
Genetic Services Policy Project

A Challenge to the Delivery of Genetic Services: Liability for Negligent Delivery of Reproductive Services, by Greg Garcia

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I. Introduction¹

Recent advancements in science and biotechnology have yielded the ability to test for over 1,500 genetic conditions (GeneTests website). Genetic testing and screening offer the promise of early detection and, perhaps, treatment of many genetic conditions. However, genetic testing and screening also carry the risks associated with health care decisions based upon incorrect results. Recipients of inaccurate or insufficient genetic services are exposed to dangers, such as life threatening treatment (or lack of life saving treatment) and reproductive decisions. Providers of inaccurate or insufficient genetic testing, screening, and counseling may be subject to civil liability.

This white paper provides an overview of the scope of civil liability arising from genetic screening, testing, and counseling in the area of reproductive services, and is prepared in conjunction with the Genetic Services Policy Project (GSPP). Providers of such services are collectively referred to as medical care providers. Part II of this paper provides a brief overview of the categories of liability and the legal theory most likely to apply to genetic services. Part III provides examples for each of the categories listed in Part II. Part IV discusses the legal trend of civil liability in cases involving reproductive services. Part V comments on the impacts of “conscience clauses” and federal regulation of genetic tests.

II. Liability for Negligence in Genetic Screening, Testing, and Counseling

Description of genetic screening, testing, and counseling

Genetic screening and testing are similar in that they both involve laboratory testing for the presence of genes that cause certain medical conditions or diseases. The difference in the terms refers to the purpose and population of the testing. In general, screening involves a population of persons, while testing will involve specific individuals. For example, persons who are of Ashkenazi Jewish ancestry may choose to be “screened” for the presence of genetic conditions which indicate that the person is a carrier of Tay-Sachs Disease due to the relatively high incidence in this population. On the other hand, individuals who have concerns over a family history of cancer may wish to be “tested” for the presence of genetic markers that may indicate a predisposition for certain types of cancer. Genetic counseling involves providing information and guidance to persons who seek genetic screening and testing.

Categories of liability

This paper discusses civil cases involving claims that genetic services were improperly rendered. Currently, most genetic testing, screening, and counseling involves the provision of services by medical care professionals. Errors by medical care professionals may result in claims of professional negligence. Generally, reported cases involving negligence in the delivery of genetic services can be separated into the following categories:

1. A failure to inform of available testing;
2. A failure to inform of test results;
3. A failure to warn a patient of test results; and/or
4. A failure to warn others of test results.

The discussion below sets forth examples of cases involving the foregoing categories.

Brief overview of the legal concept of negligence

Negligence is a legal theory which generally imposes liability where one person is harmed due to the acts or inaction of another. In more technical terms, negligence is the sum of four components: duty; breach; damages; and, causation or a causal link between the breach and the damages (57A Am.Jur.2d Negligence § 5). The duty imposed is generally to act as a reasonable and prudent person would act under the circumstances or, as stated in a landmark case, “[t]he risk reasonably to be perceived defines the duty to be obeyed...” (*Palsgraf*, N.Y. 1928) Hence, while one is generally required to act reasonably and prudent, the risk may further define the duty. One breaches the established duty by generally failing to act in conformance with a certain standard of care. In turn, that breach must be the actual cause and legal or proximate cause of injuries or damages. The terms “proximate cause” or legal cause are terms of art, but generally require that there be no intervening or superseding cause of the injury or harm.² With this concept in mind, the following discussion presents cases illustrative of the potential liabilities for those who may be negligent in the delivery of genetic services.

III. Cases Involving Negligence in the Delivery of Genetic Services

Failure to inform of availability of genetic testing or screening resulting in wrongful birth³

Medical care providers may be exposed to liability if they fail to inform patients or clients of the availability of relevant genetic testing. In a claim for “wrongful birth,” the claimants assert that but for the negligence of another, a child would not have been born with a medical condition that causes harm and economic loss to the parents. The following summaries discuss cases involving claims for wrongful birth.⁴ For each case, note the foreseeable risk that defines the duty.

Becker v. Schwartz (N.Y. 1978) was the first significant case to recognize a claim for wrongful birth. Dolores Becker was thirty-seven years of age at the time that she became pregnant with a child that was subsequently born with Down Syndrome. The Beckers alleged that the defendants, specialists in the areas of obstetric and gynecology, breached the standard of care when they failed to warn the Beckers of the risk of Down Syndrome in children born to women over the age of 35 and failed to advise them of amniocentesis testing. As a result, the Beckers alleged that they were denied the option to terminate the pregnancy and sustained damages which included the extraordinary costs associated with raising a child with Down Syndrome. The *Becker* court acknowledged that in such cases, the claim is not that a defendant doctor or medical care provider

caused the genetic defect. Rather, the wrongful act was the failure of the defendants to inform the Beckers that their child was at risk due to her age and that there was a test for the condition.

In *Haymon v. Wilkerson* the mother was 34 years old when she developed concerns over her pregnancy (D.C. 1987). The mother and father expressed concerns about the mother's age and the possibility of genetic testing, specifically inquiring into whether the defendant obstetrician would recommend amniocentesis testing. The doctor allegedly assured the parents that there was no need for testing. The child was born with Down Syndrome.

The *Haymon* court noted that there exists a "parental right of choice" (at 883). The court further noted that there was a "correlative duty of the health care provider not to deprive the parents of an opportunity to make an informed decision" (at 883). The doctor allegedly breached the applicable standard of care when he erroneously advised an at-risk mother that there was no need for genetic testing. As a direct and proximate result, the parents were unable to exercise their "parental right of choice." The court ruled that the parents could recover the additional expenses associated with raising their severely afflicted child.

In *Goldberg v. Ruskin* the parents of a child born with Tay-Sachs disease alleged that the mother's treating obstetrician failed to advise them of the risk of Tay-Sachs and the availability of screening tests (Ill.1986). The doctor argued that a doctor has no duty to "suggest" an abortion and that a doctor has no "affirmative duty to disclose facts" (at 538). Rather, the doctor argued, a doctor has only a duty to "honestly answer questions and to give the physical, medical and surgical care he is asked to give" (at 538). The parents responded that they did not expect the doctor to suggest an abortion, but rather that they had a right to terminate the pregnancy and the doctor had a duty to disclose information necessary to exercise their right.

The *Goldberg* court rebuked the notion that doctors do not have an affirmative duty to disclose facts and held that a doctor has a duty to disclose facts to patients and "to care for and advise the patient in accordance with proper medical practice" (at 538). The court concluded that if the physician failed to disclose the facts, as alleged, then the physician breached the stated duty.

The foregoing cases relate to claims made by persons who belonged to a class of persons who were arguably at a higher risk for gestational complications due to their advanced age or due to their cultural heritage. The higher risk created a duty to advise of genetic screening tests which might inform the expectant parents of potentially foreseeable genetic complications, such as Down Syndrome. The duty may arise before conception in certain circumstances. In other words, if a person belongs to a group which has a known risk for genetic conditions that may significantly and adversely impact their offspring, then a medical professional has an affirmative duty to advise of that risk and any known testing for that condition.

Medical care providers also owe a duty to persons who have medical history or family history that predisposes them to an increased risk of having children with significant and adverse genetic conditions. These persons do not belong to a class of persons who may be at a higher risk for complications, such as pregnant women over the age of thirty-four years, but rather have a specific history that places them and their children at risk. The following cases illustrate where liability

arose due to an alleged failure to recognize an at-risk pregnancy and/or advise of available genetic testing.

In *Phillips v. U.S.* the parents of a child born with Down Syndrome alleged that their medical care providers failed to provide genetic counseling, advice and testing for the parents in light of the mother's family history of Down Syndrome (D.S.C. 1981).⁵ Mrs. Phillips had a history of pregnancy complications and a previous miscarriage under the care of the same medical care providers. During her first pregnancy, she informed her medical care providers of her family history of mental retardation. During her second pregnancy, she notified multiple medical care providers that she had a sister with Down Syndrome. None of her medical care providers ever advised the Phillips family of the genetic nature of Down Syndrome or made them aware of any risk or available testing for Mrs. Phillips or their child.

Subsequent to the birth of her child, she and her child underwent genetic testing by a family practitioner. The testing revealed that she was a carrier for a translocational (hereditary) variety of Down Syndrome. The *Phillips* court noted that the genetic nature of Down Syndrome had been known for nearly two decades prior to Mrs. Phillips' pregnancy and that amniocentesis testing was a well-recognized procedure at that time. Yet, none of her medical care providers advised her of these facts or suggested any testing. As a result, the court found that her medical care providers had breached the applicable standard of care.

In the case of *Turpin v. Sortini*, two children were born with a hereditary form of deafness (Cal. 1982).⁶ After the first child was born, the parents were concerned about the child's hearing and consulted the defendant physician. The physician allegedly concluded that the child's hearing was normal even though she was allegedly "stone deaf" as a result of a genetic condition (at 956). The parents did not learn of the hereditary nature of the condition until after they conceived their second child. The parents alleged that they were deprived of important information regarding the likelihood of conceiving another child with the genetic condition and that they likely would not have chosen to conceive another child if they had been provided that information. The court allowed the parents to claim damages for related medical expenses to the age of majority and allowed the child to pursue claims for medical expenses beyond the age of majority.

In the Alabama case of *Keel v. Banach*, the parents of a child born with severe neural tube defects expressed concern during the pregnancy in light of the fact that the father had previously fathered a child with anencephaly (absence of brain and spinal cord), which was delivered stillborn (Ala. 1993). The defendant doctor performed sonograms and allegedly did not reveal any abnormalities. However, the parents argued that the sonograms did show abnormalities which should have resulted in amniocentesis testing for neural tube defects. The mother did not undergo any further testing. The child died at the age of six after numerous complications and procedures. The court held that the parents could pursue their claims for wrongful birth.

Failure to inform of test results resulting in wrongful birth

Liability for failing to inform of test results is rather straightforward because the results of genetic tests play an important role in health and other life decisions. A professional who undertakes to provide a service must do so in a competent manner. With respect to genetic test results, the risk is similar to the risk of failing to advise of the availability of genetic testing: the patient is deprived of

information important in the process of reproductive planning or health care decisions. The following case serves as an example of a claim for the failure to advise of genetic test results.

In *Garrison v. Medical Center of Delaware, Inc.*, the parents of a child born with Down Syndrome alleged that medical care providers, who performed two separate amniocentesis tests, failed to inform the parents of genetic test results in a timely manner (Del. 1990). The parents were concerned about the age (39) of the mother and the risk of the fetus having Down Syndrome. The parents sought counseling and medical advice. Amniocentesis was performed during the seventeenth week of the pregnancy. However, the parents were not informed for nearly a month that the sample size was inadequate. During the twenty-first week of the pregnancy, the mother again underwent amniocentesis testing. The medical care providers then delayed completion of the test and reporting of the results for nearly another month, or until the start of the third trimester. The test results were positive for Down Syndrome. The parents were unable to terminate the pregnancy.

The parents alleged that they were deprived of important information due to the failure of the medical care providers to properly perform the tests and report the results. The Supreme Court of Delaware held that the parents had standing to seek damages for wrongful birth arising out of the negligent performance of testing for the genetic condition. In short, due to the failure of the medical care providers to timely advise the parents of the inadequacy of the first sample and then the results of the second test, the parents were deprived of an opportunity to make an informed decision regarding the pregnancy.

Of course, a clearly erroneous test report can also deprive a patient of information vital to making health care decisions. In *Naccash v. Burger*, the parents of a child born with Tay-Sachs were advised of the availability of testing for carrier status during the second trimester of pregnancy (Vir. 1982). An employee or agent of the defendant physician advised the parents that only one parent needed to be tested because both parents had to be carriers in order for the fetus to be at risk of having the condition. Thereafter, the provider was admittedly negligent in confusing the blood samples of the parent with another, unrelated patient. The test results revealed that the parent was negative when he was actually positive. The child was born with Tay-Sachs and died at two years of age.

As in the *Naccash* case, the defendants in the case of *Gildiner v. Thomas Jefferson University Hospital* were alleged to have reported erroneous results of testing for Tay-Sachs (E.D. Pa. 1978). The parents underwent testing for carrier status after conception of their child and the tests revealed that both parents were carriers. The parents then chose to undergo amniocentesis testing to determine if the child was afflicted with Tay-Sachs. The test result was reported as being negative and one of the defendants informed the parents that the results “eliminated any possibility that the fetus would have Tay-Sachs disease.” The child was born with the fatal condition.

Medical care providers may owe duties to third parties who are not patients and with whom the professional has no relationship. If a patient does have a relationship with the professional, the duty is more definite, as illustrated by the following case.

In *Molloy v. Meier*, the parents of a child afflicted with Fragile X syndrome alleged that the defendant doctor's failure to inform the parents of the meaning and scope of the results of genetic testing on the child's older sibling (Minn. 2004).⁷ The doctor was asked by a parent to perform genetic testing on the older sibling to determine the origin of the older child's developmental delays. This request was made after the mother divorced, but before she conceived another child during her subsequent marriage. The mother's half-brother had a history of developmental problems and there was concern that the condition was inheritable.

The doctor who was asked to perform genetic testing agreed that it was appropriate to test the child for Fragile X. The mother alleged that the doctor stated that if the child tested positive for a genetic disorder, then the mother should also be tested. The doctor ordered "chromosome testing," but did not order Fragile X testing (at 714). He then reported to the older child's parents that the test results were negative. Subsequent professionals also allegedly erred in their unconfirmed opinions that the child's condition was not "genetic in origin" (at 714-15).

The child's mother subsequently gave birth to another child who also exhibited the same symptoms as the first child. A different pediatrician evaluated the second child and ordered Fragile X testing, which revealed the presence of Fragile X. Tragically, the second child was also afflicted with Fragile X. Based upon this information, the mother underwent testing which revealed that she was a carrier of Fragile X. The mother claimed that she would not have conceived a second child if she had known of her carrier status.

The plaintiffs alleged that the older child's physicians should have reported their specific concerns over Fragile X and the fact that the chromosome testing did not include a test for Fragile X. The doctor that ordered the chromosome testified that she intended to order both chromosome and Fragile X testing, but could not provide an answer as to why the Fragile X testing was not performed. The plaintiffs claimed that the defendants were liable for failing to order Fragile X testing, failing to properly read the test results, mistakenly reporting that Fragile X testing had been performed, and failing to counsel them on the risk of passing on an inheritable genetic abnormality to the mother's second child.

The *Molloy* case also addressed the question of whether the physician owed a duty only to his pediatric patient or whether he owed a duty to the child's parents, who had hired the doctor. Even where the professional is hired by a third party to exam a patient, such as for pre-employment screening, that professional likely has a duty to convey any significant test results to the examinee even if the results are not related to the employment condition. For example, while conducting an employment exam of a nurse to rule out tuberculosis a doctor may discover an abnormal mass. The physician may be liable for failing to inform of the abnormal mass even though it is not indicative of tuberculosis and even though the employer is paying for the examination.⁸ The following sections discuss the duty to warn of the results of genetic tests and consultations.

Failure to warn of import of test results or suspected genetic condition resulting in wrongful birth

A medical care provider who fails to warn a patient of the possibility or probability that a condition has a genetic origin may be subject to liability even though no laboratory or other genetic testing was actually performed. The process of obtaining a medical history for the purpose of genetic

counseling may form a sufficient basis for liability for the failure to warn a patient of the nature of the suspected condition. The following cases provide examples of such liability.

In *Vicarro v. Milunsky*, the parents of a child born with anhidrotic ectodermal dysplasia (AED), which is a severely disfiguring condition, sought genetic counseling prior to their marriage and specifically inquired as to whether the soon-to-be Mrs. Vicarro was a carrier of AED because several members of her family were affected (Mass. 1990). The parents alleged that the defendant doctor, who had some expertise in genetics, advised that there was no risk of Mrs. Vicarro having the disease or being a carrier. The couple then married and had a child who was severely afflicted with AED. The *Vicarro* court held that the parents could claim the expenses associated with the child's condition as special damages.

Liability may also attach in situations where the patient is not necessarily seeking genetic counseling or services, but such services are implicated. In the case of *Paretta v. Medical Offices for Human Reproduction*, the parents sought damages for a child born with cystic fibrosis after the parents received a donor ovum for in-vitro fertilization (N.Y. Sup. Ct. 2003). The parents allegedly relied upon the fact that the ova came from a "prescreened donor" (*Paretta* at 641). One of the defendant doctors also informed plaintiffs that the donor did not have any history of "genetic diseases" (*Paretta* at 641). In holding that the parents had a viable claim, the court stated:

There is evidence that the defendants may have known that the egg donor was a cystic fibrosis carrier; yet they failed to inform the Parettas or test Mr. Paretta's sperm to assess whether he too was a carrier. Had the Parettas been informed of the potential for cystic fibrosis they themselves may have chosen to have Mr. Paretta tested or may have altogether opted on using a different egg donor (at 647).

In *Paretta*, the defendants allegedly had knowledge of the fact that the donor was a carrier of an inheritable condition and failed to communicate these results. Moreover, they failed to warn the parents of the nature of the condition and that Mr. Paretta needed to be tested to determine if the child would be at risk for the condition. Having failed to warn the parents, the defendants were exposed to liability for the child's medical expenses and punitive damages.

Failure to warn others of test results or suspected genetic condition resulting in wrongful birth

A medical care provider who renders genetic services to one person may have a legal duty to third parties if the medical care provider has information that affects the health care decisions of third parties, even if the third parties have no relationship or contact with the professional.⁹ In *Molloy*, the defendants owed a duty to inform and warn the parents of a child born with Fragile X of the condition and the genetic nature of the condition, even though the pediatrician claimed to have only one patient, the first child born with Fragile X (*Molloy* at 716). In a sense, the case of *Molloy* was actually a claim for wrongful conception because the alleged harm was the decision to conceive, not an inability to terminate the pregnancy.¹⁰ However, a similar case brought in Colorado was held to be one for wrongful birth.

In *Lininger v. Eisenbaum*, the parents of a child born with congenital amaurosis, a form of blindness, sought consultation with multiple doctors who concluded that the condition was not hereditary (Colo. 1988). The parents were unwilling to have another child afflicted with the condition and specifically sought the consultations prior to conception of their second child. In

reliance on the advice of the doctors, the parents conceived a second child who also had congenital amaurosis. Both children were subsequently diagnosed with Leber's amaurosis, a hereditary form of blindness. The parents alleged that they would not have conceived their second child or would have terminated the pregnancy but for the negligence of the doctors.

IV. The Trend of Wrongful Birth Cases

The trend of legal cases appears to indicate that the majority of states will continue to acknowledge claims for wrongful birth. One author notes that thirty states allow claims for wrongful birth (Frantz, 2004-05). Another author identifies a majority of jurisdictions as allowing wrongful birth claims (Stein, 2007). Of the states that allow such claims, the clear majority limit recovery to expenses necessitated by the child's condition. A small minority also allow for recovery of emotional harm.¹¹ This trend is supported by juries of citizens who have recently returned large verdicts, indicative of an agreement with the legal theory and with the concept of damages for wrongful birth. The following cases illustrate this trend.

In *Granata v. Fruiterman* a Virginia jury returned a verdict in favor of a mother whose twins were born with Down Syndrome (Va. 2006). The mother, whose age caused the pregnancy to be at risk, was allegedly advised that the earliest date that she could undergo amniocentesis testing was at 16 to 18 weeks gestational age. However, at this stage she felt it would be too late to terminate the pregnancy. The plaintiffs alleged that they were never advised of the availability of chorionic villus sampling, a form of genetic testing which is available as early as 11 weeks gestational age. Had the plaintiffs learned of the condition at that stage, they would have terminated the pregnancy. The jury awarded \$4 million for the wrongful birth.

In *Chamberland v. Physicians for Women's Health*, a Connecticut jury returned a verdict of \$12 million in favor of parents who claimed that they were not advised of tests to detect the risk of spina bifida and other neurological abnormalities (Conn. Sup. Ct. 2005).

In *Tineo v. St. Joseph's Regional Medical Center*, a New Jersey jury awarded \$28 million for wrongful birth damages relating to the birth of a child with myotubular myopathy, an x-linked condition (N.J. 2007). The child's mother was a carrier and two of her nephews had died of the condition shortly after birth. The child's mother sought genetic testing of her amniotic fluid. The treating doctor sent the fluid to LabCorp of America. However, the testing was never completed and the treating physician and LabCorp each blamed each other. The child was born with severe muscle affliction, but has normal mental capacity and a life expectancy of 30 years.

Another case arising out of New Jersey, *Sharad v. Sanghavi*, involved claims by the parents of a child born with thalassemia (N.J. 2006). One of the defendant doctors tested the child's father and learned that the father was a carrier. However, the doctor did not test the mother and apparently failed to advise the parents that the mother should be tested. Thereafter the mother became pregnant and blood tests at six weeks showed anemia. Instead of testing for thalassemia, the doctor prescribed iron. A jury found in favor of the parents and awarded \$14 million (*Top 20 Personal Injury Awards of the Year*, 2006).

Currently, only a small handful of states prohibit wrongful birth claims either through case law or statutory law.¹² However, even in those jurisdictions that prohibit wrongful birth claims, a medical care provider may still be liable for the medical costs associated with a child born with a significant genetic condition if the provider is negligent in performing preconception genetic screening, testing, or counseling. For example, although North Carolina does not permit wrongful birth claims, it does permit wrongful conception cases.

In the case of *Gallagher v. Duke University* the parents/plaintiffs had lost a previous child to severe birth defects, which caused the infant's death within three weeks of birth (4th Cir. 1988). The parents sought genetic testing of the deceased child's blood to determine if there were genetic abnormalities. A defendant doctor analyzed the test results and concluded that there were no abnormalities. The parents then sought counsel from hospital staff and were informed that there was no need to test them given the negative results of the tests on the blood of their deceased child. Tragically, the parents then conceived another child who was born with severe birth defects, similar to those of the first child. Subsequent reexamination of the earlier blood tests revealed a genetic condition. The court held that this was a case of wrongful conception, not wrongful birth, and that the defendants were liable for the damages, in excess of \$1 million, awarded by the jury and that the plaintiffs could also recover for additional emotional damages.

Genetic testing, even if only in regard to gross abnormality observations (for example, trisomy or Down Syndrome), has been available for decades and has been widely utilized to detect fetal genetic conditions. As science progresses and new tests are developed, families will have access to more information when seeking medical advice on reproduction and medical professionals will have a duty to convey that information. In vitro fertilization will likely drive increased use of preimplantation genetic diagnostics or testing. Embryos will be screened and tested for genetic conditions prior to implantation. A failure to advise of the availability of such testing could lead to liability if the patients would have chosen to forego implantation of the embryo or would have chosen another embryo for implantation.

V. Present and Potential Future Liability beyond Reproductive Genetic Services

Genetic screening is likely to become more commonplace as scientific discoveries are commercialized and the tests become available and affordable. As a result, the scope of potential liability will likely widen. The following cases illustrate such liability.

In the case of *Ferrell v. Rosenbaum*, the mother of a young child afflicted with Fanconi anemia (FA) alleged liability against the child's physician, who was the Director of Clinical Genetics at the defendant hospital (D.C. 1997). In light of several indicators present immediately after birth, the doctor indicated that he would perform various diagnostic tests, including a "chromosome test" (at 643-44).

The child's blood tests revealed several indicators for FA. However, the doctor allegedly failed to read the test results and misdiagnosed the child as having a malformation syndrome known as the VATER association. The doctor allegedly had doubts as to whether all of the child's ongoing symptoms could be caused by this syndrome. Subsequent blood tests again revealed indicators for

FA. Again, the doctor allegedly failed to review the results. At the age of five years, the child was afflicted with pneumonia. A subsequent treating physician recognized the indicators for FA and confirmed a diagnosis through laboratory tests.

A critical fact in the *Ferrell* case was that the child had grim chances of survival into adulthood without a matched bone marrow transplant. The child's mother claimed that the doctor failed to advise of the test results and misdiagnosed the condition, thereby causing a five year delay in the search for a matched donor. During that time, the child's mother and father had separated; the father was then homeless and could not be found. Hence, the mother claimed that there was no chance to conceive a matched sibling donor and the overall chances of finding a matched bone marrow transplant donor were significantly reduced. The court ultimately concluded that the plaintiff had asserted a viable claim against the doctor.

In the case of *Pate v. Threlkel*, Heidi Pate and her husband sought to impose liability upon Heidi's mother's medical care providers for failing to warn her of the fact that her mother had been diagnosed with medullary thyroid carcinoma, a "genetically transferable disease" (Fla. 1995). In short, the plaintiffs alleged that the defendants knew or should have known that the condition was genetic in origin and that they should have warned Heidi's mother to have her children, including Heidi, tested for the condition. The alleged result of the doctor's failure to warn of the condition was that Heidi's medullary thyroid carcinoma was not diagnosed for nearly three years after her mother was diagnosed, thereby impacting her chances of receiving effective treatment. The *Pate* court stated:

We conclude that when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties.

....

...Our holding should not be read to require the physician to warn the patient's children of the disease. ...To require the physician to seek out and warn various members of the patient's family would often be difficult or impractical and would place too heavy a burden upon the physician. Thus, we emphasize that in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient (at 282).

The threat of liability may extend for a significant period of time with regard to latent conditions that appear during adulthood. And that liability may arise at a later date, when the risk becomes known due to advances in medical research (D.C. Ill. 1978). The following case illustrates this risk with respect to liability for genetic professionals.

In the case of *Safer v. Pack* a plaintiff who suffered from cancerous blockages and multiple polyposis filed a lawsuit against the estate of the physician who had treated her father for the same condition approximately four decades earlier (N.J. Sup. Ct. App. Div. 1996). The plaintiff's father and the physician had both been deceased for more than twenty years when the plaintiff learned of her condition. The plaintiff's mother testified that the deceased physician told her, during the courses of her husband's treatment, that he was simply treating a "blockage" or "infection" (at 1190). When the plaintiff's mother asked if the "infection" would affect her children, "she was told

not to worry” (at 1190). At no time did the deceased physician or the plaintiff’s father inform the plaintiff’s mother that the condition was cancerous. The plaintiff alleged that the deceased physician was under a duty to warn of the hereditary nature of the condition.

The *Safer* court stated:

We see no impediment, legal or otherwise, to recognizing a physician's duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition. In terms of foreseeability especially, there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion or a threat of physical harm. [citations omitted] The individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning.

....

Although an overly broad and general application of the physician's duty to warn might lead to confusion, conflict or unfairness in many types of circumstances, we are confident that the duty to warn of avertible risk from genetic causes, by definition a matter of familial concern, is sufficiently narrow to serve the interests of justice. ... We need not decide, in the present posture of this case, how, precisely, that duty is to be discharged, especially with respect to young children who may be at risk, except to require that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit....(at 1192-93).

In the future, additional fields of medical care may face liability arising from genetic services. For example, it is fairly established that early-onset Alzheimer’s Disease (AD) has a genetic origin (Kapp, 2000). When a person reports to an attending physician or other genetic services provider that early-onset AD has been diagnosed in family members, that professional likely has a duty to advise of the availability of genetic testing (at 453). Similarly, with respect to late-onset AD, patients may want information concerning the presence of apolipoprotein E (APOE) to assist with planning and counseling. Therefore, a physician likely has a duty to at least advise of the availability of APOE testing and to counsel the patient as to the meaning of the results. Research into other conditions will likely yield genetic tests and treatments that establish a legal duty to inform of such tests.

The field of pharmacogenomics brings tremendous promise and, perhaps, accompanying liability for professionals who fail to counsel their patients on the availability of pharmacogenomic services. Only one significant case involving pharmacogenomic allegations has received media attention. That case involved claims against the manufacturer of LIMERIX for a chronic autoimmune arthritic reaction associated with a certain genetic condition or variation found in nearly one-third of the general population (Marchant et al., 2006; Marchant, 2006). However, other drugs, such as Warfarin and Herceptin, could soon garner attention in light of developing research into genetic tests for sensitivity and effectiveness of these drugs (McWilliam et al., 2006). Such tests would drive a legal duty to advise all recipients of Warfarin of the availability of a test to help determine proper dosage and to at least inform persons concerned about cancer of the availability of tests for Human Epidermal growth factor Receptor 2 (HER2).

In another example, researchers investigating non-small-cell lung cancer (NSCLC) recently published information which indicates that certain patients would benefit from early-stage treatment with chemotherapy (Potti et al., 2006). Early research results also indicated that these patients, identified through genetic testing, may benefit from specific, targeted chemotherapy drugs (Cook, 2006).

Employment screening may yield genetic information which an employer is not allowed to use for discriminatory purposes, but which may require disclosure to the prospective employee. Individual states generally test newborn infants for various conditions and liability may be an issue where there is a failure to communicate the test results and/or warn of the condition. Again, scientific and medical discoveries will lead to increased information which, in turn, will lead to a duty to inform.

V. Legal Developments That May Impact Future Liability

Two legal developments are likely to impact the liability of medical care providers in the area of genetic services. The first is the developing concept of a “conscience clause.” Laws which provide medical professionals legal protection for refusing to participate in personally objectionable procedures are known as conscience clauses.¹³ For example, North Carolina law protects medical professionals who choose not to participate in “medical procedures which result in abortion” (N.C. Gen. Stat. § 14-45.1(e), 2007). In theory, a defendant in a civil action could rely upon a similar statute as a defense to allegations pertaining to genetic testing, such as amniocentesis testing, if the results would lead to an abortion. The second development relates to the regulation of genetic testing.

Genetic testing is generally performed either by laboratories utilizing tests developed and performed by the laboratory, or by service providers utilizing test “kits.” Currently, only kits are regulated and required to demonstrate safety and effectiveness (21 C.F.R. 809; Javitt et al., 2004). However, it appears that the Food and Drug Administration (FDA) is planning to regulate certain complex, laboratory-developed genetic tests as medical devices (FDA, 2007). Federal legislation was recently introduced which would also expand the scope of FDA regulation of laboratory developed tests, including genetic tests (S.736, 2007; S.976, 2007). Under the proposed FDA regulation, at least some genetic tests will be classified as Class II or Class III medical devices (FDA, 2007 at 8; 21 U.S.C. 360(c)). Although a discussion of FDA regulation of medical devices is beyond the scope of this paper, it should be noted that FDA approval of certain medical devices may provide genetic test providers and genetic service providers with some protection from civil liability.¹⁴

VI. Conclusion

Scientific discoveries continue to reveal the potential benefits of genetic screening, testing, and counseling. However, liability risks pose a challenge to the delivery of genetic services. On one hand, a system that provides redress for harm caused by negligence is still beneficial to our society. On the other hand, the risk of liability may have a considerable impact on the delivery of promising scientific discoveries. Moreover, errors on the part of medical care providers may discredit the

genetic services industry, resulting in an overall lack of trust. Developing case law and legislation will define the scope of the legal duties owed by medical care providers.

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Notes

¹ This paper does not support any particular position with respect to whether liability should be imposed.

² An intervening force is one which actively operates in producing harm to another after the actor's negligent act or omission has been committed. *Restatement (Second) of Torts* § 441 (1)(1965)

³ The term "wrongful birth" is used in reported cases, legal texts, and other commentary on this legal concept. The term is presently used to describe a legal theory for claims based upon the birth of a child with serious medical conditions or genetic defects that may have been diagnosed prior to conception or during pregnancy. The author would prefer use of the term "negligence" because the term "wrongful birth," much like the term "wrongful life," raises ethical issues not pertinent to the issue of whether a medical service provider appropriately renders genetic testing, screening or counseling. However, cases cited herein utilize the term and it is used so as to avoid confusion.

⁴ This paper presents selected cases and does not provide a comprehensive list of all cases which pertain to the legal issues discussed herein.

⁵ The parents filed suit in the Federal District Court for the District of South Carolina. Four published opinions arose from this case. The foregoing citation references the third published opinion wherein the court held that the defendants breached the standard of care by failing to provide advice, genetic counseling and testing for the parents.

⁶ In *Turpin*, the published case focused on one of the children's claim for "wrongful life," a concept not addressed in this paper. However, the parents also stated a claim for wrongful birth for medical expenses through the age of majority and the court held that the child could recover wrongful life damages for medical expenses after the age of majority or to the extent that the parents did not recover such damages. As a general matter, only a small handful of states recognize claims under the theory of wrongful life, which is a variant of negligence and akin to a claim for wrongful birth. Claims for wrongful life are asserted in the name of the child.

⁷ Relevant facts are also reported in the opinion rendered by the Minnesota Court of Appeals. See *Molloy v. Meier*, 660 N.W.2d 444 (Min.App. 2003). Minnesota prohibits "wrongful birth" cases by statute. See Minn.Stat. § 145.424, subdivision 2 (2002).

⁸ See, e.g., *Stanley v. McCarver*, 92 P.3d 849 (Ariz. 2004): absence of physician-patient relationship not determinative of duty; doctor had duty to inform of test result.

⁹ For a general discussion of the duty to disclose medical information to third parties, see Andrea Sudell, *To Tell or Not to Tell: The Scope of Physician-Patient Confidentiality when Relatives are at Risk of Genetic Disease*, 18 Journal of Contemporary Health Law and Policy 273 (Winter 2001). See also T.A. Bateman, Annotation, *Liability of Doctor or Other Health Practitioner to Third Party Contracting Contagious Disease from Doctor's Patient*, 3 A.L.R. 5th 370 (1992); *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (1976)(duty to warn of dangerous patient).

¹⁰ Minnesota law prohibits claims for wrongful birth. Minn. Stat § 145.424 (1986)(amended 2005). The *Molloy* court noted that the claim was not a claim for wrongful birth. The distinction is one of semantics in that a claim for wrongful birth infers that a pregnancy would have been terminated and a claim for wrongful conception infers that the conception would not have occurred. Obviously, the term wrongful birth is subject to different interpretations.

¹¹ See, e.g., *Greco v. United States*, 893 P.2d 345 (Nev. 1995)(emotional damages recoverable); see also *Harbeson v. Parke-Davies, Inc.*, 656 P.2d 483 (Wash. 1983)(emotional damages and wrongful life damages recoverable).

¹² One of the most often cited cases which holds that wrongful birth claims are not allowed is the North Carolina case of *Azzolino v. Dingfelder*, 337 S.E.2d 528 (1985). *Azzolino* involved two published opinions and the opinion from the Court of Appeals provides better factual background. *Azzolino v. Dingfelder*, 322 S.E.2d 567 (N.C. App. 1984). In *Azzolino*, the parents of a child born with Down Syndrome alleged liability against medical care providers who advised that there was no reason for the mother, age 36, to undergo amniocentesis testing. One of the care providers also voiced religious prejudice against amniocentesis testing. As a result, the parents did not undergo testing. The North Carolina Supreme Court found that the issue of causation could not be satisfied in a wrongful birth case because no potential defendant caused the genetic or congenital defect. The Supreme Court of Georgia adopted a similar line of reasoning in *Atlanta Obstetrics & Gynecology Group v. Abelson*, 398 S.E.2d 557 (Ga. 1990), holding that the parents (37 year old mother) of a child born with Down Syndrome could not assert a claim for wrongful birth under Georgia law. More recently, the Supreme Court of Kentucky relied heavily upon the two foregoing cases in reaching a decision to deny the claims by parents of children born with severe genetic abnormalities. *Grubbs v. Barbourville Health Center*, 120 S.W.3d 682 (Ky. 2003).

¹³ E.g., 745 Ill. Comp. Stat. 70/4 (1998)(broad conscience clause law providing for immunity from civil liability for refusal to participate in any service contrary to conscience of service provider).

¹⁴ Federal preemption of state tort law claims for harm resulting from medical devices is an evolving area of the law. See, e.g., *Riegel v. Medtronic, Inc.*, 522 U.S. ___, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008).