested, all relevant documents must be disclosed by parties to a lawsuit. Concealing medical information from insurers that may have a legitimate claim to it, for example, could expose the healthcare provider to liability. The Institute of Medicine[179] recommends that, in lieu of using two separate charts, we should use extra vigilance to protect against unauthorized disclosure of genetic information.

5.2 Failure to Follow Policies and Procedures

In conversations with colleagues, I have often been told that it is the law that we use black ink to write in a medical chart. When you think about it, however, can you imagine a federal or state law that says hospital records have to be written in black ink? Can you visualize Congress debating this issue? A recommendation has been made recently that signatures at least be in blue ink so that copies or faxes can be distinguished from the original.

An institution's administrative policies can determine the standard of care. Failure to follow the policies and procedures (P & P) of the larger institution, department, or division of genetics for which you work can increase your liability. Most hospitals, universities, and medical centers have their own policies. Many departments will have a P & P manual section addressing how care should be provided by their employees. You need to be familiar with your employer's specific policies. Your particular employer may require all medical records and notes be written in black ink. In the institution where I work, you can often distinguish among the staff based on the favored color of ink! Whether you write in blue, red, or purple, the color may matter when the medical records have to be copied. Some colors do not copy well and when the records are copies it appears as if there are gaps in the record. Of course, you should never use erasable ink or disappearing ink!

Policies and procedures address how we protect patient autonomy and privacy, since these are basic to the provision of medical services. Informed consent and

confidentiality are major areas in which we can make errors. That is one of the reasons that we talk about them so much. There are legal protections for client confidentiality and to ensure informed consent for procedures, both at the federal and state levels. Most institutions have policies in place to protect patient confidentiality and the requirements for informed consent. We will look at these two areas in greater detail.

5.2.1 Informed Consent

The phrase "informed consent" was first used in 1957.[180] The concept of informed consent is derived from the principle of respect for an individual's autonomy, or control over her own body.[181] As part of that respect, decision making for medical treatment should come from the patient herself. In order to make the best decision, the patient needs to have a substantial understanding of the medical information, she has to be free from anyone else's control, and she has to then intentionally authorize her treatment. The patient's signature on a consent form is the end point of a dynamic interaction between the healthcare provider and the patient. This process is important in enabling the patient to make her treatment decisions. Her signature on an "informed consent for treatment" form documents that the informed consent process has occurred. For consent to be truly informed, five elements must be met (Table 5.3).

5.2.1.1 Competence

The threshold element for informed consent is competence, or the capacity to make a rational choice. There is always a presumption of competence, unless shown otherwise. Incompetence can only be determined by a medical professional. Different levels of competence may be required for various activities. Table 5.4 gives some examples of this concept.

In healthcare, decision-making capacity involves the patient's ability to understand and appreciate the information provided to her, as well as the consequences of the available choices. This includes the benefits and risks of each option, and the alternatives to any healthcare decisions. To be capable of making a rational choice, a patient has to also be able to communicate that choice. Decision-making capacity is

Table 5.3 Elements of informed consent

Competence
Information
Amount and accuracy
Understanding
Consent
Voluntariness
Authorization

Table 5.4 Selected examples of the definition of competency

Consent to treatment: Possess sufficient mental capacity to understand the particular treatment choice being proposed and any relevant adverse effects associated with it.
Drive: Understand the pertinent laws of the state with regard to licensure; refrain from driving in a dangerous manner.
Make a confession: Possess sufficient capacity to make a knowing and intelligent waiver of certain constitutional rights and a knowing and voluntary confession.
Make a will: Understand the nature and object of the will, one's holdings, the natural objects of one's bounty.
Marry: Understand the nature of the marital relationship and the rights, duties, and obligations it creates.

evaluated relative to the demands of a particular healthcare decision. We have to ask: Can this individual understand and make a judgment under these circumstances?

To be competent to consent to treatment, some states require that a person must possess sufficient mental capacity to understand the particular treatment choice being proposed and any relevant adverse effects associated with it. This is different from the test of competency required for making a will, for example, which is to understand the nature and object of the will, one's holdings, and the natural objects of one's gifts. Capacity to consent is presumed in most cases. The burden of proof lies with the person who believes a specific patient is not competent to consent.

In healthcare, a person is presumed to be competent to make treatment decisions at 18 years of age. As a general rule, minors must have the consent of a parent or guardian before nonemergency treatment begins. There are exceptions to this rule. Minors can be emancipated to make some or all of their own healthcare decisions. The criteria for emancipation vary from state to state, and are determined by state statute. Table 5.5 shows some of the pathways to emancipation for a minor. An emancipated minor may consent to her own treatment. A minor who is considered "mature" by statute may be given decision-making authority by a court. She is usually at least 15 years of age and has been found to have decision-making capacity, in that she can understand the risks and benefits of a medical procedure, or is seeking treatment for certain medical conditions. Unless a person has been appointed the legal guardian by a court, she may not consent to treatment for her spouse. Marriage does not compromise a person's right to consent. It also does not give one spouse a veto, co-consent, or refusal right for the other spouse's treatment.[182] The consent of a competent patient's spouse is not a valid substitute for the consent of the patient. This is also true for other family members who have not been named the legal guardians or who are not the natural guardians of a minor. A person who is competent to authorize her own treatment is competent to refuse treatment. A legal guardian may refuse treatment for her ward.[183]

Table 5.5 Example bases for emancipation of a minor

Self-supporting and/or not living at home
Married
Pregnant
Parent of a child
In the military
Declared emancipated by court

5.2.1.2 Information Elements

Informed consent has two information elements. The first element relates to the *amount* and *accuracy* of the information provided to the patient. The professional needs to discuss with the patient the possible benefits and risks of an intervention, and has an obligation to include in the discussion the available alternatives.

In *Canterbury* v. *Spence*[184] the court defined the scope of disclosure as all "material" risks associated with the treatment being proposed. How much information is enough, and what information is material, is determined by the amount of information a patient needs to make her decision. In our practices, we have met people referred for the same indication who ask for a broad range of different information. Patient A may need to know risk figures to the nearest one-hundredth of a percent. Patient B may focus on the cost of testing, while Patient C asks specific questions about the alternatives to invasive testing. It is the duty of the provider to convey the information.

The court used the "prudent patient" standard for determining what a patient would need to know to decide about a procedure. What would make information material for the patient's decision-making process? That would include the information that a reasonable patient in the same position as the provider's patient (e.g., a family history of cancer) would likely attach significance to in deciding whether to proceed with or forego the proposed therapy (such as risks, costs, and alternatives). The provider knows, or should know, what her patient's situation is. Providing an adequate amount of information does not mean including choices that are not indicated by the situation. It does mean including only those choices that are material. Some risks are rare or insignificant. You do not have to identify and discuss every possible risk of a procedure or treatment, or every possible birth defect included in the general population risk figure.[185] It is the relevance of the information to the patient in making her decision, and not the length of the information listed, that makes it sufficient.

A patient can recover financial damages for injuries caused by undisclosed information. In an informed consent action, the plaintiff must first prove that the undisclosed risk was medically accepted and material, that a reasonably prudent person in the patient's situation would not have undergone the treatment if she was aware of the risk, and that the risk occurred.

In *Bedel* v. *University of Cincinnati Hospital*[186] a woman who had a miscarriage following an amniocentesis claimed that the physician failed to discuss the risk of miscarriage. The case was dismissed on the grounds that the patient was verbally informed of the risk[187] and had signed three consent forms. The duty to disclose risks (sometimes called the "duty to warn") includes a broader obligation to educate the patient in order to ensure that, if the patient decides not to give consent, that decision is also fully informed. The information needed by the patient should be volunteered by the professional if necessary. The duty to disclose significant risks that are known to accompany a medical treatment includes a duty to disclose subsequently discovered risk information to former patients.

Although the duty to disclose significant risks relates to the consequences of a medical treatment, it may be applied to the results of tests. The Apolipoprotein E

(APOE) story is a good example of the issues that can arise when testing for one purpose yields information that might be used for a different purpose. Data suggesting an association of APOE epsilon-4 and Alzheimer's disease was evaluated by a Working Group from the American College of Medical Genetics and the American Society of Human Genetics. The consensus was that at that time APOE test results did not provide sufficient specificity to be used for diagnostic or predictive purposes. Those patients who had testing in the course of an evaluation for cardiovascular disease, therefore, could not have expected to be given a risk assessment for Alzheimer's disease.[188]

The amount and accuracy element of informed consent can also apply to the limits of the testing being offered. The importance of this is illustrated by prenatal testing counseling situations. We have all encountered patients who do not understand the limitations of the testing or who are not aware of the general population risk for problems in children. A good example is the frequently heard: "This means my baby is normal," when a patient receives normal amniocentesis results.

A second example, the case of Diana Platt Frenkel,[189] was presented at a workshop as part of the 1999 NSGC Short Course on Legal Issues. A couple who had genetic counseling and amniocentesis because of advanced maternal age delivered a baby with hypotonia and dysmorphic features. A diagnosis of Prader–Willi syndrome was made. The parents claimed that they were not told of every type of test available on the sample or on themselves. They demonstrated no comprehension of the limitations of the testing.

The rule of truth-telling, or veracity, is essential to this element of informed consent. Deception can occur through commission or omission. The physician in *Call* v. *Kezirian*[190] was found to have a duty to inform his patient, who was over 35 years old, of the availability of amniocentesis and of the risk of having a child with Down syndrome.

A provider violates her duty to the patient if she withholds any fact the patient would find necessary in forming the basis of intelligent consent.[191] The information provided to the patient should not only be truthful, it should also be consistent with the facts. When you tell a patient who has married her first cousin that there is statistically a 1:8 risk for genetic problems in her offspring, you are telling the truth. It is more consistent with the facts, though, to tell her that research with consanguineous couples suggests that the risk for problems is actually less than 1% for first cousin marriages. That is closer to the facts as we know them. If there is uncertainty about the facts, such as the specific disorders for which the consanguineous couple may be at risk, or what long-term consequences of a procedure may be, that uncertainty should be acknowledged. When obtaining informed consent, the question of whether the patient really wants to know the truth is not an issue. Consent that is obtained by misrepresentation, fraud or duress is void, and has no legal weight.

The second information element is the necessity that the patient *understands*. This element highlights a myriad of barriers to informed consent. Patients may be nervous, uneducated, preoccupied, or have an illness or impairment that effects their cognitive ability. They hold unscientific beliefs, are in denial, do not speak the same

Table 5.6 Factors that can interfere with a patient's understanding

Fear
Illness
Lack of education
Belief system
Denial
Language

language as the provider (Table 5.6). It is the obligation of the provider to identify these barriers and to endeavor to overcome them.

The institution where I work is located in a multicultural city. Over 1 in 3 of the patients who come for genetic counseling do not speak English. Many bring their own translators, including children. At one point, my colleague and I investigated the adequacy and effectiveness of the translators brought by patients to their genetic counseling sessions.[192] We found that the father of the fetus was more likely to be an adequate translator than other relatives or friends. Children under 16 years of age were found not to be acceptable translators. When speaking with your patients, the information provided should be in lay terms to enhance patient understanding. Assumptions about the level of knowledge of a patient should not be made on the basis of her employment or education. Because the doctrine of informed consent presupposes essential ignorance on the part of the patient with respect to medical issues, the duty to inform arises from that ignorance and the patient's need to make informed decisions. Even if the patient is partially informed, the physician's duty is to provide the missing information. There is no duty on the patient's part to seek out information from any other source.

5.2.1.3 Consent Elements

The consent elements of informed consent involve *voluntariness* and *authorization* by the patient. As used here, voluntariness means the absence of control by others. The absence of control must be substantial. It is not enough for the patient to say she will have a procedure because her spouse/friend/physician says she should have it. You should be able to document that the consent comes from the patient, that it is she herself who is agreeing to have testing. Of course, a physician may not impose her values on her patient or substitute her level of risk aversion for that of the patient.

Not only should the patient's authorization be voluntary, but it also needs to be an active agreement. Consent can be expressed or implied. The patient voluntarily gives permission that may be written or oral consent. Obtaining consent in writing presents less of a problem if you need to document the consent process in court. Oral permission may present a problem with credibility if you have to substantiate it in court. An active agreement, whether oral or written, is one that is more than a mere yielding to or a complying with an offer of testing. A shrug of the shoulder or a nod of the head can be misinterpreted or denied at a later time.

There are some situations where consent may be implied by the patient's conduct. Situations in which implied consent is acceptable may even be delineated by state law. A patient who comes to your office for blood drawing, for example, implies her consent for the procedure by keeping her appointment and holding out her arm for you to take a sample. Careful documentation in the patient's chart of the treatment or procedure, and any explanations you have given to the patient may be helpful if questions arise. It is risky to imply consent, and you should not do it on a regular basis.

If treatment is provided with neither express nor implied consent, or the treatment provided is different from the care that the patient agreed to, medical assault or battery can be claimed. The scope of the consent will usually be limited to whatever was discussed during the consent process. There is no need for the plaintiff to prove actual harm in battery cases. Specific examples of medical battery cases that would have implications for genetic counselors would include amniocentesis or research or treatment programs in which genetic counselors assist or in which they take part. A defense to an accusation of battery, clearly, is a valid consent.

There are exceptions to the need for informed consent. For more common, low-risk interventions where the risks and benefits are obvious to everyone, such as drawing blood for testing, explicit agreement may not be required and consent is implied. In an emergency situation it is a common assumption that the patient is unable to make decisions about her care or to participate in that care because of her pain and fear, her lack of understanding of the danger she may be in, or her unconscious state. The objective, or reasonable person, standard is applied in these situations. That is, if a reasonable person under the same or similar circumstances would consent to treatment, then consent is presumed.

Once all the elements of informed consent have been met, we can then say that the patient has been truly informed. Many states have codified some aspects of the informed consent doctrine. You should become familiar with any statutes in the state in which you practice.

Informed consent actions were first brought as battery lawsuits. Over the years, the action for failure to obtain patient consent became one of negligence. Courts now agree that negligence is the appropriate cause of action for the failure to properly inform a patient about a procedure for which consent was sought. Battery is still used in some cases. If the patient consented to one procedure but another was performed, or the physician failed to disclose a disability that was certain to result from a procedure, battery may apply. Performing an experimental procedure on a patient without telling the patient that it was experimental would also be considered a battery.

Some states have codified the duty to obtain informed consent. In those states, failure to obtain informed consent would give rise to an additional negligence action for violation of that state's statute.

The requirement to obtain informed consent applies to anyone doing genetic testing. It is not limited to physicians. The EEOC brought suit against Burlington Northern and Santa Fe Railway[193] for doing genetic tests on employees for markers linked to carpal tunnel syndrome without their knowledge or consent. Subsequently, the company stopped doing the testing and agreed to a settlement with the employees.

5.2.1.4 Right Not to Know

The principle of respect for autonomy requires that we respect the choices a person makes for herself. Some people feel that their interests are better served by not having specific information. They claim a right to ignorance, or a right not to know. A person cannot exercise a right not to know unless she has at least some knowledge. It is never safe to assume that a person does not want information or to accept someone else's report that she does not want certain information.

It is sometimes impossible to find out whether or not an individual wants to know without asking her and possibly invading her privacy. This is true for the patient herself and for possible at-risk relatives. You may have a patient who is referred because of a family history of mental retardation, and find that her history strongly suggests that she is at risk for a cancer syndrome. If she told you at the start of the counseling session that she does not want any information other than that regarding mental retardation, should you talk to her about her cancer risk anyway?

Rhodes[194] discusses the professional positions one can take in such a situation when the information relates to genetics. She argues that for a patient to be autonomous requires that she be informed. Genetic knowledge may be necessary especially to make some informed decisions. She concludes that a right to genetic ignorance does not exist. If there is no right not to know, does it then follow that there is a duty to always give people information they may not want? Where the choice is between depriving an individual of personal information which she might find important if she knew about it and invading her privacy, many feel that the greater harm is in remaining silent.

Another way to look at the right not to know is as the right to refuse treatment. An informed consent process does not have to result in a patient's having a procedure. After weighing the pros and cons, and the risks and benefits, of a medical treatment as presented by the healthcare provider, an autonomous individual may refuse treatment. This was clearly supported by the court in the case *In re Quinlan*.[195] Your accurate and timely documentation should include any informed refusals made by the patient.

5.2.1.5 Waiver for Research

An IRB can make the determination to waive some or all of the consent requirements in situations that are specifically described in the federal regulations. These requirements are that (1) the research poses no more than a minimal risk to the subjects, (2) no adverse effects would occur to the subjects as a result of the waiver, (3) without the waiver the research cannot be done, and (4) additional information will be provided to the subjects after participation is completed, if appropriate.[196]

For a project that is limited to the use of charts for review, the waiver of written consent may be considered reasonable. Some projects may require consent, but verbal consent may be acceptable. Written consent may be waived by the IRB with

the submission of a verbal consent script that provides all the elements of informed consent, but in a more informal manner.

Having documentation of informed consent does not, in general, waive the patient's right to sue for medical malpractice. A patient can always claim that consent was not informed because she did not understand the language used, she was intimidated by the provider, she was emotionally distressed or sedated, or that she did not have enough time to think about the issues and get input from significant others.

5.2.1.6 Defense to Failure of Informed Consent

The best defense against a charge of failure to obtain informed consent is a well-documented counseling session. Documentation enhances your credibility. A signed consent form or a note in the chart made at the time of the informed consent process is evidence that a valid consent was obtained. Some states have made some informed consent defenses statutory. These include that the patient did not want to be informed or would have had the procedure in any case, that the risks are commonly known or too remote a possibility to be substantiated, or that the situation was an emergency.

5.2.2 Confidentiality

When we talk about confidentiality, we are referring to the practice of not sharing information that someone has told us with the intention that it be only for our ears. The principle of confidentiality has both public health and individual health rationales. Socially and medically, it is important to encourage people to seek out and obtain medical care when it is needed. The promise of confidentiality enables vulnerable individuals to share what may be personal and otherwise embarrassing information with the physician. We all know someone who uses any opportunity to share her most intimate stories and the details of her medical problems. Most of us are not so open. We would think twice about talking about ourselves to a provider if we knew, or even worried about, our personal histories becoming cocktail conversation or common knowledge. In the long term, confidentiality leads to a healthier, more productive, population. The role of confidentiality in healthcare has been recognized since Hippocrates.[197] It is considered the cornerstone of the therapeutic relationship. As such it has been given strong protection by legislatures and by the courts.

There is a difference between privacy and confidentiality. Privacy relates to a person's physical integrity or personal information. Freedom from unwanted intrusion by other people is *physical privacy*. It is the right to be left alone. Some years ago, I was giving a talk to a small group of about 10 people. I decided on an informal arrangement, and sat among the attendees looking at the slides projected onto a

screen. Every time the woman sitting to my right asked a question, she put her hand on my back. In doing that, she continuously invaded my physical privacy.

Informational privacy relates to the right of an individual to determine what particular information and how much information about herself she wants to share with other people. As professionals, we are encouraged to share our salaries because such information can be helpful to colleagues when they negotiate with their employers. Many people do share, but others are reluctant to divulge this information and make it public. Informational privacy is the personal control over information that an individual would prefer to keep secret. The right to privacy is important in protecting the patient's interests.

Confidentiality is a way of protecting a patient's privacy. In a healthcare situation, a patient is inherently vulnerable and at a disadvantage in relation to the provider. A person will not be able to get the most out of her medical care if she does not feel secure in disclosing information about herself to her physician. The provider can only work with the information she has been given by the patient.

The professional has a duty to safeguard the secrecy of the patient's information which was disclosed within the professional confidential relationship. In general, everything said by a patient or her family to a physician in the context of obtaining a medical diagnosis and treatment is confidential. Those confidences belong to the patient. The physician may not use confidential information without the patient's consent.[198] Sharing patient information with a colleague in the same office in the course of dealing with a matter related to the operation of that office is not considered as a nonconsented, nonprivileged disclosure to a third party.[199] The healthcare provider's duty of confidentiality is not absolute. There are some exceptions to the duty of confidentiality that are recognized by law, such as the reporting of instances of child or elder abuse. Legal exceptions aside, confidentiality is now a cardinal rule of medicine, and is justifiably relied on by patients.[200]

5.2.2.1 Privilege

Some communications are specifically protected by law. For example, remarks made between spouses, physicians and patients, attorneys and clients, confessor and penitents may be protected from a forced disclosure on the witness stand. Privilege is a rule of evidence that is created by state law. In a federal court, the issue of privilege is determined by the laws of the state in which the court is located.

Physician licensing acts usually specify the physician–patient privilege. The law enables the holder of the privilege (the patient) to prohibit the person with whom the confidential information was shared (the physician) from testifying in court without her consent. In the physician–patient relationship, the patient holds the privilege. She can keep the physician from testifying about confidential information. If my physician is called to testify in court on a matter that would require her mentioning some information that I provided in the course of my care, I can invoke the physician–patient privilege and prevent her from doing so.

In a lawsuit, the privilege can be lost if it is not asserted in a timely manner. It is waived in a malpractice suit. In general, it is not the physician who may invoke the

privilege, although there are instances when it is invoked by physicians on behalf of the patient. The physician–patient privilege is not limited to information that has been obtained from a patient for the purpose of treatment. Any information shared within the relationship is privileged. However, information about a person that anyone can observe would not be privileged.

During an appointment with my physician, I may tell her that I have been dying my hair since it turned white when I was 18 years old. If I have done a poor job and anyone who looks at me can see that my hair has been dyed, the fact that I dye my hair is not privileged. The same lack of privilege would apply to surgery scars that are visible. The physician–patient privilege is considered to extend to information contained in medical and hospital records. If the communication between a patient and her physician is made in the presence of a third party whose presence is not reasonably necessary for the communication—such as other people sitting in the waiting room—that communication then is not privileged.

5.2.2.2 Waiver

The physician–patient privilege may be waived, or relinquished, by the patient. A waiver can be either express or implied. Making a statement to the effect that you are waiving the privilege is an expressed waiver. Bringing a malpractice lawsuit against the physician or a company in the form of a products liability suit creates an implied waiver. You cannot claim that the physician has been negligent or that you have been injured by a product and then try to prevent the use of information obtained during your care if that information would aid in the defense of the lawsuit.

5.2.2.3 Release of Patient Information

In the 1970s, the professional genetic counseling community was small. Everyone knew one another. When a counselor needed information about a patient or family member, it was easy to pick up the telephone and talk with a colleague. A formal release of information was always required, but was not always in hand during that conversation. I am embarrassed to say that I have been burned once or twice after sharing information and never receiving the promised release. That situation would not happen today.

HIPAA[201] now protects the privacy rights of patients by limiting the use and disclosure of health information, and by providing patients with greater access to and knowledge about the use of their health information. As a general rule under HIPAA, a patient's written authorization is required for any use or any disclosure of protected health information for any reason that does not involve treatment, payment health operations or as required by law. "The release is in the mail" is no longer acceptable under any circumstance.

A person can assign her right to review her own records to anyone she chooses, including her attorney. Requests for patient records, whether from the patient herself

or from another source (an attorney), should be authorized by the patient in writing. I have had patients who have refused to sign any releases.

If the information requested is the patient's and is important for her care, most people would not object to signing the proper release forms. Valid authorization should not only be signed by the person whose information is being requested, it should also clarify the parameters of the release. This should include the specific type of information to be disclosed, the identity of the healthcare provider the records are being requested from, and for whom they are being requested.

The release should specify the length of time that the authorization is valid. If you work with a person over time, you will need to obtain a new release on a regular basis. A release signed by your patient when you first met should be redone if you need information, even if it is from a previous source. The minimum information needed for the authorization includes the information to be disclosed, the intended recipient, and a purpose. Consent to disclosure by a patient should be informed, voluntary, and complete. It will need to comply with the regulations of your state. If the patient is a minor or incapacitated, a surrogate must consent to disclosure or authorize the release of information. When the surrogate is not a parent, a court may have already determined who has that authority. The legal responsibility to maintain confidentiality ends with a person's death in some states. If you are seeking information about a deceased patient, the executor or next of kin should be asked to sign an authorization. You need to check your state's statutes regarding the release of information on deceased individuals (Table 5.8).

There are a few circumstances for which written authorization is not required. These include disclosures to people involved in the patient's care. In general, you do not need a release from the patient to communicate with the referring provider. If you refer the patient to another provider, when a child needs an eye examination, and the patient complies, there is an implication of permission for you to provide the patient's information to the ophthalmologist. You should keep the patient informed, and as long as she does not object, you do not need to obtain written authorization. Disclosures required by law, public health activities, and health oversight activities do not need written authorization. Some standards of care authorize disclosures without written authorization, such as to funeral directors or for tissue donation programs.

A colleague of mine had a patient who was seen because her cousin was diagnosed and treated by a nephrologist. The diagnosis was important to the patient for

Table 5.7 Differences among Privacy, Confidentiality and Privilege

Privacy
• Physical integrity: the right to be left alone.
• Informational privacy: the right to decide who can know what about you.
Confidentiality
• Sharing information under circumstances that show the speaker intends the comments only for the ears of the person spoken to.
Privilege
• Communications that the law protects from forced disclosure on the witness stand.

Table 5.8 A valid authorization should include:

What information is being requested
From whom the information is being requested
The provider who will receive the information
The length of time the release is valid

her family planning. The affected child's parents signed a release of information so that relevant testing could be offered to the family. The physician who received the release would not provide the medical records. She insisted on sharing only the diagnosis. After much pressure was put on her, she finally agreed to send the pathology report. It contradicted the information that she had given verbally. A valid authorization for release of information cannot be ignored. You cannot refuse to make records available to a person who is entitled to them. Doing so could be considered fraudulent concealment.

When you receive a release of information, you need to think about how much information to include in your response. A minimum amount of information should be included in disclosing health information. You do not have to send a copy of the entire chart unless it is requested. The "minimum necessary" general rule states that you should make reasonable efforts to limit the health information that is disclosed to the minimum necessary to accomplish the purpose of the request. The nephrologists who would share only the patient's diagnosis was not complying with the release of information and not providing sufficient information to accomplish my colleague's purpose.

This rule does not apply to the information that you give to the patient herself. It also does not apply to requests by healthcare providers who need it for treatment of the person herself. A patient may authorize the release of more than the minimum information. The patient has a right under HIPAA to an accounting of the disclosures of her health information going back six years. This accounting would include the date of disclosure, what information was disclosed, and to whom and why the disclosures were made. It would be helpful for you to have a list that included each time you gave information about your patient to someone else.

In the day-to-day running of an office, concerns about confidentiality need to be considered. However, HIPAA regulations were not meant to make practical procedures impossible. It is acceptable to use sign-in sheets and to ask patients to fill out registration forms in the waiting room. You can talk to a patient at the reception desk, and you can leave a chart in the examination room door, facing the patient's name towards the door. If you send your patients an appointment reminder in the mail, the patient information should be covered or sealed.

5.2.2.4 Duty to Breach Confidentiality (Duty to Warn)

A patient was referred to me because of multiple miscarriages. Chromosome analysis revealed that she was a balanced translocation carrier. We reviewed her family tree to identify those family members who may be at an increased risk for reproduc-

tive complications. The patient rejected the idea of sharing her chromosome results with a particular sister who, she said, was currently pregnant and "too nervous" to handle the information.

The issues raised by this situation have broad ramifications. We need to think very carefully before ignoring a patient's desire not to share her genetic information. The doctrine of confidentiality, however, is not absolute. The confidentiality of a patient must be maintained unless there is some significant public interest that would be served by breaching confidentiality. Examples of significant public interest include the prevention of contagious disease and the protection of children and the elderly. Because of these goals, states have mandated the reporting of suspected child abuse and the occurrence of sexually transmitted diseases, among other things. In such cases, the risk of harm to third parties has been balanced against the social, economic and medical consequences of a breach of confidentiality to the patient (Table 5.9).

In the context of genetic counseling, the issue of third-party interests comes up in relation to two main areas: testing for disease causing mutations and the diagnosis of an inherited disorder. Genetic status is often compared with that of having an infection that can be transmitted from individual to individual. The analogy is not really accurate. Genes are shared with some family members and transmitted to some offspring. When a person is identified as a disease gene carrier or as having a genetic disorder, there are a limited number of individuals who may be impacted by the information. Any need to breach the patient's privacy should arise only in a narrowly defined context, that is, when the risk of immediate harm is significant and the patient refuses to share the information with those family members who may benefit from it.

In real-life patient encounters, the situation is not usually as grim as we imagine it might be in our theoretical discussions. In general, researchers have found that people feel a strong obligation to inform their family members of the results of genetic tests.[202] Those who decide not to tell certain relatives do so for many reasons. Some have a desire to protect relatives from painful knowledge. Others find it is difficult to overcome conflicts within the family, while some feel that their relatives do not need to be told.

We expect that only a small number of individuals will not want to notify relatives and will refuse to notify specific at-risk relatives. The debate regarding the need to breach confidentiality concerns only these few individuals. There are professional policies that we can refer to when considering this issue. The NSGC COE states that genetic counselors will maintain a patient's information as confidential unless released by the patient or required to disclose by law.[203] The American Medical Association[204] encourages the provider to offer assistance in communicating the

Table 5.9 Conflicts created by third party claims to information.

- Privacy rights of patients
- Statutory prohibitions against disclosing medical information to others without appropriate permission
- Harms from not providing information

risk of disease to relatives, and the American Society of Clinical Oncology[205] supports limiting the provider's obligation to the communication of familial risks to the individual who is being tested.

In 1976, the California court held that psychotherapists may have a duty to warn third parties of the danger threatened by their patients in *Tarasoff* v. *Regents of the University of California*.[206] This familiar case has often been used as a basis for arguing that geneticists also have a duty to warn at-risk relatives. The duty that was recognized by the California court was very narrow. It was limited to situations where the harm was foreseeable, serious, and immediate, and the victim was known or identifiable. These parameters cannot be easily applied to inherited disorders.

The exceptional circumstances that may permit disclosure are subjective. What is a serious condition or a high likelihood of occurrence may be open to interpretation. The foreseeability of harm is uncertain when it is applied to possible future genetic disease. My patient was found to be a translocation carrier. The risk of her relative also being a translocation carrier is not necessarily a harm to that individual. Any reproductive implications of that possible carrier status are not immediate. Genetic risk is often incompletely defined and the interventions available may be ineffective for reducing future harm.

There are very few court cases that directly address breach of confidentiality of genetic information. The following cases are some of the most relevant to genetic information.

In California, the court did not find a duty to warn for an adoption agency.[207] The plaintiff had placed her son for adoption. Several years later she had a second son who had severe combined immunodeficiency (SCID). After learning that her first child had also been affected, she claimed that the adoption agency knew, or should have known, the genetic nature of the SCID diagnosis of the first child, and therefore should have warned her of the risk for having other affected sons. The court found that knowledge of a genetic condition does not create a duty to disclose such information to genetic relatives.

There are two cases from New Jersey that are of interest to the genetics community. In 1981, the New Jersey Supreme Court found that parents are foreseeable victims because of the parent–child relationship.[208] After the birth of their second child affected with cystic fibrosis, the parents brought a suit against the child's physician. The court found that the child's physician had an independent duty to the parents to disclose the child's diagnosis. The physician could reasonably foresee the consequences of his negligence in failing to tell the parents until she was 4 years old that their child had cystic fibrosis.

More recently in New Jersey, the plaintiff in *Safer* v. *Estate of Pack*[209] claimed that the physician had never warned the family that her father had an inherited cancer (familial adenomatous polyposis). The New Jersey court held that in terms of foreseeability, there is no essential difference between the risk from an inherited genetic disease and that from infection. The physician was found to have had a duty to warn the patient and the members of his immediate family of the genetic nature of his diagnosis. Reasonable steps were required to be taken to assure the

information would reach, or be made available for, those family members likely to be affected by the information. The duty to warn, however, may not always be satisfied by warning the patient and may, according to the court, require a breach of confidentiality.

Florida addressed the issue of a duty to warn in *Pate* v. *Threlkel*.[210] The mother of the plaintiff had been treated for medullary thyroid carcinoma. When the plaintiff developed the same cancer as her mother, she claimed that the physician had had a duty to warn her of the risks. The Supreme Court of Florida held that any duty to warn a patient of genetic risk extends to those third parties who would benefit. The patient's immediate family would be known to the physician. However, such a duty may not require warning the family directly. Informing the patient of the risk to the family may satisfy the duty to warn. The court found that to require a physician to seek out and warn various family members would often be difficult or impractical. The burden placed on the physician would be too heavy.

Case law suggests that a minimum requirement is that the patient needs to know the inherited nature of a genetic disorder and which family members may be at risk. Many states now have regulations that protect patient genetic information. On a federal level, the Health Insurance Portability and Accountability Act (HIPAA)[211] has very strict standards for protecting the privacy of patient health information, and those standards apply to all covered entities. If you are considering sharing a patient's information without authorization, keep this standard in mind. A genetic counselor is considered covered entities by virtue of being a certified and/or licensed professional. HIPAA also applies to those who are employed by, or are a business associate of, a covered entity.

One of the arguments for allowing a breach of confidentiality is the improved care of third parties. It is not clear, however, whether breaching the confidentiality of a patient's genetic information actually leads to the testing and/or treatment of at-risk relatives. When assessing a breach of confidentiality, courts take into consideration and weigh (1) what the risk is (is it 1% or 50%), (2) how serious the condition is (is it life threatening), (3) whether family members can learn about the risk from other sources (shared family history), and (4) whether breaching confidentiality will result in preventing harm.

There are steps you can take to avoid a confrontation with a patient. In a testing situation, you can go a long way toward fulfilling your responsibility by discussing with the patient prior to testing the importance of the information that may be obtained to at-risk relatives. You can identify which relatives would be in the at-risk category, explore different ways to inform them, offer support, and encourage the patient to discuss her results with these at-risk family members. Offering written materials to the patient or group counseling sessions for the family may also be helpful.

5.2.2.5 Defense to Breach of Confidentiality

If you release patient information without proper authorization, you need to be prepared to show that your disclosure was made because of interests that are more vital

and have greater protection under the law than the patient's right to confidentiality. An explanation could be that a public interest in the information that requires the disclosure of the information for health reasons, or that there is a public policy that permits disclosure to the patient's spouse. Of course, as mentioned above, there are laws that require disclosure in some situations, such as gunshot wounds. You will not be able to defend the disclosure if the plaintiff can show that it was malicious.

5.2.2.6 Publications

It is very exciting to have your first professional paper accepted for publication. Genetic counselors who have faculty positions may be under pressure to publish, but most are not. Professional publications are intended to facilitate communication among researchers and clinicians, and to provide a forum for professionals to present research results or clinical cases to scientific colleagues. It can be disheartening when you get pages of comments and suggestions from an editor. There are, however, professional editorial standards with which authors must conform.

Issues of both consent and confidentiality are especially important when we are presenting patient-related findings. The publication of information or photographs without consent, a discussion of a particular patient without consent, and allowing a patient to be identified by name, description, or appearance have all been considered a breach of confidentiality and an invasion of privacy. The need for permission applies to every individual in the published article. Consent to publish photographs also has to be obtained from all the individuals depicted in the photograph.

I had a patient whose child was born with an unusual syndrome. She would not consent or give permission to add the baby to the published literature. In the course of our discussion about the syndrome, the parent saw published photographs of an affected child. She accused us of publishing the baby's photograph without permission! Fortunately, we could demonstrate by the copyright date of the photographs that they were not of her child.

In the publication of pedigrees, Botkin et al.[212] found that it is not uncommon to publish pedigrees without notifying the family depicted and without obtaining informed consent to publish. They also found that there is poor adherence to the recommendations of the International Committee of Medical Journal Editors for the protection of patient privacy in research publications. Bennett[213] discusses the issue of masking or altering pedigrees to protect the privacy and confidentiality of the family depicted, and the implications for the scientific information presented. The format of the publication, whether it is a medical journal with education or with scientific purposes, is not relevant when patient information or photographs are included.

Intellectual property law applies to publications. Protection of copyrights and trademarks, defamation, and piracy are issues that may apply when you disseminate information to the public. Complying with a publisher's requests for releases helps protect you from any possible claims.

5.3 Improper Techniques

When we think of techniques, we think of phlebotomy students practicing drawing blood first on fruit and then on one another. We think of medical students working on their cadavers. Improper technique is not easy to pinpoint in a consultative setting. Usually it refers to treatment services. However, in genetic counseling practice we learn by talking with patients.

There is a growing body of literature on counseling techniques and the practice of genetic counseling. Some techniques, such as nondirectiveness, have been guiding principles of the profession. The ASHG definition of genetic counseling[214] and the NSGC Code of Ethics[215] support nondirectiveness as a standard for genetic counselors. There are genetic counseling textbooks that address genetic counseling techniques.[216] These can be used by plaintiffs as sources of the techniques that contribute to the standard of care. Examples of directive and nondirective statements can be found in Baker et al.[217] As the profession of genetic counseling grows to include new areas of expertise, such as cancer counseling, practitioners may find there is a need to develop other counseling approaches.

5.3.1 Nondirective

The one question a patient can ask me that usually gives me pause is: "What would you do in this situation?" This is one way of asking for direct guidance, to be told what to do. I often think I know what I would do if I were the patient. I also know that what I would do is irrelevant to the patient's life. How to respond to this question in a constructive way took me a lot of time to figure out.

Early in the development of genetic counseling as a profession, opinions differed widely on how directive the genetic counseling process should be. In 1974, Fraser[218] reported that only a minority of counselors believed that counseling should stop at the point where an estimate of risk is given, and that the parents should make up their own minds what to do, without further advice from the counselor. At the other end of the spectrum was the authoritative father figure who felt comfortable telling people whether or not to even have children. As may be expected, most counselors did not support either extreme. In line with the early definition of genetic counseling, it was thought that many people seeking counseling needed both help to understand the meaning of a statistical probability, as well as the opportunity to discuss the pros and cons of their situation with someone who was not only sympathetic but also well informed. The counselor was expected to avoid projecting her own personality into the situation. It was also recognized that the counselor would not be of much help to the counselee if she remained completely detached, concerned only with the statistical probability and not with the unique combination of factors that enter into the patient's personal situation.

Today, genetic counselors learn counseling techniques during their graduate training. The respect for autonomy that genetic counselors espouse has continued

to support the traditional nondirective philosophy of counseling. Nondirectiveness describes an approach to counseling that is aimed at promoting the autonomy of the client. It is a way of interacting and working with a client, with the goal of raising the client's self-esteem in order for her to have greater control over her life and the decisions she makes. It is also a way of thinking about the professional–client relationship in which at each stage the professional works to evoke the client's competence and ability for self-direction.[219] Nondirective counseling implies that it is the patient who makes the decisions, such as whether or not to pursue genetic testing based on her own values and family situation. Most important, it does not involve taking a passive role in the counseling process.

Whether genetic counseling is in fact nondirective, and whether it should continue to be nondirective, are questions that are beyond the scope of this book.[220] For our purposes here, we need to keep in mind that the standard of practice that is applied in a lawsuit is that practice which was accepted at the time of the alleged breach of duty. The research and reflection about the continuing role of nondirectiveness in genetic counseling is a continuing process. Until there is consensus within the profession that it is no longer a central tenet, however, it will stand as a technique that genetic counselors strive to maintain.

5.3.2 Nonjudgmental/Value Neutral

Genetic counselors are also trained to be nonjudgmental. The commitment of genetic counselors to the principle of autonomy also requires that patients be given information in a value-free, or neutral manner. The counselor is expected to not voice an opinion about the patient's choices or decisions regarding what to do with the information provided in the counseling session, or about what tests the patient ultimately decides to have or not have. The decision should be based on the values and preferences of the patient. Value neutral is not necessarily value-free.

Biesecker[221] points out that in fact genetic counselors have professional values that include the value and respect of the personal nature of decision making, the importance of personal freedom, self-determination, and reproductive choice, and the need for confidentiality. The goal of nonjudgmental counseling is to avoid imposing those values into the patient's decision-making process. Although he does not support continuing the ethos of nonjudgmental counseling, Caplan[222] states what could be considered a standard of care for genetic counselors: It would be considered a gross violation of the ethos of counseling by most counselors for a counselor to criticize or disagree with the ultimate reproductive decision of a client (Table 5.10).

There is a similarity between being nondirective—not telling the patient what to do even when you think you know what is best in a given situation—and being nonjudgmental, keeping your opinion about her decisions to yourself. Both of these counseling techniques involve not influencing a patient's choice with your personal agenda.

Table 5.10 Genetic counselors respect and value:*

The personal nature of decision making
The importance of personal freedom
Self-determination
Reproductive choice
The need for confidentiality

* From Biesecker (Note 220)

5.3.3 Transcultural Competency

The 2000 U.S. Census[223] shows that the population of this country has become increasingly more ethnically and culturally diverse. This trend is expected to continue through the next century. Culture is important in everything genetic counselors do. Many genetic counselors work with a culturally diverse client population. Whether we label our interactions with people from diverse backgrounds as transcultural, multicultural or cross-cultural, the issues and the need for cultural competency remain the same.

Cultural competency in healthcare refers to the ability to provide care to patients with diverse values, beliefs and behaviors in a manner that meets the patients' social, cultural and linguistic needs. The client's concept of health and disease will be informed by her own culture, religion, education and family standards. I had a couple who came for counseling because of consanguinity. The entire four-generation family was present. Because of space limitations, the counseling had to be done in shifts to include everyone. Decisions in this family were made by the group. This may not be the counselor's view of what is normal and what is not. It was certainly a new decision-making process to me at the time. I have heard a number of interesting causes of death from various clients. The "evil eye" has seriously been offered as a cause of death in many of the family histories I have obtained. Such a response has to be accepted and respected as a part of the patient's understanding of life and death.

The patient's approach to health and her expectations of us as professionals may even be diametrically opposed to how we have been trained to interact with clients. More than once I have found myself in the position of having to speak only to the male head of the family. It was the only way I had to provide information to the mother of an affected child or fetus. The man would then decide what would be shared with the woman, including what information she did not need to know. In some cultures, offering options to patients instead of choosing a course of action for them may be interpreted as a lack of medical expertise. A provider who is directive may be held in high esteem and not questioned about treatment recommendations. The provider's lack of understanding of the values of a patient, as well as the decision-making process as it occurs in the patient's culture, can serve as a barrier to an individual's benefiting from your services.[224]

Patient values should hold the greater weight and should prevail when there is a difference between those of the provider and those of the patient. Some patients

may have beliefs that seem to sometimes interfere with the exercising of their autonomy. We have to be aware not only of what cultural issues the client brings to a consultation, but also of our own biases, values, and assumptions. Awareness of the multicultural scope of our practice has to be translated into actual performance. Multiculturalism and diversity are in the forefront of our professional commitments.

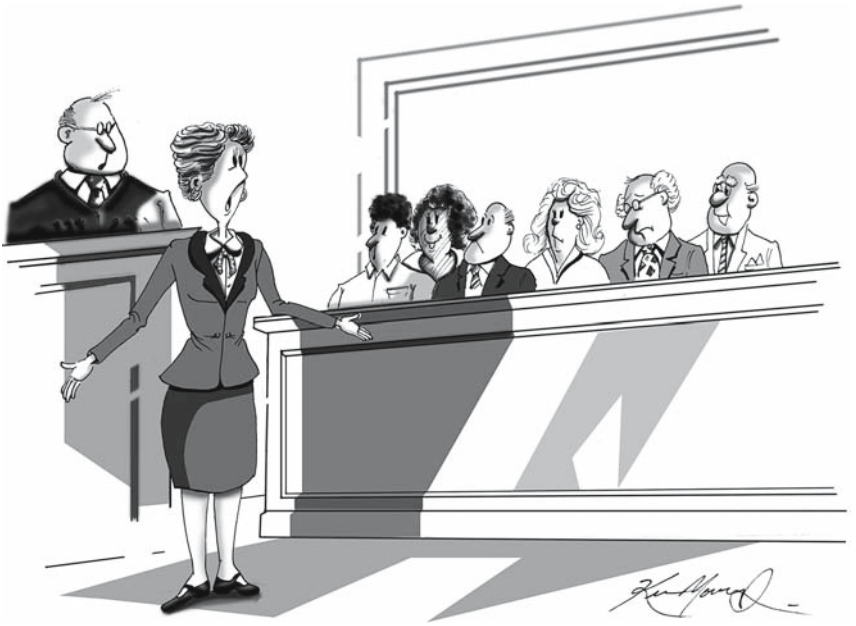
Transcultural sensitivity has been recognized to be an important goal.[225] It is a goal that genetic counselors have set for themselves. One focus of the 1992 Asilomar Conference was ethnocultural issues in genetic counseling.[226] A practitioner who strives to approach client consultations with culturally appropriate strategies, as opposed to a monocultural attitude, would be working within the standard of care for genetic counselors. Although these issues present challenges for genetic counselors, continuing education is an important way to achieve competence in working with a diverse population.[227]

5.3.4 Defenses for the Duty Element

The first defense to the duty element is that you did not owe the plaintiff a duty because there was no professional relationship between you and the plaintiff. You have to show that there was no professional relationship established. This is not always easy. Some courts have considered whether a professional relationship can be claimed on as little basis as a telephone call.[228]

The second line of defense to the duty element is the argument that even though there was a relationship and therefore you did owe a duty to the plaintiff, the duty you owed to her was not that which she claims you breached. In *Munroe* v. *Regents of the University of California*,[229] the court found there was no duty for genetic counselors to test or advise parents regarding the possibility of Tay–Sachs disease when they were not in a high-risk population for being Tay–Sachs disease gene carriers.

You can demonstrate that the duty you did provide was within the standard of care as established by the profession. If a genetic counselor wants to maintain a professional standard of care in her individual practices, she should (a) read the literature and know about online resources; (b) know the NSGC Code of Ethics and any practice recommendations as they are published by the NSGC; and (c) be able to demonstrate competency by taking the certification examinations, or having some other equally standardized mechanism to demonstrate competence, such as a license or continuing education credits.



"Any prudent genetic counselor would have done the same."

Chapter 6
Breach, Causation and Damages as Elements of a Lawsuit

6.1 Breach

Once the plaintiff, Ms. P., has demonstrated that there was a professional relationship between you and her, she has also established that you had a duty to her because of that relationship. Her next step is to demonstrate what that duty was. Once she has done that, she then has to show that you did not fulfill that duty. She has the burden of proving that you in fact breached the duty you owed her; that you did not do all you could for her within the expectations of your relationship, or that you did not have and/or use the required skill and judgment. Her goal is to show that you did not meet the standard of care.

The breach element is probably the most frequently disputed element of a malpractice lawsuit. How does one breach a duty? The question to be answered usually comes down to: "Did the genetic counselor meet the appropriate standard of care?" We have already discussed what standards are and how they are established for a profession. We also know where Ms. P. will look to define the standard of care that existed at the time of the alleged breach. Who now decides if the duty that was established by the professional standards has not been met?

6.1.1 Decision Makers

The question of breach is one of fact and not of law. It is, therefore, a question a jury or the court (whoever is the trier of fact in the case) will have to answer. A case may be tried by a judge alone, with no jury present. This is called a bench trial. In a jury trial, the jury has to know what standard of care is imposed by law. Based on common knowledge alone, and without technical training, jurors usually cannot always know what conduct constitutes the standard in a medical practice. They will learn this by hearing evidence regarding what the duties of a genetic counselor are.

There are some situations where what the plaintiff claims to have happened is so obviously lacking in reasonable care, and the results are so bad, that the lack of reasonable care would be apparent to a lay person. It would then be considered to be

within the common knowledge and experience of the general population as represented by the jury. A familiar medical example would be the removal of a patient's left kidney when it is the right kidney that is diseased. The exception to the rule requiring expert medical testimony is called the "common knowledge exception." It is safe to say that it is common knowledge that surgically removing the wrong kidney represents a lack of reasonable care. Otherwise, the standard of practice may be furnished by expert testimony. In *Gold* v. *Davis*[230] the trial court was not required to give a common knowledge instruction to the jury on the genetic counselor's standard of care because the court decided the issue was to be determined by expert testimony.

6.1.1.1 Expert Witnesses

An expert is a person who by knowledge, training or experience is deemed by the court to be qualified to testify and to express an opinion on scientific, technical or medical subjects. In an informed consent case, some courts do not require expert testimony, while others allow expert testimony regarding the materiality of the information that the plaintiff claimed had been omitted. In Section 4.2.7, we presented some guidelines for a counselor who is considering testifying as an expert witness.

6.1.1.2 Reasonable and Prudent Behavior

Genetic counselors engage in the informed consent process with patients. If a problem arises from treatment or testing, the plaintiff's claim of a deficiency of the consent can be used to shift the responsibility to the provider. In an informed consent case, the jury determines whether the plaintiff would have refused treatment if she had been fully informed.

The question of the importance of the information that was not provided, or the materiality of that information, may be decided by the jury. One of two tests can be used by the jury in making its decision, depending on where the case is heard. The *subjective* test requires the jury to decide if the particular individual bringing the claim, this specific plaintiff, would have refused the treatment or testing. The *objective* test requires the jury to ascertain if a reasonable person in the plaintiff's position would have refused treatment.

The plaintiff will use the expert testimony given to assist the jury in understanding the evidence or in determining whatever fact is in issue. Her burden of proof is satisfied by the submission of evidence that indicates there is a reasonable probability of negligence. She is not required to prove beyond a reasonable doubt, nor does she need a preponderance of the evidence, that there was a breach of duty. She only needs to show that the breach may be reasonably inferred by the evidence. The fact that the plaintiff had a poor outcome is not sufficient to meet her burden of proof to show there was a breach of duty.

The jury will also determine what a reasonable and prudent genetic counselor would have done in the same or similar circumstances at the time of the alleged negligence. This determination is based on the evidence and on the expert's testimony. The question will be: "Did your action, the way you practiced, rise to or come within the applicable standard of care for genetic counselors?" Ms. P. will try to prove that a competent genetic counselor would have acted in a manner that is different from yours and would have achieved better results than you did, that is, that there would have been no harm. You will have to introduce evidence to show that a competent genetic counselor would have done the same thing you did or practiced in the same manner.

6.1.2 Defense to Breach Element

The plaintiff has the burden of proof for the breach element. She has to show that you breached your duty. You can argue against the breach element by demonstrating your compliance with the standard of care. You do not want to lose a lawsuit based on evidence that you do not have. Files should be easily located and properly documented so that you do not have to rely on your memory or on inadequate notes. You can call your own expert witness. You can show that your skill and knowledge are on a par with that of other genetic counselors, and that you applied them appropriately.

In a wrongful life action, the defense usually focuses on the facts of the case. Often the provider claims that the patient was not completely open with her and did not reveal all the relevant information that was needed to determine fetal risks or assess the genetic nature of a problem. Another defense that has been used is that because of the timing of the pregnancy when the patient was seen, the patient would not or could not have had the option of an abortion. Your opinion of what the patient's choice may have been does not determine what the standard of care is that is owed to her.

To use the rule of law that "ignorance of the law is no excuse" as a model, remember that ignorance of the standards of care is no excuse.

6.2 Causation

The law of negligence does not hold a defendant liable for damages she did not cause. The law also does not consider any and all harms worthy of being rectified. And showing only that there was negligence on the part of a provider is not sufficient. The plaintiff has to show that the negligent act she has accused you of committing was a substantial factor in, or resulted in, an injury to her, for which the law allows compensation. The question of causation involves both the injury that is causally related to the negligent act, and also the extent to which the negligent individual may be held liable for the consequences of her conduct.

6.2.1 Remote Causation

There is a difference between a remote cause and a proximate cause. A remote cause may have started the process that resulted in the injury. The original negligent individual is liable for all the consequences that flow naturally from that negligent act. However, if any new, intervening acts occurred between the initial cause and an injury, the individual who may have been the original cause may not be held liable for the resulting injury. For example, a patient finds a lump in her breast. The biopsy is done in a way that makes a lumpectomy not a viable option, and mastectomy is recommended. The physician who performed the biopsy negligently is responsible for the patient's need for more extensive surgery than may have been originally required. The patient's friends advise her to use a nutritional program in lieu of surgery. She follows their advice, declines surgery, and eventually dies of breast cancer. The physician who performed the biopsy is not responsible for the patient's death, because the patient's choosing to follow her friends' advice was an intervening act. The negligent biopsy was not the proximate cause of her death. This is an example of the doctrine of superceding causation.

An intervening act, however, is not always considered a superceding act. An example is the death of a patient when life support is withdrawn, when the actions of an individual result in the injuries that had required life support in the first place. The initial tortfeasor would be held responsible for the death. The life support merely kept the effects of the injuries in suspension, and when it was removed the original injuries caused the death.

Figure 6.1 illustrates the sequence of causation. A New Jersey court found that the decision to conceive a child despite knowing that the child was at an increased risk for birth defects is not a supervening cause of those disabilities.[231]

6.2.2 Proximate Cause

Causation requires a factual connection between the breach and the injury. A significant degree of connectedness justifies imposing liability. It is the proximate cause, that which is closest to the injury and without which no injury would have occurred, that is considered. It does not have to be the only proximate cause, just a proximate cause.

Proximate cause is tested by hindsight. As a general rule, an act or an omission is the proximate cause of an injury if it was a substantial factor in bringing about the injury. A reasonable person would regard that act or omission as a cause. The

Remote Cause	Intervening Cause	Proximate Cause	Injury
Poorly Done Biopsy	Friend's Advice	No surgery	Death

Fig. 6.1 Causation

professional accused of negligence did not have to foresee the exact extent of the results of her actions. Medical practice during prenatal care that negatively impacts the parents' ability to decide whether or not to have a termination of pregnancy is an example of a causally related injury.

In a wrongful birth action suit for failure to warn of the risks of taking Provera during pregnancy, the test of proximate causation required several findings according to the court ruling. These are the showing (1) that the possibility of a fetal defect would be material information to the mother, (2) that the risk for that defect did occur, (3) that the risk was reasonably foreseeable and not remote in relation to the negligence, and (4) that the mother would have terminated the pregnancy had she known.[232] The patient must establish a causal relation between the drug she took (Provera) which she claims she was inadequately warned about and the harm that occurred, which in that case was the bilateral limb reduction defect in her son.

6.2.3 Informed Consent Cases

Like wrongful birth lawsuits, an informed consent suit is based on a patient's right to self-determination. In an informed consent case, the provider is required to disclose medically accepted risks to the patient. The patient claims that she would not have consented to a treatment if she had been told of all the risks. This is the argument commonly used in drug-use lawsuits. It is also used when a procedure results in an injury.

The patient claims that she did not have all the information she needed about the risks from the treatment or procedure. She has to show that the information that she did not have caused the injury. That is, that the injury that she suffered, like having a child with a birth defect, would not have occurred but for the consent she gave for the treatment. Her position is that she would have withheld consent if she had all the information about the risks of the treatment. This is an application of the "but for" rule. The "but for" test considers whether the injury would have occurred in the absence of the negligence of the provider.

A patient falls out of a bed where the railing was not raised and breaks a leg. Would that patient otherwise have a broken leg? Based on this test, an act is not considered a cause of an event if the consequences would have happened even if the act had never occurred. If the patient had osteogenesis imperfecta and would have broken her leg by moving around in the bed, the position of the railing would be immaterial. The causation in fact is one issue of fact for a jury.

A second factual issue in causation is foreseeability. Being hit by a train is a foreseeable consequence of lying on the tracks of a busy railroad. Infection is also the foreseeable consequence of using needles that have not been sterilized between patients. The provider is liable for the foreseeable consequences of her act. In malpractice, the injury must be the foreseeable result of the provider's substandard practice. When we do not assess a patient's ethnic background, it is foreseeable that an at-risk couple would not be identified and could have a child with an autosomal recessive disorder. The plaintiff has to prove that the injuries that occurred would

have been foreseen as a likely result of a breach of standard of care by a reasonable provider.

Plaintiffs in informed consent cases can make use of the medical literature to prove that the risk that did occur was known to the medical community. When it can be demonstrated that the risk is one that is professionally known and the patient was not advised of the risk that occurred, a case has been established. The testimony of an expert witness may not be needed. When the standard for disclosure is imposed by law, it is not necessary to use an expert witness. When the standard is established by medical consensus, expert testimony is used to show causation.

When an injury is caused, the negligent individual is responsible for that injury, and for those injuries caused as a result of the original injury. In *Schirmer*,[233] the patient had chorionic villus sampling (CVS) because she has a balanced 11/22 chromosome translocation. Having been given the results of the CVS that indicated a female balanced translocation carrier, the patient continued the pregnancy. A boy with an unbalanced translocation was born. The breach in this case was the failure to correctly diagnose a pre-existing genetic defect in the fetus. This failure was the proximate cause of the injury. The unbalanced translocation was not the injury. The negligent genetic testing caused the patient to make an ill-informed decision that resulted in the loss of her opportunity to terminate the pregnancy.

In a California case,[234] the treating physician and an imaging facility did not identify the presence of spina bifida prenatally, and thus prevented the parents from considering the possibility of ending the pregnancy. The child, born with spina bifida, hydrocephaly, and a cleft palate, experienced anoxia during the repair of the cleft palate. The treating defendants were held liable for the additional harm that resulted from the original negligent acts.

Causation is established through expert testimony when the injury is not one that is traditionally within the knowledge of a layperson. The expert witness gives an opinion as to whether or not the negligence caused the plaintiff's poor results. The plaintiff must show that there is a reasonable probability that the injury was caused by the provider's negligence.

Once all the evidence has been presented, the jury weighs the evidence in a light most favorable to the plaintiff. The verdict reached by the jury is presented to the court. A court does not usually set aside a jury verdict. It may, however, set it aside if the verdict is conclusively against the weight of the evidence. "Conclusively against the weight of the evidence" means that the verdict was one no reasonable juror could arrive at.[235] A verdict may also be set aside if it was the result of a mistake, partiality on the part of the jury, or corruption.

6.2.4 Defense to the Causation Element

Causation is established through expert testimony. The expert discusses the nature and predictable course of a condition or disease. She explains the basis of her opinion—that the alleged deviation from proper practice altered/did not alter the medical result that otherwise would be expected. She argues that the harm was not

"but for" the alleged breach. Expert testimony can be used to minimize or negate causation.

The defense can also suggest that an act or omission by the plaintiff contributed to, caused, aggravated, or exacerbated the injury. For example, the defendant can demonstrate that the plaintiff failed to follow medical advice or to keep her appointments.

6.3 Damages

The last element of the tort of malpractice is damages. In general, the concept of damages involves the actual loss of or damage to the interests of the patient caused by the breach of the standard of care.

The purpose of awarding damages is to ensure that the person who has been injured is "made whole." That is, the court aims to return her to the position or condition that existed before the breach or negligent act occurred. Since most medical malpractice results in injuries that are usually impossible to correct, monetary awards are made as compensation for the loss sustained by the plaintiff. The plaintiff has to establish that the damages arose from the injury that was caused by the malpractice. Damages must be ascertainable. If they are not measurable, or are remote, uncertain, or speculative, they cannot be used as a basis for recovery. There are two main categories of damages: punitive and compensatory.

6.3.1 General Damages

General damages are those that cannot be figured out or arrived at with any degree of financial accuracy. They include noneconomic losses, including pain and suffering, mental anguish, grief, and other related emotional complaints. Special compensatory damages are based on the actual result of the injury. These include past and future medical, surgical, hospital, and other related costs, past and future loss of income, funeral expenses in a death case, and unusual physical or medical consequences occurring from the breach.

These two types of compensatory damages are also called intangible damages and tangible damages. A reasonably precise computation is used to calculate tangible, or economic, damages. This can include past and future medical expenses, caretaking expenses, and physical therapy, among other things. The parents in *Howard* v. *Lecher*[236] recovered money for medical, hospital, nursing and funeral expenses for their child, who had Tay–Sachs disease. The costs of treating their child with Down syndrome were awarded to the parents in *Becker* v. *Schwartz*.[237]

Projected future damages are calculated as the amount of money that, if invested with a reasonable rate of return, would be expected to produce the amount projected

for when the future loss is expected to occur (such as expenses needed over time for living). The parents in *Schroeder* v. *Perkel*[238] were awarded the cost of the extraordinary medical expenses associated with raising a child with cystic fibrosis. Many states recognize some of these costs as damages.[239]

6.3.2 Compensatory Damages

Compensatory damages are those damages that are intended to compensate the injured person for the losses she sustained because of a negligently inflicted injury. The assessment of this type of damages involves the effect of the injury on the plaintiff, with the aim of finding a monetary, dollar, amount that will make the plaintiff whole. Injuries from ordinary negligence give rise only to compensatory damages.

6.3.3 Noneconomic Damages

Noneconomic damages include pain, which can be physical or physiological, and suffering, which includes mental anguish and loss of enjoyment of life, among others. These are among the most significant elements of damages.

Situations where an injury to one person produces a substantial intangible injury to another, such as to the parents or children of the injured individual, are also recognized. Loss of society or loss of guidance, for example, may be included and recoverable. The court in *Curlender* v. *Bio-Science Laboratories*[240] stated that, in a wrongful life lawsuit, a child with Tay–Sachs disease had the right to recover damages for the pain and suffering she would endure during her lifetime.

This was the opposite of the conclusion of the court in *Gleitman* v. *Cosgrove*,[241] which rejected the child's action for wrongful life because damages were impossible to ascertain. The court refused to weigh the value of life with impairments against nonexistence. The court in *Gleitman* also decided not to recognize a cause of action for the parents' emotional suffering because the child's right to live was considered greater than the parents' right not to endure emotional and financial injury. Although they recovered economic damages, the parents in *Howard*[242] did not recover for emotional suffering (Table 6.1).

Table 6.1 Damages

Punitive: meant to punish and make an example of the tortfeasor
Compensatory: meant to compensate injured party
General: cannot be fixed with financial accuracy
Special: based on actual results of injury

6.3.4 Punitive Damages

Punitive damages may be awarded along with compensatory damages. They are based on the conduct of the defendant. The intention of awarding punitive damages is to punish the defendant for grossly negligent, willful and/or malicious conduct. Punitive damages are meant also to deter others from doing the same thing or acting in the same way by making a public example of the defendant. Punitive damages are rarely awarded in medical malpractice cases.

6.3.5 Assessing Damages

The jury assesses damages, both general and special, that reflect the facts and circumstances of the case. The jury determines the value of intangible damages. One goal of the tort reform movement is to limit the recovery of intangible damages. A jury is not allowed to use the amount the members would want for themselves as compensation for the injury, pain, and suffering claimed as a guide for determining damages. They may also not disregard obvious injuries. They do not have to believe that every injury causes pain in general or the specific pain that has been alleged. Juries are required to base their decision on what a reasonable person would find to be fair and adequate in the circumstances. The jury is expected to act reasonably and intelligently, and to make a judgment that is consistent with the evidence. The decisions of the jury usually stand. Judicial review and modification of a jury award could occur if the award has been the product of bias, passion, prejudice or other improper motives, or if the amount arrived at does not reflect a deliberate and conscientious conviction in the minds of the jury, shocks the conscience of the court, or is obviously contrary to the weight of the evidence.

Many states have statutes that limit the amount that can be received for damages in a malpractice lawsuit. The doctrine of avoidable consequences is used to reduce the amount of damages in proportion to the fault of the injured party. This does not mean that the injured party has a duty to act. It comes into consideration when the injured party's carelessness, for example, occurs after the breach of duty and increases the risk of harm.

6.3.6 Defense to the Damage Element

A claim of contributory negligence can also be used as a defense to the damage element. This is not available in all states. In those states that do recognize contributory negligence, a patient who does not exercise the ordinary care that a reasonable prudent person would, may be found to have contributed to the poor result.

Chapter 7
Defenses to a Lawsuit

7.1 Helping Yourself

What have we learned so far in managing our risks? The first line of defense in a malpractice suit is to show that a professional relationship did not exist between you and Ms. P. By understanding how professional relationships can be established, you will be better able to avoid an uncomfortable situation and an unexpected claim of a relationship. In the absence of such a relationship, Ms. P. has no grounds for an expectation of care or services. You do not have a duty to someone who is not a patient or client.

Lawsuits are most often brought by people with whom you have established a professional relationship. You can argue that the duty you owed the patient because of your relationship was not the duty that Ms. P. claimed you had. She will claim that you breached your duty. You have to be able to provide evidence to show that you performed the duty expected of you by the patient and by your profession. You also have to show that your services did not fall below the professional standard of care. This can be done by comparing your services to those in the professional guidelines or recommendations, the NSGC Code of Ethics, and the professional literature. It will be important to demonstrate that your skills and knowledge (1) at least meet a minimum standard by having certification and a valid license if available and (2) are up to date through continuing education credits.

For breach of confidentiality claims, you will have to demonstrate that there was a legal mandate to do so, or that the public interest outweighed the right to confidentiality. In an informed consent case, the signed consent and documentation of the informed consent process will support your defense. If the lawsuit gets to the jury, it would be helpful to be able to demonstrate that your actions did not result in the injury. You should also show any intervening/superceding acts that may have occurred.

7.2 Affirmative Defenses to Malpractice Lawsuits

In a civil action that seeks damages for personal injuries there is no presumption of innocence. The defendant is required to meet the plaintiff's allegations at trial. There are some defenses that are used besides the defenses already discussed for

each element of a malpractice lawsuit. Instead of arguing against the truth of the plaintiff's claim, a defendant can assert that the plaintiff did not have a legal right to bring the lawsuit in the first place. These arguments are called affirmative defenses.

7.2.1 Statute of Limitations

States have established specific timeframes within which a person may bring a lawsuit. If this period of time has elapsed, the court will not allow the lawsuit to go forward. The point at which the time begins to run is defined by the state in the statute of limitations. Many valid malpractice lawsuits have been dismissed because they were not brought in a timely fashion. There is a discussion of statutes of limitations in Section 5.1.3 as they apply to the required length of time for availability of medical records.

7.2.2 Contributory Negligence

The theory of contributory negligence traditionally requires that in order to recover damages the plaintiff has to be free of any fault or negligence on her own part which may have contributed to the severity of the injury. It has all-or-nothing consequences. In medical malpractice lawsuits, contributory negligence is not usually, but may be in some states, available to the defendant healthcare provider to lessen her negligence. The average person is not ordinarily expected to know if the treatment or procedure performed was done negligently, or whether there were risks that may have influenced her decision to undergo a procedure that were not disclosed.

7.2.3 Comparative Negligence

If a plaintiff acts in a manner that contributes to her injuries, fault for the injuries can be apportioned. Any damages that are awarded can be reduced by the percentage of the negligence attributed by the jury to the plaintiff.

7.2.4 Assumption of the Risks

The defense of assumption of the risks focuses on what the patient actually knew when she was informed of the risks of a procedure and agreed to assume responsibility for those risks. The assumption of risk can be express, as through a consent form, or implied by the circumstances. There must be clear evidence that the patient had knowledge of the risk, appreciated and understood the nature of the risk, and

voluntarily chose to incur the risk. Documentation of an informed consent process goes a long way to satisfy the requirements. The patient cannot assume the risk for a provider's negligence.

7.2.5 Good Samaritan Statute

The Good Samaritan defense is appropriate for a defendant who acted as a volunteer in an emergency. It would be difficult to demonstrate that an emergency existed that required genetic counseling.

7.2.6 Indemnity or Release

Indemnity or release is an agreement in the form of a contract under which the entire responsibility is shifted from one individual to another. A valid release would be a total defense to a malpractice lawsuit.

7.3 Countersuits

Not all medical malpractice lawsuits are legitimate. A possible recourse to these claims is a counterclaim by the provider. There are a number of different causes of action available for countersuits. We will discuss some of those countersuits, but keep in mind that such suits are rarely successful. This is a result of the weighing of public policy issues by the courts. On the one hand, individuals need to be protected from unjustified litigation. On the other hand, protecting the right of an individual to seek redress for injuries is seen as a greater good. The policy concern is that people with legitimate claims may be reluctant to pursue a lawsuit if they think they may be successfully sued by the provider for bringing the lawsuit in the first place. Such favoring of an individual's free access to the courts makes it very difficult to bring a successful countersuit.

7.3.1 Malicious Prosecution

The remedy of a claim of malicious prosecution began as a move against those who bring criminal charges. It has been extended to include those who wrongfully bring a civil action. In a medical situation, malicious prosecution would not be brought until after the malpractice suit has been settled. The defendant provider has to have a favorable outcome from the malpractice suit first. This can be a dismissal of the case by the plaintiff or by the court, but not on procedural grounds.

These suits are usually brought against the plaintiff in the original medical malpractice action, and may also name the plaintiff's attorney and possibly the expert medical witness. The provider has to prove each of four elements of the cause of action: (1) the initial suit was terminated in favor of the plaintiff in the countersuit (the original defendant), (2) it was brought without reasonable or probable cause, (3) it was driven by malice, and (4) the counterclaimant suffered a special grievance. The probable cause element is the most difficult to show. It is also difficult to show malice on the part of the patient. The special grievance element requirements differ by state, and may include a showing of business losses or the seizure of property, for example. The costs of defending against the original suit, increases in insurance premiums, or loss of community standing are accepted grievances in some states.

7.3.2 Abuse of Process

The abuse of process involves showing that the use of the legal process in bringing the original lawsuit has been perverted, and the process itself has to be shown to have been used for a purpose that was not contemplated by the law. The elements of this cause of action include: (1) unauthorized use of an otherwise legal process, (2) existence of an ulterior purpose in bringing the original lawsuit, (3) and the provider suffered damages as a result. There does not have to be a favorable determination for the provider from the original lawsuit prior to initiating an abuse of process action. The ulterior motive is the most difficult element to prove. It is not usually sufficient to claim that the medical malpractice negligence lawsuit was brought to coerce a monetary settlement.

7.3.3 Defamation

A provider's reputation can be damaged by either written or oral false statements made by one person to another about her or her professional abilities. In the course of a lawsuit, however, there is an underlying privilege that covers oral and written statements made in the course of the actual legal proceeding that makes it difficult to succeed in a defamation action. Such a privilege allows for the free exchange of facts and opinions that are needed for a jury to make a decision in the case. If false statements are made outside the legal proceedings, where the privilege that applies to the judicial proceeding no longer applies, defamation may be a viable countersuit.

7.3.4 Negligence

A charge of negligence can be brought against the plaintiff's attorney for negligently bringing an unfounded lawsuit in the first place. The first, and mostly impossible, hurdle would be to show that the plaintiff's attorney owed the defendant provider a duty. Courts have held that an attorney owes a duty only to her client, and that duty

is to zealously represent her and prosecute the claim. To expect an attorney to owe both her client and the provider/defendant a duty would be to create a conflict of interest for the attorney.

7.3.5 Intentional Torts

Courts have also rejected causes of action in countersuits that were based on invasion of privacy, intentional infliction of emotional distress and the persistent incitement of lawsuits. *Prima facie* tort countersuit actions involve the intentional infliction of harm, without excuse or justification by an otherwise lawful act, causing special damages to the provider. These actions have not been more successful than any of the other counterclaim suits.[243]

"Electronic Communication."

Chapter 8
Communication

8.1 Face-to-Face

Up until now, we have been talking about the legal issues that may arise from the face-to-face provision of genetic services in real space. We have learned that there may be liability in what we say and what we do not say to patients. When we accept a patient, we have a responsibility to maintain a minimum standard of practice. The patient expects to be informed of any increased risks she may have based on her family or personal histories, or on her ethnic background.

The information shared with us by the patient must be maintained as confidential. Unauthorized disclosure of confidential information can lead to legal difficulties for you. We also learned that there are responsibilities with regard to testing. Tests that are indicated should be offered. Those who do testing must obtain informed consent, do the test properly, interpret the results correctly, and communicate those results to the appropriate people. The issues inherent in using traditional, paper medical records were also discussed. There are federal and state regulations in place to protect patients from the misuse of confidential communications and medical information. Medical negligence lawsuits are supported by a showing that a duty that the provider had to the plaintiff was established by the provider–client relationship. The plaintiff then has to show that the provider breached that duty by not meeting the standard of care, and that failure resulted in an injury with damages.

There are, however, methods of communicating and providing genetic services other than in person. When we consider these alternatives, we cannot assume that the use of these methods implies simply transferring techniques and automating existing paper medical records or creating databases. We also cannot assume that the provider–client relationship or the duty that is expected because of the relationship will remain the same. The professional standard of care will be influenced by the increasing use over time of these alternate methods of communication.

8.2 Electronic Communication

8.2.1 Internet

In 1999, it was estimated that up to 70 million people in the United States went online to use the Internet to obtain health information. The Internet allows individuals with problems to find information and support from others with similar problems. The recognition of a disorder was brought about through the postings on the Internet of a woman who could not get help through traditional channels. More than 7,000 people registered on her site claiming similar symptoms. She named her condition Morgellon disease, and the medical community began investigating the disorder.[244] Although not all the information found on the Internet is reliable, patients who have some information about their health issues can begin a dialogue with their provider with some basis of understanding that leads to truly informed consent for treatment.[245]

The beginnings of telemedicine were developed and in use as early as the 1960s when Massachusetts General Hospital transmitted video images by a fixed camera from the hospital's airport clinic to the hospital itself.[246] Many practitioners have begun to provide medical care, both information and counseling, through telecommunication technology. We think of telemedicine as the application of interactive audiovisual technology, live teleconferencing, to patient care.

Here we will use a definition of telemedicine that is broader. It encompasses the use of telecommunication or computer technology with a geographic separation between provider and patient. This includes the telephone, e-mail and fax machines, as well. Telemedicine is a rapidly developing method of providing healthcare because of its many benefits, and has become an integral part of healthcare delivery in diverse settings. Legal issues of telemedicine parallel those of traditional medical care. These issues include licensure, privacy and confidentiality, informed consent, credentialing, jurisdiction and choice of law, rules of evidence, as well as economic issues. This aspect of medical care is developing and expanding, with the protocols and standards that apply continuously evolving.

In California, the law has found telemedicine in its relationship to medicine to be the same as distance learning is to education. It is a method of practice that happens to use interactive radio, video, or data communication. The same standards are applied to telemedicine as are applied to the face-to-face provision of healthcare. The traditional laws that regulate healthcare fraud and abuse can be applied to healthcare business on the Internet.

8.2.1.1 Licensing

Using telemedicine techniques, professionals can provide services across state borders. Licensing is a state responsibility. A practitioner in one state may be taking a risk of violating another state's licensing laws when using or providing telemedicine consultations. Some states distinguish between consultation services and ongoing

care, though. Kansas,[247] for example, requires a physician to be licensed in that state if the person she is taking professional care of is located in that state. Utah[248] only allows an out-of-state licensee to teach, but not to practice, medicine.

Other states allow consultations on a limited basis. South Dakota,[249] for example, allows a nonresident physician to practice electronically on an irregular basis. If a state does not include telemedicine in its definition of medical practice, it may be a violation of that state's law to provide telemedicine services to patients in that state. The physical location of the physician or the patient may determine the legal guidelines for both the medical license and the legal jurisdiction.

8.2.1.2 Professional Relationships

Telemedicine increases the opportunities for consultations. We have learned that the provider who sees a patient in her office has a professional relationship with that patient if the patient has a reasonable expectation of care. The question then becomes: "Does doing telemedicine establish a provider–patient relationship, with all the duties and obligations that flow from that relationship?"

The issue of when a relationship is established and what duties are then owed to the patient is an area of telemedicine that is also still evolving. Parallels to face-to-face relationships provide guidance for those standards. When a professional enters into a dialogue with a patient, complies with a request for an evaluation and offers advice on which the patient relies, a physician–patient relationship has been established. It does not matter which medium was used. A provider who has an ongoing relationship with a patient and who consults with another provider through the use of electronic techniques, still maintains a professional relationship with the patient. As a specialty consultant, your relationship with the patient will depend on the circumstances. You may be involved as a consultant in the patient's care either by working with the provider or with the patient directly. In a formal consultation setting, a relationship with the patient is established. Failing to provide ongoing care may be construed as abandonment.

As a resource to the primary care provider, the issue will be whether your consultation was performed with the express or implied consent of the patient. In a more informal setting, the primary provider may discuss the patient's medical and family history with you as a consultant. Consider: "A 6′5″ person with long fingers came to see me because of poor sight. What would my differential diagnosis include? Should I send her for a cardiology consult?" No professional relationship between you and the patient would be established if you answered that inquiry. You can decrease your exposure to liability by the accurate and complete documentation of your encounter with the patient or with her primary provider, as well as any disclaimers that you shared.

8.2.1.3 Informed Consent

There is concern that patients cannot give true informed consent for the use of telemedicine, since there is not enough knowledge of the problems that may be

inherent in the practice. Telemedicine requires an additional piece to the informed consent process, so that patients have an understanding of the risks and benefits of the communication technology used and of the record-keeping process.

8.2.1.4 Storage of Data

Storage of telemedicine data raises concerns that are similar to those of traditional medical record storage. Patient medical records must be protected against unauthorized access. Data compression is useful for storage of such records, because it allows more data to be stored on smaller devices. Data compression software, however, drops out excess bits of information, which can slightly alter the record.

No matter what method of transmission is used, the risk to data security increases with the use of electronic communication methods, and the data can be compromised. Encryption provides added security. The laws that govern the protection of patient confidentiality include telemedicine and electronic communications. Prior to federal regulations being enacted, states had different confidentiality laws which could have applied to data regarding the same patient. Since patient information was in different locations, there were difficulties adhering to the law.

8.2.1.5 Cybermedicine

The nontraditional, unique, technology-enabled interactions among healthcare providers and patients does not fit into the real space system of rule making that is based on borders between physical spaces. The areas of potential problems with cybermedicine include fraud, authenticity of sources, and reliability of information. Telemedicine involves providers who are known and who are communicating with other providers or with the patient for the benefit of that patient.

Cybermedicine involves unknown providers who create websites that can be used to diagnose unknown patients. These websites can be informational and/or interactive. A website that creates or develops information that is provided on the Internet is called an information content provider, as opposed to an Internet service provider. The service provider hosts services and others in the distribution process.

Some cybermedicine sites provide links to the content of other sites. Such sites are unlikely to be liable for negligent medicinal advice provided on those other sites. A site that has content that has been created for and/or posted on it, however, will have liability, especially where a direct relationship between the health provider on that site and the patient accessing the site has been established. Reviewing Internet advertising and websites is done by the Federal Trade Commission, which is responsible for checking the online information to ensure that it contains no false or misleading information.

Blogging is the newest method of relaying information on the Internet. A blog is a type of webite composed of postings (comments) arranged in chronological order, and archived by category and date. They are useful resources for news and research, are usually content-rich, and can become trusted sources of information.

Search engines aggregate and index blogs, and there are online blog directories. To be effective, blogs should be updated regularly by someone who is knowledgeable about the subject.

Any person who disseminates information to the public, including through the use of Internet websites, is liable under the intellectual property regulations that usually apply in the publishing arena. These regulations include defamation, piracy, and trademark or copyright infringement, among other things. Intellectual property issues that would also apply to websites include protection of the website design, and the domain name and address. Statutes of limitations that apply to print material also apply to information posted on the Internet.

In the course of providing medical services, signatures are required on documents, chart notes, prescriptions. This is true for face-to-face consultations, and it is true for cybermedicine. An electronic signature standard has been developed by a coalition of biopharmaceutical companies, a pharmaceutical industry organization, and government agencies. The standard provides legally enforceable digital signatures that meet global regulatory requirements.[250] Electronic signatures were included in the draft of HIPAA, but not in the Final Rule. Digital signatures can be used to meet certain requirements of the Final Security Rule, but they are not required.

The issue concerning the identity of the other party—either the provider or the site visitor—goes both ways. The standard of care that applies and jurisdiction that would cover a claim have yet to be resolved in the context of cybermedicine. In a lawsuit based on telemedicine services, the question of where the trial will be located depends on whether the patient can claim sufficient contact between the provider and the patient's home state.

If you decide to establish a cyber-presence, providing genetic counseling through telemedicine is a professional activity. Being paid for your time and expertise should be expected. Some states have legislation that specifically includes compensation for telemedicine. You need to be familiar with the regulations in the state in which you practice.

8.3 Privacy

Protecting the privacy of online communications cannot be taken for granted. A threshold level of protection is provided by the password you use to log on. A study of the practices of computer users showed, however, that at least 25% of users never get around to changing the password originally assigned to them. Another 25% choose new passwords that are obvious, like the name of a pet or their birthday. Passwords are best when made up of nonsensical combinations of letters, numbers and symbols and when they are changed frequently.[251] Some of us cannot remember random series of characters that are regularly changed. If you have to write your password down, keep it in a secure place that is not obvious. I had a secretary who hid the password to our database, and then left a note in the middle of her desk: *The password to my system is on the pink paper in the lower right hand drawer of my desk.*

The service provider hosts services and others in the distribution process. The privacy policy of any Internet service provider you use should be in writing. You should have a copy provided to you. Avoid any service that does not have such a policy. Websites that you visit should also have privacy policies which are posted. There are technologies available to help protect your online privacy and your online communications. Keep in mind that the identity of other people online is not always what they say it is. The federal privacy protections discussed earlier have evolved to protect telephone and other communication methods, through the Electronic Communication Privacy Act (ECPA).[252]

8.3.1 Transmission of Information

Some states have adopted the recommendations of the National Conference of Commissions on Uniform State Laws regarding electronic transmissions, which states that an electronic record, signature or contract has the same legal impact as paper forms.[253] This has been applied to electronic records as of July, 2000. Federal electronic signature legislation took effect in 2000, and ensures that an electronic signature in the form of a sound, symbol or process that is attached to a contract by a person who intended to sign that contract is legal.[254] Protecting the integrity and confidentiality of electronic information is an important part of the use of online resources.

Many online activities are available to public scrutiny. The level of privacy of an activity is usually related to the nature of the activity, but there is no guarantee of absolute privacy. Public activities are archived in searchable databases and are available to anyone to view at any time. It is not illegal to do this under the ECPA. Some "semi-private" activities, such as password-restricted bulletin board services, are available. The communications made using these facilities may initially be read-only by members, but there is nothing to prevent members from copying or recording messages, and sharing them with others who do not have password access.

The utilization of e-mail, fax machine or telephone—although these are common methods of transmitting information—can jeopardize patient confidentiality. Any one of these method can expose a genetic counselor to liability. E-mails, faxes, and voice mail messages can be forwarded to someone you do not know or did not intend to have access to the message. E-mail and faxes can be printed out, copied, and circulated by hand. Even though the following information may seem obvious to you, it bears mentioning. Not everyone maintains the best practice procedures. I consider these the "Duhs" of these types of electronic communication.

8.3.1.1 E-mail

E-mail is a written exchange. It can be easily stored, forwarded, copied, or printed. When used in telemedicine, it is used as part of the ongoing relationship between the provider and the patient. E-mail can be thought of as a method or type of consul-

tative telemedicine. When you use electronic communication to respond to a patient with advice, and the patient relies on that advice, the interaction will likely satisfy the threshold requirements needed to show a provider–patient relationship and thus establish a duty of care.

E-mail is included in the definition of telemedicine in general telemedicine legislation, and by the Institute of Medicine and the American Medical Association.[255] It is covered under the ECPA as a digital communication, which makes it unlawful to read or disclose the contents of an electronic communication that is not meant for you. The exceptions to this law include employers who own the e-mail system. If you send e-mail from work it may be viewed by your employer. Online service providers that suspect there is an attempt to harm the system or another user, or have the consent of either the sender or the recipient may also view your e-mail.

Your e-mail message may be handled by several different servers during delivery, each of which may view messages under the ECPA exceptions. If you use a privately owned computer, commercial services have the capability of prying into the memory of that computer. Reviewing the privacy policy of any service you are considering using will help in limiting this type of activity.[256]

Deletion of an e-mail message from your computer does not erase it from the server on which it is stored. Remember that the "delete" command does not make the message disappear. If you use e-mail as a method of communication, you will find it difficult to deny sending or receiving a message. In general, you should avoid leaving e-mail open on your computer screen, and use a password-protected screen saver if possible. When you leave your office for extended periods of time, the "out of office" response is important.

There are some things you can do to protect privacy in cyberspace. Precautions should be taken to secure any patient-related e-mail by using enhanced technological security practices. Encrypted e-mail is like the delivery of a registered letter. Unencrypted e-mail is more like a postcard.[257] Confidentiality notices attached to your e-mail serve to remind people of the privacy issues involved when receiving an e-mail not meant for them. One long but clear example of such a notice would be:

> The information in this message, and in any documents attached to it, is confidential and may be legally privileged. It is intended solely for the addressee. Access to this message by anyone else is unauthorized. If you are not the intended recipient, any disclosure, copying, distribution or any action taken, or omitted to be taken, in reliance on it is prohibited and may be unlawful. If you have received this message in error, please delete all electronic copies of this message (and the documents attached to it, if any), destroy any hard copies you may have created and notify the sender immediately by replying to this email. Thank you.

There are many variations of this warning. You should discuss your choice of warning with your attorney or risk manager before including it.

When you have decided to use e-mail as part of your professional interactions, it is important to establish with the recipient a time frame for your responses. E-mail lends itself to casual and informal use of language. This may seem to be a benefit in that it may better reflect the writer's thinking. However, there is a line between informality and the impression of unprofessional language that you do not want to

cross. There is also an increased risk of misinterpretation of what you mean if you are not clear and precise.

We are going to briefly mention some basic and practical suggestions that may help reduce the possibility of compromising the patient's privacy. Use a "return receipt" for delivery to a patient to ensure its receipt. Double-check all the addresses in the "to" field before sending your message. Your e-mail communications should all have a disclaimer. Do not forward any patient messages without written permission from the patient. If you communicate with others about a patient, remember not to use patient identifiers. All e-mails should be copied to the patient's chart as part of the patient's medical record. If there are any questions or a lawsuit, these communications can be important in your defense. In some lawsuits, the production of e-mail messages is part of the preparation of the case. You should not assume that people who use e-mail in other situations understand the implications of its use in medical communications. This might necessitate a discussion with the patient about the risks and benefits of using e-mail to communicate medical information. You should obtain written permission from a patient to communicate via e-mail as a form of medical communication, and document that permission in the chart. There is no guaranteed privacy when you use e-mail. Clearly defined practices for your office should be followed.

8.3.1.2 Telephone

The telephone is probably the most frequently used piece of equipment in a medical office. A telephone conversation between a provider and a potential client does not necessarily create the provider–client relationship that is needed to meet the criteria for a malpractice lawsuit. The court can find that advice and counseling have been given over the telephone. When advice is offered by telephone, however, a relationship can be found to have been established. If advice is given over the telephone to a prospective patient, but the patient does not follow that advice, a defense to a malpractice claim would be that no provider–patient relationship existed because the patient did not accept the provider's services.[258]

Telephone consultations or conversations may be used to demonstrate a continuing professional relationship. The location of a malpractice trial may be determined by where the advice has been received, or in what state the patient has her telephone. The court in Michigan decided that the county where the caller received advice was the proper venue, not the county where the physician was located.[259]

It is essential to document your conversation in the patient chart. Some offices make use of a telephone logbook. The guidelines for medical record documentation apply to telephone calls. You should detail the dates of every call, with a brief note on what was said. Write in ink, note errors and corrections, and make your notes immediately after the telephone conversation. Some aspects of genetic counseling are done on the telephone.

Taking a history and getting the important information is more difficult over the telephone than in person. Visual cues are replaced by tone, expression, and choice of words. If you give advice and counseling over the telephone, a legal duty to

the patient is established. If you violate the standard of care, the same standard that applies to face-to-face encounters, a malpractice lawsuit might ensue. There are genetic counselors who conduct counseling sessions on the telephone. Ormond et al.[260] offer recommendations as to who, what, when, and where to make such telephone calls.

Proper technique extends to the use of the telephone. A telephone encounter has the same requirements as those for other methods of communication. Some of the following discussion may seem more obvious than the e-mail discussion above. I realized that proper use of the telephone is not common knowledge or practice when I was sitting in one room and listening in on a telephone conversation between a doctor, who sat several doors down the hall using a speaker phone, and his patient. Not everyone thinks about these issues. Needless to say, do not use a speaker phone when talking to patients. As with written records, do not give medical/genetic information to anyone without the patient's consent and whose identity you have not confirmed.

You may sometimes have to call patients at home. When you do, speak only with the patient or with an authorized "other." If you leave a message on an answering machine, limit your message to your name and place of employment, and a telephone number. Document in the patient's chart that you tried to call but could not reach anyone, if that was the case. This should include how many times you left a message, and whether a voice mail message or a message was left with which person. Leave a message with specified family members with permission of the patient. Any decisions that were reached during the telephone conversation also need to be documented in the patient's chart.

In your office, consider the privacy of your communications. Although it may seem somewhat extreme, do think about the security of your telephone. If your telephone has a redial function, the last number you dialed is stored in the redial memory. Anyone using your telephone can learn the name of the last person you called. For a fee, you can obtain the phone number of the last person who called your telephone. The activation code can be found in the local phonebook. Some cellular phones have memory for both the last several calls dialed and for the last several received. There are security options to prevent others from accessing the list of your calls that can be used if you want to protect the privacy of those phones. Information transmitted by telephone is not considered to fall under the Security Rule of HIPAA because it is not in electronic form before it is transmitted. If, however, you use the telephone to request information from a computer which is then faxed to you, this fax-back system does fall under HIPAA's Security rule. Following up on newborn screening using your state's automated system would be included.

8.3.1.3 Fax

Using a fax machine to transfer information may actually be a more secure environment than using the Internet. Privacy issues apply to the use of a fax machine. There are still concerns to be aware of regarding how you protect patient confidentiality when you fax patient information. You need to think about where the machine is

located and whether the faxes coming in and going out can be observed by third parties. The machine should be located in a secure area. Use of a cover sheet should not be influenced by how many individuals have access to the machine. Each fax cover sheet should have a disclaimer such as the following example:

> *Warning*: Information in the following faxed material is intended for the use of the individual/entity to whom it is addressed. It may contain information that is confidential, privileged, and exempt from disclosure under applicable law. Any unauthorized dissemination, distribution or copying of this communication is strictly prohibited.

Check the recipient's number before hitting the send button for the fax. Keep the message and the record of the transmission in the patient's chart.

8.3.1.4 Listserves and Message Boards

Listserves and message boards offer the opportunity to communicate with other people who have similar interests or problems. Some have closed membership, but many are often open to the public. Confidentiality issues are a concern when your posting is about a case. Be sure to have the client's consent before revealing any privileged information. Be careful of offering advice, soliciting business or commenting on professional colleagues or other third-parties if you make use of these forms of communication.

8.3.1.5 Electronic Medical Records

California had one of the country's first laws to address data management of electronic medical records containing personal data.[261] The trend of the modern healthcare system is toward computerized health information. This raises issues that are similar to, yet different from, the use of paper records. The benefits include rapid access to patient records, and more legible, timely, and accurate records. Transfer of records between institutions providing care can be automatic, with reduced duplication of services and testing. The Security standards of HIPAA can be met by following the Privacy Rules that are discussed in Section 2.2.1.2, above.

Storage

Electronically stored and transmitted data can be accessed remotely, silently, and possibly undetected without the intruder putting herself at physical risk. Large numbers of records can be accessed, altered or copied in seconds or minutes. The access, use, disclosure, interception and privacy of electronic communications were initially protected by the Electronic Communications Privacy Act.[262] The law was enacted in 1986, and covered "transfer of signs, signals, writing, images, sounds, data or intelligence of any nature transmitted in whole or in part by a wire, radio, electromagnetic, photo electronic or photo optical system . . .. "

The use of encryption provides confidentiality and can deny access to information in a file. The Final Rule of HIPAA covers electronically protected health information at rest, or in storage, as well as during transmission. It requires corroboration that data have not been altered or destroyed in an unauthorized manner. Who can authorize the release of information under HIPAA is defined as the person who is able to give consent to treatment, either the patient or the patient's personal representative. The personal representative would be the person named in a general power-of-attorney with specific authorization regarding health information; named in a living will or other advanced directive; a parent or court-appointed guardian of a minor child or incapacitated adult; or the executor/administrator of the estate of a deceased patient.

Use in Court

The admissibility of a computerized medical record may be needed in the defense of a medical malpractice lawsuit. Its usefulness may depend on how the record was created and maintained. It must be reliable and trustworthy. This can be achieved by making entries at or near the time of the service, with the time and date recorded automatically, and the person entering the information identified by the computer. Corrections may be made, but should be additions to the record with the time and date of the correction recorded.

There may come a time when you decide to replace the computer you have been using. There is no mechanism available at this time to ensure that the hard drive is completely clean of client information. You may want to have it physically destroyed by a company that has the equipment to do the job, or encrypt the hard drive before passing it along to someone else or trading it in for a new model. This may also seem extreme, but it is important to at least be cognizant of these possible pitfalls.

8.3.1.6 Tips for Online Research

The Internet is used by genetic counselors not only to communicate with or about patients, but also as a source of information in preparation for a counseling appointment. The amount of information is vast and accessible in a very short period of time. Using the Internet for research has its own set of potholes. The following are some suggestions for making that research more successful.

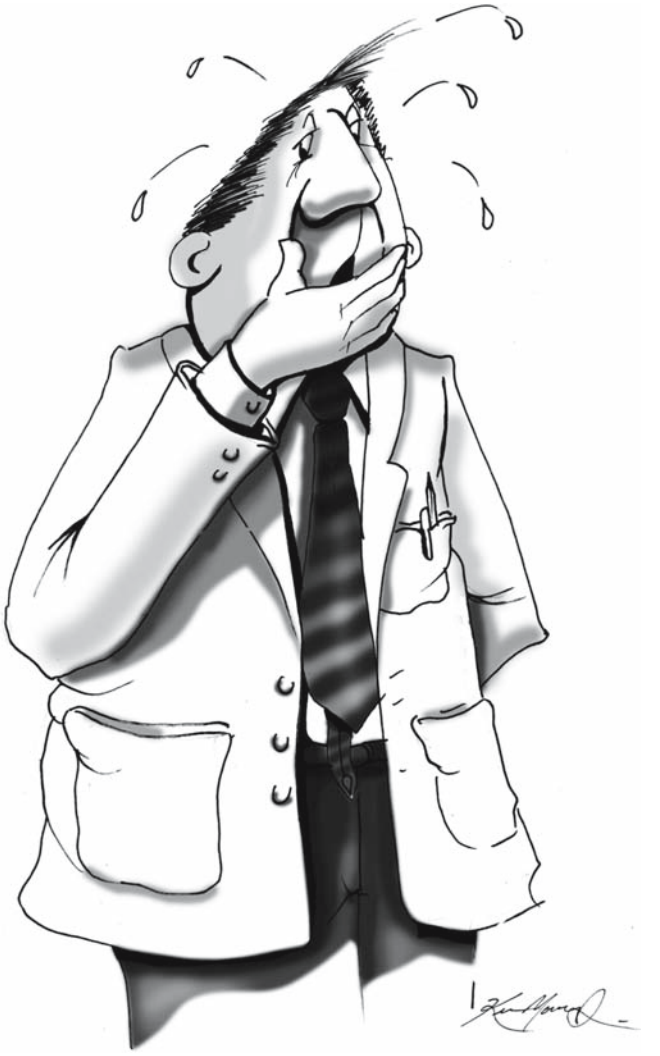
1. The most important aspect of performing any research on the Internet is verifying that the websites you use are legitimate sources for the information you need. The most straightforward way to do this is to use sites that are offered by recognized companies, institutions, corporations or government agencies. If you come across what looks like helpful information on a site sponsored by someone you have

never heard of, be sure to determine the objectivity of the site's author/sponsor by checking the author's/publisher's credentials and reading the site documentation ("About Us").
2. Not every online provider of medical information includes up-to-the minute changes, additions, or corrections to its site. It is up to you to make sure the information you retrieve from a site is the most recent. Ms. P. will be searching for policies and procedures, standards of care, or industry guidelines that apply to the time period during which her alleged injury occurred. Most websites provide a "last updated" reference. Others have a frequently asked questions (FAQ) section that explains how and when the data was updated. If the site does not indicate how current its data is, you can contact the site's author or sponsor.
3. As is true when doing research in the print literature, you may find different opinions about diagnoses or treatments. One way to confirm the reliability of the data on which the opinions are based is to check multiple sources of legitimate information until you start to build a consensus. You will know you are done when you begin to repeatedly see the same data.
4. Free information on the Internet has limitations. Many of the research websites are limited to one type of material and relatively simplistic search capabilities.
5. Before providing your name, snail mail and e-mail addresses, and possibly your credit card data, to register at a website in exchange for full access to data, check the website's privacy policy. You may or may not mind that your e-mail address will be provided to third parties that do business with that website. It is most important to know upfront what the site's sponsor will do with private information.
6. One constant truth about Internet research is that your output is only as good as your input. Be sure to check the search words you use so your query will be as complete and precise as possible.
7. There is no search engine that will pick up everything in the cyberworld. Password-protected information, proprietary information (information for which you need to be registered or pay money), and data collected in databases, for example, are generally not retrieved in the average Internet search. Just because your search does not retrieve the information you are looking for does not mean the information does not exist.
8. The Internet does not offer a sophisticated, easy-to-use trail of your research. Be sure to keep notes about the sites you have visited and the information which you located on each as your research proceeds.
9. Do your best to have a focused research strategy in place before you even log on in order to avoid information overload.

8.4 Managing Your Malpractice Exposure in Cyberspace

If you plan to build a website or provide services through the Internet, there are some basic approaches to use when you begin. These suggestions are only highlights of those that are available to help you manage your risks:[263]

1. Health on the Net Foundation (HON) is an advocate organization for the development and application of technologies in healthcare and medicine. The organization has developed a code of conduct for medical or health sites that addresses personnel, information, confidentiality, and funding. You should read the code and decide if you are willing to meet its standards. Displaying the code logo on your site announces to the public that you voluntarily comply with this code.[264]
2. Disclaimers may be used to suggest that the informational content of your website is for educational purposes and should not be used to replace a consultation with a healthcare provider. Wording such as "If you have symptoms or illness, contact your physician" can be included. You can specifically reject any responsibility for the content of other sites. You can also reject the possibility of establishing a provider–patient relationship: "No provider on this website will enter into a professional relationship with you."
3. You can segregate your site visitors into different populations, such as healthcare professionals and consumers, restricting access to a professional area by requiring a password or other form of identification. Using site zoning allows you to present different content to different populations.



"You are responsible for what you say, and don't say."

Chapter 9
Conclusions: Lessons Learned

9.1 Defensive Practice

One consequence of the expansion of medical malpractice torts and the pressures that it has put on the medical profession is an increase in defensive medical practice. Defensive practice is meant to protect the professional from litigation and not necessarily to benefit the patient. Practices that are defensive may supplement, replace, or reduce care. They are by definition not necessary.

There are two types of defensive medicine. Positive defensive medicine involves the addition of services, or the performance of extra tests and procedures. Negative defensive medicine involves declining to supply care, or the avoidance of patients needing complex care. In a study of the physicians in Pennsylvania, Studdert et al.[265] found 93% of specialists in high-risk medical practices (including obstetrics/gynecology, neurosurgery, and radiology) reported that in order to lower their risk of lawsuits they do not practice sound medicine. Interestingly, a physician's experience with lawsuits was found not to be associated with the tendency to practice defensive medicine. There has been a greater impact on diagnostic rather than on therapeutic treatment decisions. We all know of tests that are ordered to avoid a lawsuit. While the positive defensive practice of ordering costly studies may be wasteful, the negative defensive practice of reducing the availability of care in obstetrics/gynecology or radiology may have an affect on women's health. There are movements for reforms that improve medical productivity by reducing malpractice claims rates and the compensation based on those claims. Such reforms also reduce the time spent and the amount of conflict involved in defending against a claim.[266]

A lawsuit is not the only available method for resolving disputes. Alternative dispute resolution (ADR) includes methods that lead to an agreement by the parties rather than an imposed decision that is binding on the parties. The aim of ADR methods is to reduce the time spent over a dispute, lower the costs, and make it less cumbersome to arrive at a solution. Arbitration, mediation, and fact-finding all avoid the use of the judicial system.

Arbitration is done through a neutral third party who has the responsibility of resolving a specific controversy. When the arbitration is voluntary and contractual, it may be binding, unless there is a question of procedure. Nonbinding arbitration permits appeal or review. Arbitrating medical malpractice claims is not a new idea.

There is a growing list of jurisdictions that accept binding arbitration in resolving medical malpractice claims.[267]

Mediation involves having the parties to a dispute directly negotiating a settlement through the facilitation of a third party. For malpractice cases, a screening panel is available as part of the pretrial procedure. The recommendations of the panel are not binding. One or more experts can be asked to review the facts of the case and recommend a settlement or negotiation as a *fact-finding* panel. By clarifying the issues, the basis for a settlement can be identified.

Deficient communication is one of the reasons patients initiate lawsuits.[268] Out of 127 families who sued following perinatal injuries, 43% reported the suspicion of a cover-up[269] or felt ignored or neglected because they had not received an explanation of an error that was made.[270] It was the patient's perception of her care and of the provider that led to the lawsuit being filed. Disclosing medical errors respects patient autonomy and the value of truth-telling. It has been supported by many professional organizations. Patients express a desire to be told about errors that could harm them.[271] Some states have laws or regulations requiring the reporting of medical errors. Genetic counselors are trained in communications skills. The NSGC Code of Ethics supports telling the truth to patients.

9.2 Advice from Experience

Good practice is defensible practice. You should keep your practice within the limits of your expertise. If you (1) keep your skills and knowledge current and up to date, (2) know the parameters of your professional duties, (3) thoroughly and properly document your sessions, how will Ms. P. fare in her lawsuit against you? For one thing, she will have a hard time pointing to areas of negligence, and that will certainly weaken her case. She may not even find an attorney to work for her. If Ms. P. cannot prove either the duty element and/or the breach element, then her case will end there. It will not get to the causation and damages elements, because they are then moot. Will you be off the hook? Hopefully.

Recommendations by Ross[272] for anesthesiologists include some suggestions that might be adopted by all practitioners. Based on his finding that a substantial number of patients were unhappy with the care that was provided and felt themselves wronged by the system, he suggested, among other things, that careful personal conduct, good rapport, providing a realistic expectation and reviewing potential risks can go a long way toward helping to reduce exposure to lawsuits (see Table 9.1).

Table 9.1 What you can do to reduce exposure to lawsuits

Careful personal conduct
Establishment of good rapport
Involvement in patient education
Providing realistic expectations
Regular review of potential risks

What else can you do in your day-to-day practice to help manage your risks? Let me answer that in the negative and tell you what *not* to do. Do not look at each client as a potential plaintiff in a malpractice action. And please do not practice defensively by suggesting unnecessary diagnostic studies or consultations if they are not in the client's best interest. You have to continue to do the best you can as a competent, compassionate, and caring professional. And just in case, be sure to have adequate malpractice insurance.

Appendix

A.1 Definition of Genetic Counseling

A.1.1 1975[*]

Genetic counseling is a communication process that deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family to:

1. comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available managements;
2. appreciate the way that heredity contributes to the disorder, and the risk of recurrence in specified relatives;
3. understand the options for dealing with the risk of recurrence;
4. choose the course of action that seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and
5. make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.

A.1.2 2006[†]

Genetic counseling is the process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. This process integrates the following:

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[*] *Ad hoc* Committee on Genetic Counseling of the American Society of Human Genetics. (1975). *American Journal of Human Genetics*, 27:240–242.

[†] The National Society of Genetic Counselors' Definition Task Force: Resta, R., Biesecker, B. B., Bennett, R. L., Blum, S., Hahn, S. E. Strecker, M. N. and Williams, J. L. (2006). A new definition of genetic counseling: National Society of Genetic Counselors' Task Force Report. *Journal of Genetic Counseling*, 15(2):77–83.

- Interpretation of family and medical histories to assess the chance of disease occurrence or recurrence.
- Education about inheritance, testing, management, prevention, resources and research.
- Counseling to promote informed choices and adaptation to the risk or condition.

A.2 Scope of Practice[††]

This "Genetic Counselors Scope of Practice" statement outlines the responsibilities of individuals engaged in the practice of genetic counseling. Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling who help people understand and adapt to the implications of genetic contributions to disease. Genetic counselors interact with clients and other healthcare professionals in a variety of clinical and nonclinical settings, including, but not limited to, university-based medical centers, private hospitals, private practice, and industry settings.

The instruction in clinical genetics, counseling, and communication skills required to carry out the professional responsibilities described in this statement is provided in graduate training programs accredited by the American Board of Genetic Counseling (ABGC) or the equivalent, as well as through professional experience and continuing education courses.

The responsibilities of a genetic counselor are threefold: (i) to provide expertise in clinical genetics; (ii) to counsel and communicate with patients on matters of clinical genetics; and (iii) to provide genetic counseling services in accordance with professional ethics and values. Specifically:

Section I: Clinical Genetics

1. Explain the nature of genetics evaluation to clients. Obtain and review medical and family histories, based on the referral indication, and document the family history using standard pedigree nomenclature.
2. Identify additional client and family medical information relevant to risk assessment and consideration of differential diagnoses, and assist in obtaining such information.
3. Research and summarize pertinent data from the published literature, databases, and other professional resources, as necessary for each client.
4. Synthesize client and family medical information and data obtained from additional research as the basis for risk assessment, differential diagnosis, genetic testing options, reproductive options, follow-up recommendations, and case management.

[††] Approved by the National Society of Genetic Counselors, 2007

5. Assess the risk of occurrence or recurrence of a genetic condition or birth defect using a variety of techniques, including knowledge of inheritance patterns, epidemiologic data, quantitative genetics principles, statistical models, and evaluation of clinical information, as applicable.
6. Explain to clients, verbally and/or in writing, medical information regarding the diagnosis or potential occurrence of a genetic condition or birth defect, including etiology, natural history, inheritance, disease management and potential treatment options.
7. Discuss available options and delineate the risks, benefits and limitations of appropriate tests and clinical assessments. Order tests and perform clinical assessments in accordance with local, state and federal regulations.
8. Document case information clearly and concisely in the medical record and in correspondence to referring physicians, and discuss case information with other members of the healthcare team, as necessary.
9. Assist clients in evaluating the risks, benefits and limitations of participation in research, and facilitate the informed consent process.
10. Identify and access local, regional, and national resources such as support groups and ancillary services; discuss the availability of such resources with clients; and provide referrals, as necessary.
11. Plan, organize and conduct public and professional education programs on medical genetics, patient care and genetic counseling issues.

Section II: Counseling and Communication

1. Develop a genetic counseling agenda with the client or clients that includes identification and negotiation of client/counselor priorities and expectations.
2. Interpret individual client and family experiences, behaviors, emotions, perception, values and cultural and religious beliefs in order to facilitate individualized decision making and coping.
3. Assess client understanding and response to medical information and its implications, and educate client appropriately.
4. Utilize appropriate interviewing techniques and empathic listening to establish rapport, identify major concerns and engage clients in an exploration of their responses to the implications of the findings, genetic risks, and available options/interventions.
5. Identify the client's psychological needs, stressors and sources of emotional and psychological support in order to determine appropriate interventions and/or referrals.
6. Promote client-specific decision making in an unbiased noncoercive manner that respects the client's culture, language, tradition, lifestyle, religious beliefs, and values.
7. Use knowledge of psychological structure to apply client-centered techniques and family systems theory to facilitate adjustment to the occurrence or risk of occurrence of a congenital or genetic disorder.

Section III: Professional Ethics and Values

1. Recognize and respond to ethical and moral dilemmas arising in practice, identify factors that promote or hinder client autonomy, and understand issues surrounding privacy, informed consent, confidentiality, real or potential discrimination, and potential conflicts of interest.
2. Advocate for clients, which includes understanding client needs and perceptions, representing their interests in accessing services, and eliciting responses from the medical and social service systems as well as the community at large.
3. Recognize personal limitations in knowledge and/or capabilities and seek consultation or appropriately refer clients to other providers.
4. Maintain professional growth, which includes acquiring relevant information required for a given situation, keeping abreast of current standards of practice as well as societal developments, and seeking out or establishing mechanisms for peer support.
5. Respect a client's right to confidentiality, being mindful of local, state, and federal regulations governing release of personal health information.

A.3 The Code of Ethics of the National Society of Genetic Counselors**

Preamble

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. The National Society of Genetic Counselors (NSGC) is the leading voice, authority, and advocate for the genetic counseling profession. As such, the NSGC is an organization that furthers the professional interests of genetic counselors, promotes a network for communication within the profession, and deals with issues relevant to human genetics.

With the establishment of the code of ethics the NSGC affirms the ethical responsibilities of its member and provides them with guidance in their relationships with self, clients, colleagues, and society. NSGC members are expected to be aware of the ethical implications of their professional actions and to adhere to the guidelines and principles set forth in this code.

Introduction

A code of ethics is a document that attempts to clarify and guide the conduct of a professional so that the goals and values of the profession might best be served.

** Adapted January 2006. *Journal of Genetic Counseling*, 15(5): 309–311.

The NSGC Code of Ethics is based upon the relationships genetic counselors have with themselves, their clients, their colleagues, and society. Each major section of this code begins with an explanation of one of these relationships, along with some of its values and characteristics. These values are drawn from the ethical principles of autonomy, beneficence, nonmaleficence, and justice. Although certain values are found in more than one relationship, these common values result in different guidelines within each relationship.

No set of guidelines can provide all the assistance needed in every situation, especially when different relationships appear to conflict. Therefore, when considered appropriate for the code, specific guidelines for prioritizing the relationships have been stated. In other areas, some ambiguity remains, allowing for the experience of genetic counselors to provide the proper balance in responding to difficult situations.

Section I: Genetic Counselors Themselves

Genetic counselors value competence, integrity, veracity, dignity, and self-respect in themselves as well as in each other. Therefore, in order to be the best possible human resource to themselves, their clients, their colleagues, and society, genetic counselors strive to:

1. Seek out and acquire sufficient and relevant information required for any given situation.
2. Continue their education and training.
3. Keep abreast of current standards of practice.
4. Recognize the limits of their own knowledge, expertise, and therefore competence in any given situation.
5. Accurately represent their experience, competence and credentials, including training and academic degrees.
6. Acknowledge and disclose circumstances that may result in a real or perceived conflict of interest.
7. Avoid relationships and activities that interfere with professional judgment or objectivity.
8. Be responsible for their own physical and emotional health as it impacts on their professional performance.

Section II: Genetic Counselors and Their Clients

The counselor–client relationship is based on values of care and respect for the client's autonomy, individuality, welfare, and freedom. The primary concern of genetic counselors is the interests of their clients. Therefore, genetic counselors strive to:

1. Serve those who seek services regardless of personal or external interests or biases.
2. Clarify and define their professional role(s) and relationships with clients, and provide an accurate description of their services.
3. Respect their clients' beliefs, inclinations, circumstances, feelings, family relationships and cultural traditions.
4. Enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences.
5. Refer clients to other qualified professionals when they are unable to support the clients.
6. Maintain information received from clients as confidential, unless released by the client or disclosure is required by law.
7. Avoid the exploitation of their clients for personal advantage, profit, or interest.

Section III: Genetic Counselors and Their Colleagues

The genetic counselors' relationships with other genetic counselors, students, and other health professionals are based on mutual respect, caring, cooperation, and support. Therefore, genetic counselors strive to:

1. Share their knowledge and provide mentorship and guidance for the professional development of other genetic counselors, students, and colleagues.
2. Respect and value the knowledge, perspectives, contributions, and areas of competence of colleagues and students, and collaborate with them in providing the highest quality of service.
3. Encourage ethical behavior of colleagues.
4. Assure that individuals under their supervision undertake responsibilities that are commensurate with their knowledge, experience and training.
5. Maintain appropriate limits to avoid the potential for exploitation in their relationships with students and colleagues.

Section IV: Genetic Counselors and Society

The relationship of genetic counselors with society include interest and participation in activities that have the purpose of promoting the well-being of society and access to healthcare. Therefore, genetic counselor strive to:

1. Keep abreast of societal developments that may endanger the physical and psychological health of individuals.
2. Promote policies that aim to prevent discrimination.
3. Oppose the use of genetic information as the basis for discrimination.
4. Participate in activities necessary to bring about socially responsible change.

5. Serve as a source of reliable information and expert opinion for policymakers and public officials.
6. Keep the public informed and educated about the impact on society of new technological and scientific advances and the possible changes in society that may result from the application of these findings.
7. Support policies that assure ethically responsible research.
8. Adhere to laws and regulations of society. However, when such laws are in conflict with the principles of the profession, genetic counselors work toward change that will benefit the public interest.

A.4 Suggested Readings

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20. 410 U.S. 113, 93 S. Ct 705, 35 L. Ed.2d 147 (1973).
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22. 519 S.W.2d 846 (Tex. 1975).
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25. 575 F.Supp. 1309 (D.S.C. 1983); 566 F.Supp 1 (D.S.C. 1981).

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33. 84 A.D.2d 482 , 446 N.Y.S.2d 801 (1982).
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41. 490 A.2d 839 (Penn. Super. 1985).
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65. 15 Cal. Rptr. 2d 512 (Cal. Ct. App. 1992).

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69. *Pedroza* v. *Bryant*, 677 P2d 166 (Wash. 1984).
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73. See Appendix A.2.
74. For the required content of the notice of privacy practice see HIPAA § 164.520.
75. 42 U.S.C.1395, called the Stark Law
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158. 408 A.2d 496 (Pa. 1979).
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161. 677 A.2d 1188 (N.J. App.), appeal denied, 683 A.2d 1163 (N.J. 1996).
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Glossary

Action: a lawsuit, a formal complaint

Allegation: the statement of what a party to a lawsuit expects to prove

Alternative dispute resolution: any method of resolving an issue by agreement rather than through the normal legal process

Appeal: a claim of error in process or law by a lower court brought to a superior court and asking that court to repeal or reverse the lower court's decision

Authentication: the corroboration of a person or product as being the one claimed

Burden of proof: the responsibility of presenting sufficient evidence to prove a fact or facts that are in dispute

Case law: those laws and legal principles that are derived from judicial decisions in similar cases in a jurisdiction

Cause of action: a set of facts that support a legal right to file a complaint

Claim: a cause of action or a demand against a person or institution for money or property

Common law: the principles and rules that are derived from statutory and judicial decisions made in England and the American colonies prior to the American revolution

Common rule: the federal policy that formalizes and enforces the protection of human subjects in federal agencies and departments

Community Standard: see Locality Rule

Complaint: an initial document that is filed by a plaintiff which begins a civil lawsuit

Confidentiality: that property of information which makes it not available to or disclosed to unauthorized persons

Cybermedicine: the practice of medicine over the Internet

Damages: the sum of money a court or jury awards as compensation for a tort or breach of contract

Defamation: a false statement which can be made orally (slander) or in writing (libel) that injures a person's integrity and reputation, and which lowers that person in the esteem of the community or deters third parties from dealing with that person

Defendant: the person against whom recovery for damages is sought in a civil lawsuit

Discovery: a procedure used by one party to obtain facts and information about a case from another party in order to assist in the preparation of a case

Disclosure: the release or divulging of information outside the entity that holds the information in any form or manner

Due care: a level of reasonable and ordinary awareness owed by one person to another in specific relationships or circumstances

Due diligence: a measure of prudence, activity or assiduity, that is expected from, and ordinarily exercised by, a reasonable and prudent person under the circumstances

Duty: an obligation that is recognized by law

Electronic media: Storage media, which would include computer memory devices and removable/transportable digital memory medium

Encryption: the use of an algorithmic process that transforms data into a form that has a low probability of access without a confidential process or key

Expert witness: someone who has special training, knowledge, skill or experience and can provide information beyond the knowledge of the average person

Ex post facto: after the fact

Foreseeability: the reasonable anticipation that some harm or injury is likely to result from certain acts or omissions

Frivolous case: a groundless lawsuit with little prospect of success

Good faith: the honest intent to avoid taking advantage of another

Information system: an interconnected set of information resources under the same direct management control that shares common use

Integrity of data: a property of data or information that have not been altered or destroyed in an unauthorized manner

Intentional tort: the willful act which violates someone's rights

Joint Commission on Accreditation of Heathcare Organizations (JCAHO): a private credentialing organization whose standards and findings are accepted by state and federal authorities

Liability: an obligation, responsibility, or duty

Locality Rule: the test historically use by courts to determine the standard of care that is owed by a health care provider to patients

Malice: the performance of a wrongful act with the intention of inflicting injury

Negligence: conduct that deviates from a standard of care

Negligent tort: the performance or failure to perform an act which a reasonable, prudent person would or would not do

Nexus: a connection

Obligation: a responsibility that is imposed by law or by society

Password: the confidential authentication information which is usually composed of a string of characters

Physical safeguards: those physical measures, policies and procedures put in place to protect electronic information systems

Plaintiff: the person who files a civil lawsuit seeking relief from an injury or a violation of rights

Protected health information: individually identifiable health information defined by HIPAA* that is transmitted by or maintained in electronic media, or any other form or medium

Proximate cause: an act or omission that produces an injury with no intervening cause

Rely (on): to believe in a representation which then motivates an act

Required by law: a mandate contained in a law that compels some action

Respondeat superior: the legal principle that makes an employer or supervisor liable for a civil wrong committed by an employee or trainee who was acting within the course and scope of her employment (see vicarious liability)

Security measures: the administrative, physical and technical safeguards incorporated into an information system

Standard of care: the level of performance which is expected of an individual in a given situation

Standard of practice: a broad guideline that outlines the minimum level of quality of care

Statute of limitations: the time limit established by law within which a person may file a lawsuit

Statutory law: those laws which are enacted by a legislature

* 45 CFR 160–164

Technical safeguards: the technology, and the policy and procedures for its use, that protect electronic protected health information and that control access to it

Telemedicine: the use of technology to diagnose, treat or examine patients at a distance

Tort: a civil wrong that is committed against a person or property

Tortfeasor: a person who commits a tort, a wrongdoer

Transmission media: which are used to exchange information already in electronic storage media, such as internet, extranet, dial-up lines

User: a person or entity with authorized access

Vicarious liability: civil liability for the wrongful acts or omissions of another person based on the relationship

Waiver: the intentional or voluntary agreement to forego a known right

Workstation: an electronic computing device (such as a laptop or computer), or any other device that performs similar functions, as well as electronic media stored in its immediate environment

Index