THE IMPACT OF GENETIC MEDICINE ON CIVIL LITIGATION

BY:

STEPHEN C. HALL

Earlier this year, scientists, working jointly with the National Institutes of Health and private industry, published the results of the Human Genome Project. This study reveals the structure of the 3 billion or so chemical units that form the DNA in each one of our cells. DNA is so important because our genes are found at various intervals along that long, chain-like molecule. Each one of the trillion or so cells in all of us has the exact same copy of DNA as every other cell, though from one individual to the next the copy will be slightly different. These differences account for our diversity in appearance, gender, intelligence, athleticism, size, etc. And these differences also play a major role in one's susceptibility to certain diseases and illnesses. This last point makes the Human Genome Project very important to science, medicine, and the pharmaceutical industry.

Genetic medicine flows naturally from the Human Genome Project. It involves four interrelated fields of study:

- Genomics, the study of human DNA, is informing scientists about DNA's structure and how human cells make proteins.
- Proteomics, the study of how proteins function and interact with each other, is cataloging all human proteins and identifying the role that proteins play in many diseases.
- Toxicogenomics, the study of how chemicals affect genes, is telling scientists not only how, but why, our bodies respond to toxins.
- Pharmacogenomics, the study of how drugs interact with the proteins of our bodies, is transforming pharmaceutical research, offering the potential for

tailoring drugs to fit a patient's individual genetic information, thereby providing treatment that is more effective and less risky.[1]

Just as they are impacting science and medicine, these advances will also affect our legal system, and the kinds of cases and issues that are litigated. Already, the DNA technology that preceded the Human Genome Project has revolutionized the practice of law in certain kinds of cases, such as criminal and paternity. The emerging applications of the Human Genome Project should have a similar impact on civil litigation. These applications are creating a whole range of issues that the legal system will have to address. Some issues are obvious, such as how legislatures and courts will ensure the confidentiality of an individual's genetic information, whether insurance companies and employers should even have access to a person's genetic information, and how to protect the individual from improper use of his genetic information. Others may be less obvious, though, such as how these advances will affect the standard of care in medical cases, or proof of causation in toxic injury cases. This article examines some of these other effects.

The developing knowledge of DNA and human genes will enable parties to prove facts that could not have been proven before. In some cases, it may help injured persons to prove that they are entitled to recover, while in others it may absolve innocent defendants of liability. But regardless of how this technology plays out in an individual case, these developments will have a far-reaching effect on civil litigation.

---

[1] *The Science of Proteomics and What It Might Mean for Drug Development*, (National Public Radio, Talk of the Nation, Friday, March 16, 2001) (2001 WL 7836828).
.

A PRIMER ON DNA AND GENES

Genes are substantial factors in many diseases. A gene simply provides the cell with a chemical code for making a certain protein. A normal gene acts as a molecular blueprint for making a functioning protein, but a defective one may not produce some protein that is essential to a person's health. Cancer, Alzheimer's disease, sickle cell anemia, and Parkinson's disease are but a few examples of diseases that are caused by genetic defects. Thus, knowing how proteins relate to diseases is the key to understanding genetic medicine, as well as its likely impact on civil litigation. This is because, inside our cells, proteins perform thousands of basic functions. However, when proteins are not properly formed because of a genetic defect, it can result in disease. The following are but a few of the thousands of diseases whose roots are found in some genetic defect.

- Hemoglobin is the protein in red blood cells that transports oxygen. But if a genetic defect hinders the formation of hemoglobin, the body will not possess the tools (hemoglobin) to perform this function efficiently. This causes anemia, and we call this disease sickle cell anemia.
- Cystic fibrosis is a disease characterized by a genetic defect that affects the quality and quantity of mucous that the body produces, causing the lungs to become filled with too much mucous. This fosters infections that can seriously damage the lungs.

- In Parkinson's disease, a genetic defect prevents the formation of a protein in the brain that is supposed to break down toxins.
- With some forms of cancer, the immune system fails to make proteins that are supposed to suppress tumor growth.[2]

Realizing the connection between diseases, proteins, and genes, scientists in the 1990's began the Human Genome Project, an international effort to determine the exact chemical structure of human DNA. As a result, the exact location and structure of every human gene found on the DNA molecule have been determined. Genomics tells doctors how a normal gene should look. This standard can then be compared to any individual's DNA, his genes. Individual differences can be thought of as genetic markers. Some genetic markers are associated with significant, even catastrophic, diseases, while others appear meaningless. It all depends where on the DNA chain the marker is found, and which gene is involved. The study of genetic markers is generating a huge industry aimed at developing new drugs, new diagnostic tests, and new therapies. For example, it is expected that soon genetic tests will be used identify these markers in individual patients. Such tests will replace biopsies and x-rays as a diagnostic test for cancer.[3]

But simply knowing the structure of a functioning gene is only a start. Through proteomics, toxicogenomics, and pharmacogenomics, scientists are discovering:

- Why some genetic defects are harmless, while others are fatal.

---

[2] *The Future of Drugs: Brave New Pharmacy*, Time, January 15, 2001, at 59.

[3] Chris Meyers, et al., *Genomics: Implications for Health Systems*, 17 Frontiers Health Serv. Mgmt. 316 (April 1, 2001).

- Why some diseases can result from a single genetic defect, while others require complex interrelationships of multiple genetic defects.
- Why some diseases are present at birth, while others develop late in life.
- How to predict the likelihood of disease years before the first symptom is seen, and to tailor a treatment regimen based on a specific individual's genetic makeup.
- How to determine if a chemical exposure might be harmful to a specific individual.

Genetic medicine seeks to answer these and many other questions. The remainder of this article illustrates some of the legal applications of genetic medicine, and discusses some of the impacts it will have on civil litigation.

APPLICATIONS IN MEDICINE

Because of these scientific advances, over the next decade, medicine will become more proactive, as opposed to reactive. Traditional medicine generally treats symptoms, as opposed to the root cause of a disease. On the other hand, genetic medicine predicts diseases before they manifest themselves. With some diseases, genetic research has even gone beyond prediction and is helping to find cures. For example, many experimental cancer therapies now target the proteins and genes involved in that disease, instead of merely fighting the tumors. But even for diseases that do not yet have a cure, like cancer or diabetes, the ability to predict a disease years before it occurs may enable patients to have testing, or modify their behavior to reduce the effects of a disease.

One commentator described the shift from traditional medicine to genetic medicine in this way:

> In the past, genetic testing concerned the next generation: decisions about whether to have a child [examples listed, Tay-Sachs disease, cystic fibrosis, and Down syndrome] and screening of newborns [phenylketonuria and sickle cell anemia]. Increasingly, genetic testing now concerns the current generation: testing ourselves for chronic disease.[4]

Thus, in the foreseeable future, genetic advances will likely change clinical medicine in the following ways:

- Medical schools will place more emphasis on genomics. Doctors will be challenged to integrate emerging technology into their practices.
- The front lines of diagnosis and treatment will shift away from middle-aged and elderly "sick" patients, to pre-natal and youthful "well" patients.
- General practitioners, pediatricians, and board certified geneticists will frequently collaborate to treat those younger patients.
- On the other hand, average life expectancy, which is estimated to reach 95 years by 2050, will increase. This could significantly impact damage awards based on a person's average life expectancy.
- Treatment will be more effective, because it will not involve as much trial and error. Specific knowledge of an individual's genetic blueprint will enable doctors to prescribe treatments that maximize efficiency and minimize side effects.
- Adverse reactions from taking a certain medication, or receiving a certain type of anesthesia, may be easier to avoid, based on susceptibility testing.

---

[4] H. Gilbert Welch, M.D., M.P.H., Wylie Burke, M.D., Ph.D., *Uncertainties in Genetic Testing for Chronic Disease*, JAMA, November 4, 1998, Vol. 280, No. 17, at 1525.

- Counseling patients will become increasingly important. A patient will seek advice on issues ranging from whether to conceive a child, to what activities might cause a disease that he is susceptible to.[5]

The recent Kentucky case of *Bogan v. Altman & McGuire, P.S.C.* highlights some of these issues.[6] This case involved a claim of negligent genetic counseling. It involved a child born with severe impairments from spina bifida, a congenital disease. The plaintiffs alleged that their obstetrician failed to inform them of certain prenatal genetic tests that were available to them which would screen for this disease. The Court held that the alleged failure to provide the parents with "information necessary to make a decision regarding the continuation of pregnancy stated a viable cause of action for medical negligence."[7] It is interesting to note that in Bogan there was no cure, no prenatal treatment and no medical advantage to detecting the disease early. The plaintiffs simply argued that had they been given the information that was available through genetic testing, they would have had an abortion. The Court agreed that this entitled them to maintain their action.

Thus, how courts define what is a reasonable use of genetic information will be very important in terms of public policy. Consider that soon there will be a dramatic increase in the number of genetic diseases that can be prenatally screened. Today, doctors generally screen for the most serious genetic diseases, and the ones requiring the highest level of care. But someday, doctors will screen for less catastrophic defects, for example blindness or deafness. In Bogan,

---

[5] Meyers, *supra* note 3.

[6] *Bogan v. Altman & McGuire, P.S.C.*, Ky.App., 2001 WL 201848 (not final).

[7] *Id.*

the Court accepted that if a couple had been informed that their fetus had spina bifida, then they would have aborted the pregnancy. Could a Court accept the argument that a couple was legally injured by not having the opportunity to abort a blind fetus, or a deaf one? The answer seems certainly "no," but where will the line be drawn in terms of the thousands of genetic defects that exist?

These genetic counseling issues are not limited to birth defects. For example, susceptibility testing for breast cancer and ovarian cancer "makes it technically possible to identify . . . individuals with an increased risk of developing such malignancies."[8] Considering this, should a woman be allowed to sue if she is not notified that this test exists? Many other tests for genetic diseases besides cancer are now being developed. In many situations, it will be up to those doctors on the front lines of medicine, the general practitioners and pediatricians, to select, administer, interpret and relay information and advice to patients based upon these tests.

In these settings, courts may be asked to compensate because one party failed to properly inform another about her genetic makeup, thereby costing her the opportunity to make choices, or modify behavior. For example, a person diagnosed with skin cancer may sue the doctor who failed to diagnose her predisposition to the disease based on a genetic test performed ten years ago. She may argue that, with this information, she would have sought monitoring more regularly to diagnose and arrest the disease in its earliest stage. Likewise, another person diagnosed with late-onset diabetes may sue his former pediatrician, claiming that the failure to

[8]American College of Medical Genetics Foundation, *Genetic Susceptibility to Breast and Ovarian Cancer: Assessment, Counseling and Testing Guidelines*, at http://www.health.state.ny.us/nysdoh/cancer/obcancer/at12.htm (June 1998).

diagnose this predisposition deprived him of the chance to modify his diet and exercise habits, which might have reduced the effects of the disease later in life.

The classic loss of chance case involves a disease like cancer, in which a person with advanced symptoms argues that he lost the opportunity to have timely treatment. In the future, loss of chance cases may involve people who had no symptoms when they were tested, and in some cases diseases with no treatments, arguing that they were not provided important information about their genetic makeup.

APPLICATIONS IN TOXIC INJURY CASES

Toxicogenomics, the study of how chemicals affect genes, becomes important in toxic injury cases. As stated previously, genomics involves comparing someone's DNA to a known standard. As with genomics, making a comparison of someone's genes is key in toxicogenomics. But here, instead of using a normal gene as the standard, the comparison is to the condition of a person's own genes, as seen in prior genetic tests. Such comparisons may allow doctors to determine whether a change has occurred in someone's DNA since the previous test, and following some toxic exposure, by looking for tiny molecular changes in the affected gene. These changes are called biomarkers of effect.[9]

A biomarker of effect could be a toxic chemical that attaches itself to a person's DNA, or even an actual change in the chemical structure of the DNA. This is called a mutation, which can be thought of as a change in the code for a certain gene. That defect could lead to a given

[9] Gary E. Marchant, *Genetic Susceptibility and Biomarkers in Toxic Injury Litigation*, 41 Jurimetrics 67, 72-73 (2000).

disease associated with that gene. Thus, biomarkers are especially significant, because merely being exposed to some toxic agent, by itself, does not meet all the required elements for recovery. The exposure must also cause injury.[10] In the past, the plaintiff who had a disease would rely mainly on circumstantial evidence in trying to prove that exposure plus symptoms equaled liability. But many would argue that such circumstantial evidence is inadequate, because it does not sufficiently rule out the possibility of other causes.

Toxicogenomics, on the other hand, may show exactly what happened, or did not happen, to the person's genes following the exposure, thus revealing the root cause of a person's symptoms. For example, finding a biomarker in the mother's gene that is associated with a certain birth defect might help to prove causation. Conversely, the absence of a biomarker, something one would expect to find if the condition had indeed been caused by a toxic exposure, may similarly assist the defense. Proof of this kind will become increasingly more common in our courts. As one commentator noted, the use of such evidence will increase "as more biomarkers undergo validation and the legal community becomes more aware of their advantages."[11]

DEFINING ILLNESS AND INJURY

There are many contexts where a court must determine whether a person has an illness or an injury. Health insurance is one way that such issues arise. A second way is with toxic exposures. This section examines both situations.

---

[10] *See Capital Holding Corp. v. Bailey*, Ky., 873 S.W.2d 187 (1994).

[11] Anthony P. DeCaprio, *Biomarkers: Coming of Age for Environmental Health and Risk Assessment*, 31 ENVTL. SCI. & TECH. 1837, 1842 (1997).

Should a genetic predisposition to a disease like cancer be considered an "illness" for purposes of health insurance coverage, or does coverage hinge on whether the disease itself is actually present? A recent Nebraska case addresses this issue in a scenario that will become increasingly common.[12]

A woman sued her HMO for rejecting coverage of a "prophylactic" hysterectomy, which would have included removal of her uterus, ovaries, and fallopian tubes. Her doctor testified that she had a genetic predisposition to ovarian cancer (in addition to breast cancer). The woman was roughly the same age as her mother and aunt were when they were diagnosed with the same, fatal disease. Because ovarian cancer is often incurable, even when diagnosed early, the doctor recommended that this patient have a hysterectomy, even before cancer had developed.

The insurer denied coverage, arguing that if the cancer "was not detectable by physical evidence or a physical examination," then Katskee could not establish an "illness." The Court rejected this argument, holding that her genetic predisposition to cancer was covered as an "illness," because:

> Appellant's condition is a deviation from what is considered a normal, healthy physical state or structure. The abnormality or deviation from a normal state arises, in part, from the genetic makeup of the woman. The existence of this unhealthy state results in the woman's being at substantial risk of developing cancer. The recommended surgery is intended to correct that morbid state by reducing or eliminating that risk. [13]

(Emphasis added.)

---

[12] *Katskee v. Blue Cross/Blue Shield of Nebraska*, 515 N.W.2d 645 (Neb. 1994).

[13] *Id*. at 652-53.

Thus, the Court placed the emphasis on predisposition and on the probable success of the treatment, as distinguished from actual disease. Such cases obviously present important policy concerns. If insurers must cover treatment of – as opposed to monitoring for – a disease before it has manifested itself, then one would expect them to argue even more vigorously for the right to request genetic information from their insureds. But this result seems to contradict some other competing interests, such as preventing genetic information from being used as a basis for calculating health insurance premiums. This particular interest has led to legislation in several states protecting the confidentiality of a person's genetic information.[14] Thus, courts will face increasingly difficult decisions when balancing individual interests (such as the person who needs a hysterectomy because of her genetic condition) against broader policy concerns (such as whether the insurer may request any genetic information before writing the policy).

The other issue that courts have confronted is whether a toxic exposure can create liability. At least twice in the last decade, the Kentucky Supreme Court has addressed this issue, once in determining whether mere exposure, by itself, supported a cause of action, and the other time concerning whether an exposure started the statute of limitation running. Both cases foreshadow the impact that genetic medicine may have on civil litigation.

In *Capital Holding Corp. v. Bailey*, *supra*, the plaintiff was exposed to asbestos while demolishing a building. He sued to recover for the increased risk and fear of developing cancer in the future, because asbestos is a known carcinogen. Even though he feared cancer, the disease had never developed. The Court dismissed the action, reasoning that a person could not sue "for

[14] Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They Are So Hard to Protect*, 26 Journal of Law, Medicine & Ethics, 199.

the consequences of a negligent act where no harmful change was yet made manifest."[15] Thus, in the words of *Katskee v. Blue Cross/Blue Shield of Nebraska, supra,* in spite of his exposure, the worker's condition did not deviate from the normal, healthy state or structure, nor was there yet any "unhealthy state [resulting in a] substantial risk of developing cancer."

More recently, *Carroll v. Owens-Corning Fiberglass Corp.* addressed similar issues in the context of a statute of limitation defense.[16] For thirty years, the plaintiff had been exposed to asbestos while working. He was diagnosed in 1983 "with a mild, non-progressive form of asbestosis, a chronic lung inflammation caused by prolonged inhalation of asbestos particles" that was not disabling[17]. Thus, *Carroll* was different from *Bailey* because, although the worker did not immediately develop cancer, he was diagnosed with asbestosis, an intermediate condition for which he could have sued, whereas Bailey did not have an intermediate condition. Carroll did not sue initially, but then eight years after his initial diagnosis, he was diagnosed in 1991 with terminal lung cancer. After Carroll passed away, his estate sued the manufacturer of the asbestos in United States District Court.

That court started the statute of limitation running in 1983, because the decedent knew that he at least had some type of injury (asbestosis) from the exposure. In dismissing the claim for cancer, the federal court also applied the rule against splitting causes of action, reasoning that the Plaintiff could have appended a claim for the likelihood of cancer to his claim for asbestosis.

---

[15] *Capital Holding Corp.,* 873 S.W.2d at 193.

[16] *Carroll v. Owens-Corning Fiberglass Corp.,* Ky., 37 S.W.3d 699 (2000).

[17] *Id*. at 700.

The plaintiff then appealed the dismissal to the Sixth Circuit, which certified to the Kentucky Supreme Court.

The Kentucky Supreme Court ruled that the cause of action did not accrue until 1991, when the cancer was diagnosed. It characterized cancer as "a distinct and separate disease from the asbestosis."[18] It also distinguished toxic exposure cases from other kinds of injury cases, because toxic injury is difficult to trace, the exposure may occur over time, the harms are more susceptible to misdiagnosis, and there are usually multiple victims.[19]

One questions whether toxicogenomics will soon make this reasoning obsolete. This technology has the potential to make toxic injury – both the existence of the injury as well as its cause – easier to trace, with more certainty in diagnosis.

But even beyond this, toxicogenomics may affect when the statute of limitation begins to run, perhaps causing it to start even before the symptoms of disease are first seen. Such a ruling might be proper in cases where a biomarker of effect shows that a "harmful change," constituting a "deviation from the normal, healthy state or structure" has occurred.[20] Obviously, such a change or deviation would support a cause of action, at least under the reasoning of *Katskee, supra*. It thus might seem incongruous to allow a plaintiff to sue for his exposure, based on the evidence of a "harmful change" that produces fear of disease, on the one hand, while on the other refusing to start the statute of limitation running once a biomarker of effect has been identified.

---

[18] *Id*. at 700, 703.

[19] *Id*. at 702.

[20] *See Katskee v. Blue Cross/Blue Shield of Nebraska*, 515 N.W.2d 645, 652-53 (Neb. 1994).

Thus, these two cases provide a good example of the challenges that genetic advances will create for the courts.

ANCILLARY APPLICATIONS

Is having a plaintiff submit to a genetic test to determine if her injury has a genetic root any different than having her submit to an x-ray to determine if osteoporosis played a role in her bone fracture? One of the questions that courts may face is whether to compel a plaintiff to submit to genetic testing as part of a Rule 35 medical examination. Courts in paternity actions have faced similar questions for some time now. In such cases, courts possess the authority to order genetic testing of the plaintiff, if the defendant shows a "reasonable quantum of individualized suspicion to support" the testing.[21] This quantum might include evidence of symptoms consistent with a certain genetic disease, or family history of the disease. Provided this threshold is met, it is fair to require genetic testing of the plaintiff. At the same time, plaintiffs themselves may wish to use genetic testing to establish the absence of a genetic cause for the illness, placing the focus more directly on the defendant's product or activity.

Life expectancy is another ancillary application of genetic medicine. This can often be a key factor in determining how much a person will recover in a personal injury lawsuit. When awarding damages for pain and suffering, or for future expenses, juries may consider how long a person is expected to live, which is based on statistical data. As technology advances, the ages listed in the life expectancy tables will likewise advance, increasing the damages that can be blackboarded. In some cases, even a few additional years of expectancy can increase the

[21] *M.A. v. Estate of A.C.*, 274 N.J.Super. 245, 643 A.2d 1047 (1993).

requested damages by several hundred thousand dollars. As time passes, not only will medical costs probably continue to rise, but the length of time that the plaintiff seeks to receive those expenses will also increase with life expectancy. This could have a noticeable impact on damages awards in some cases, assuming liability can be established.

Conversely, in other cases, the defendant may want to show, based on genetic testing, that a person's life expectancy is substantially reduced by a genetic disease for which there is no cure, such as Huntington's disease. Can a defendant compel genetic testing to determine if such a genetic predisposition exists? If so, then the jury could consider whether its award for future something like impairment of earning capacity should be limited by the reduced life expectancy. One could argue that, provided a reasonable quantum of suspicion is established (such as family history), the testing should be allowed. This argument could be further supported given that the plaintiff has put her own physical condition in issue.

On the other hand, the plaintiff may object because the injury asserted in the lawsuit has nothing to do with the particular genetic condition. For example, she might argue that certain serious injuries caused by a motor vehicle accident, which will prevent her from working in the future, are completely unrelated to Huntington's disease. Further, she might argue that her right not to know of this predisposition outweighs the defendant's right to compel the genetic testing, even where she has put her own physical condition in issue. This is another example of the kinds of disputes that courts will face in the near future. As with many things related to genetics, the issue of life expectancy has the potential to cut both ways, for example either by allowing a potential for greater recovery, based on increased life expectancy, or limiting recovery, based on evidence of diminished life expectancy.

CONCLUSION

Medicine is changing at a rapid pace. The changes that began ten years ago with the Human Genome Project are upon us, and will continue to multiply. They will continue to have an impact on civil litigation, on everything from the duty to provide genetic information to people, to our ability to identify effects of an exposure to a chemical, to modifying how we perceive "injury," "disease," and "illness." The new technology may directly benefit plaintiffs in some cases, and defendants in others, or it may play an ancillary role such as quantifying life expectancy. We already notice the impact on our legal system from some of these changes. With others, the impact will be here soon. And still with others, those five or ten years away or more, it may be difficult to see now what we as attorneys will be able to prove about disease and injury in court. But one certainty is that genetic medicine has the potential to make our legal system more just by providing more - and more reliable - information upon which to decide cases.

217546.7