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Genetic Research: Are More Limitations Needed in the Field

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GENETIC RESEARCH: ARE MORE LIMITATIONS NEEDED IN THE FIELD?

I. INTRODUCTION

Each year scientists uncover new mysteries, make miraculous discoveries, and perfect processes that will aid them in curing thousands of debilitating and fatal diseases. In the past century, several of the most fascinating discoveries were made in the field of genetic research. For instance, in 1997, scientists cloned a sheep. The infamous cloned sheep became known as Dolly.

The importance of genetic research today is overwhelming. Although genetic research presents many legal and ethical concerns, the benefits drastically outweigh the costs. For instance over 140 million people stand to benefit from human embryonic stem cell research, including those Americans suffering from Parkinson's and Alzheimer's disease.[1]

In an attempt to quell the legal and ethical concerns associated with genetic research, legislation has been developed and several administrative committees have been formed. The present restraints placed on the field of genetic research by the Legislature and the administrative committees are sufficient to deal with the legal and ethical issues raised.

This Note will focus on the medical achievements that have been made, in large part, because of advances in genetic research. Specifically, this Note will focus on the genetic advances associated with the Human Genome Project, Gene Therapy, Genetic Testing, and Human Embryonic Stem Cell Research.

The last year of the twentieth century brought scientists one step closer to the successful completion of the Human Genome Project.[2] The Human Genome Project is a government-funded project with the underlying goal of sequencing and mapping the entire human genome.[3] Scientists believe that the completion of this project will aid them in answering many questions associated with diseases currently afflicting thousands of Americans.[4]

Additionally, researchers have made significant advances in the science of gene therapy. Researchers have developed a method referred to as gene replacement therapy. Through the use of gene replacement therapy researchers will be able to replace incorrect genetic material contained in a cell with the correct genetic material.[5] In addition to gene replacement therapy, scientists have also discovered a method of gene therapy that instructs a cell to internally correct a genetic mistake.[6]

Genetic testing is another area in which scientists have made important advances. One advance is the availability of genetic testing for familial polyposis and non-

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[1]Glenn McGee, *Bioethics at the End of the 1900's*, *at* http://www.msnbc.com/news/336361.asp (website expired) [hereinafter McGee I].

[2]*See id*.

[3]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[4]M. Warman, *Maps in the Study of Genetic Variation and Human Phenotypes*, *at* syllabus.cwru.edu [hereinafter Warman I].

[5]LYNN B. JORDE ET AL., MEDICAL GENETICS 283 (2d ed. 1999).

[6]Lisa Laurence, *Gene Therapy Breakthroughs Delight Geneticists*, *at* http://www.genesage.com/geneletter/0299/genetherapybreakthrough.html (website expired).

hereditary ployposis colon cancer.[7] Genetic testing is extremely important, because research has proven that early disease detection can drastically improve the quality and longevity of life.[8]

In November 1998, scientists isolated stem cells in early human embryos.[9] Researchers feel this discovery will lead them to possible therapies for diseases such as Parkinson's and Alzheimer's.[10] Furthermore, scientists feel that they will be able generate human organs from isolated stem cells.[11] This development will enhance the therapeutic advantages of transplantation science. Those individuals drastically in need of organ transplants will no longer have to wait for an organ. With the ability to generate organs, doctors can help more patients, and significantly reduce the number of deaths associated with the unavailability of organs for use in transplantation surgeries.

In addition to discussing the benefits of genetic research, this Note will outline some of the ethical and legal concerns associated with the field of genetic research. The most prevalent concerns associated with advances in genetic research center around the availability of genetic information and how this information will effect privacy rights and employment and insurance practices. There are several other concerns and many other benefits associated with genetic research; however, this Note does not encompass them. The availability of genetic information has caused people to become concerned about their privacy.[12] Additionally, individuals are concerned about how genetic information will be used by insurance providers in determining insurance coverage.[13] Similarly, the use of genetic information in employment practices presents another concern associated with the availability of genetic information.[14]

There are special concerns associated with human embryonic stem cell research. Stem cells are isolated from human embryos.[15] Therefore, a major controversy associated with human embryonic stem cell research is the destruction of potential human life.[16] A secondary concern is that human embryonic stem cell research will encourage women to have abortions.[17] This Note will demonstrate how both of these concerns are unwarranted.

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[7]Monique K. Mansoura & Francis S. Collins, *Medical Implications of the Genetic Revolution*, 1 J. HEALTH CARE L. & POL'Y 329, 341 (1998).

[8]*Id.*; Louis J. Elsas II, *A Clinical Approach to Legal and Ethical Problems in Human Genetics*, 39 EMORY L.J. 811, 825 (1990).

[9]McGee I, *supra* note 1, at 2.

[10]*Id.*

[11]*Id.*; Dorthy C. Wertz, *Human Embryonic Stem Cells: A Source of Organ Transplants, at* http://www.genesage.com/geneletter/0299/humanembryonicstemcells.html (website expired).

[12]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[13]*Id.*

[14]*Id.*

[15]Wertz, *supra* note 11.

[16]*Id.*

[17]*Id.*

Even though there are some ethical and legal issues associated with genetic research, further restrictions should not be placed on the field. This Note will discuss how the present limitations placed on the field of genetic research, by the Legislature and administrative committees, are sufficient to effectively suppress the aforementioned ethical and legal concerns.

The Genetic Privacy Act and the Genetic Privacy and Non-Discrimination Act have been developed to address the issues previously raised.[18] The Americans with Disabilities Act is broad enough to cover concerns about the use of genetic information in employment practices.[19] The Health Insurance Portability and Accountability Act of 1996 addresses problems associated with the use of genetic information by insurance providers.[20]

Additionally, several committees have been developed to specifically address the issues raised by genetic research. For example, the National Institute of Health and the Department of Energy developed the formal Ethical, Legal and Social Issues [hereinafter "ELSI"] programs.[21] These administrative committees are responsible for making policy recommendations to federal and state legislatures.[22]

The benefits of genetic research clearly outweigh the costs. The present limitations placed on the field, by the Legislature and administrative committees, are sufficient to effectively quash the concerns.

II. SCIENTIFIC BACKGROUND

The study of genetics dates back to the discovery of the human chromosome in 1870.[23] Following this important discovery, scientists determined that most human traits were heritable.[24] By the early twentieth century, Gregor Mendel developed his law of inheritance.[25] This law of inheritance became known as Mendelian inheritance.[26] With the development of Mendelian inheritance, the term "gene" was used to define the fundamental unit of heredity.[27]

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[18]George J. Annas, et al., *The Genetic Privacy Act and Commentary (1995)*, *at* http://www.ornl.gov/hgmis/resource/privacy/privacy1.html; Michael M. J. Lin, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J.L. & MED. 109, 127, 129 (1996).

[19]Mansoura, *supra* note 7, at 344; Anne Lawton, *Regulating Genetic Destiny: A Comparative Study of Legal Constraints in Europe and the United States*, 11 EMORY INT'L L. REV. 365, 398-404 (1997).

[20]Mansoura, *supra* note 7, at 344.

[21]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179 (Leg. Hist.).

[22]Mansoura, *supra* note 7, at 344.

[23]M. Warman, *Human Genetics*, *at* syllabus.cwru.edu [hereinafter Warman II].

[24]*Id*. at 3.

[25]*Id.*

[26]*Id.*

[27]*Id.*

Expanding on Mendelian inheritance, Oswald Avery discovered that deoxyribonucleic acid or DNA is the chemical basis for inheritance.[28] The unveiling of DNA as the chemical basis for inheritance encouraged scientists to ascertain the structure of this molecule. James Watson and Francis Crick eventually unearthed the structure of DNA.[29] Watson and Crick determined that the structure of this molecule represented a winding ladder.[30] Therefore, the structure of DNA became known as a "double helix."[31]

Each prong of the winding ladder represents a gene and is composed of nucleotides.[32] There are four nucleotides that make up a DNA sequence:[33] adenine, guanine, cytosine, and thymine.[34] The nucleotides are held together by weak bonds, and once bonded they become known as base pairs.[35] Base pairs consist of adenine-thymine bonds and guanine-cytosine bonds.[36] The organization of these base pairs delineates the type of information a gene or piece of DNA will carry.[37]

Once scientists codified DNA as the chemical basis for inheritance and determined that genes are the fundamental unit of heredity, the term "genome" was coined to refer to the total amount of genes and DNA found within an organism.[38] Scientists have yet to determine exactly how many genes are in the human genome; however, researchers estimate the number to be between 75,000 and 100,000.[39]

After scientists came to understand the process of heredity, they moved on to more fascinating topics. Researchers began to ascertain why disease affects certain individuals and not others. Additionally, research established that all genetic disorders and many other diseases result from a mutation or change within the DNA sequence of a genome.[40] This change or mutation can be dramatic or slight.[41] Genes are comprised of base pairs, and scientists estimate that there are approximately three billion base pairs in the human genome.[42] Consequently, there are about three billion genetic loci that can be mutated.[43] Because researchers have concluded mutations

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[28]Warman II, *supra* note 23, at 3.

[29]*Id.*

[30]*Id.*

[31]*Id.*

[32]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[33]*Id.* (a DNA sequence is composed of several genes).

[34]*Id.*

[35]*Id.*

[36]*Id.*

[37]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[38]Warman II, *supra* note 23, at 3.

[39]*Id.*

[40]*Id.*

[41]*Id.*

[42]*Id.*

[43]Warman II, *supra* note 23, at 3.

are the root of many debilitating and fatal disorders, one can see the vast importance of enhanced genetic research.

III. BENEFITS OF GENETIC RESEARCH

A. The Human Genome Project

Every individual carries at least twenty harmful genes.[44] Until recent developments in genetics, physicians have been unable to identify these harmful genes.[45] Recognizing this immense problem, Congress developed the Human Genome Project. The Human Genome Project is federally funded and operated jointly by the National Institutes of Health and the Department of Energy.[46] Because of the medical and scientific importance of this project, Congress apportioned approximately $3 billion, or about $200 million per year for fifteen years to aid in its completion.[47]

The ultimate goal of the Human Genome Project is to sequence, map, and decode the entire human genome. Researchers are striving to reach this goal by creating comprehensive linkage maps, disease maps, gene maps, physical maps, radiation hybrid maps, and body maps.[48] Scientists believe that these maps will prove to be extremely useful in disease gene discovery.[49] Researchers explain that one can look at a genetic map to determine if other investigators have independently placed a disease gene in the same region as the corresponding disease locus.[50] If the disease gene is placed in the same region as the disease locus, the gene becomes a candidate for causing the disease.[51] Once the gene is determined to be a disease-causing candidate, scientists can test the gene to ascertain if it is actually responsible for a particular disease.[52]

Through mapping, researchers were able to identify the disease gene responsible for causing Huntington's Disease, or HD.[53] Huntington's Disease is believed to effect an estimated three to eleven out of every 100,000 persons.[54] The disease normally presents itself in patients sixty-years old and older.[55] Only five percent of patients afflicted with Huntington's Disease present symptoms in the first decade of

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[44]Aubrey Milunsky, *The "New" Genetics: From Research to Reality*, 27 SUFFOLK U. L. REV. 1307, 1310 (1993).

[45]*Id.* at 1310.

[46]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[47]*Id.*

[48]Warman I, *supra* note 4, at 5.

[49]*Id.*

[50]*Id.*

[51]*Id.*

[52]*Id.*

[53]Warman I, *supra* note 4, at 3.

[54]*Id.*

[55]*Id.*

their lives.[56] Huntington's Disease is an extremely debilitating disease; HD patients suffer from progressive dementia, involuntary movements, and physchiatric disturbances.[57] Before the HD gene was isolated, physicians lacking conclusive evidence of a family history of Huntington's Disease would spend months to years attempting to determine whether an individual was afflicted with this disease.[58] Now that researchers have identified the disease-causing gene, individuals can be rapidly diagnosed for HD.[59] Rapid diagnosis is not a cure, but it will allow physicians to improve the patient's quality of life.

On Monday, June 26, 2000, scientists announced the completion of the first rough map of the human genetic code.[60] Over ninety-seven percent of the human DNA is now mapped.[61] This is an amazing accomplishment, and it was completed ahead of schedule.

The next step in the Human Genome Project is to identify the individual gene and the proteins that make up the gene.[62] This process will allow geneticists to understand how the gene functions, why some genes cause disease, and how to develop therapies and cures for thousands of life-threatening diseases.[63]

Even though the Human Genome Project is only partially complete, many disease-causing genes have been placed in the same region as the corresponding disease locus.[64] Obviously, the importance of the Human Genome Project is immense. Researchers believe that vast amounts of beneficial scientific information will be gained from this project, and as we all know: "knowledge equals power."[65] Therefore, researchers need the freedom to complete this project.

B. Gene Therapy

Gene therapy is the "genetic alteration of the cells of individuals with genetic diseases."[66] Gene therapy targets two types of cells: germ cells and somatic cells.[67]

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[56]*Id.*

[57]*Id.* Those patients under twenty years of age present with a rapid progression of bradykinesia, rigidity, epilepsy, and severe dementia. Warman I, *supra* note 4, at 3.

[58]Milunsky, *supra* note 44, at 1308.

[59]*Id.*

[60]Charlene Cairo, *Scientists Complete Genetic Milestone* (June 26, 2000), *at* http://www.msnbc.com/news/424682.asp.

[61]*Id.*

[62]*Id.*

[63]*Id.*

[64]Warman I, *supra* note 4, at 3.

[65]Julia Walsh, *Reproductive Rights and the Human Genome Project*, 4 S. CAL. REV. L. & WOMEN'S STUD. 145, 147 (1994).

[66]JORDE, *supra* note 5, at 283.

[67]Walsh, *supra* note 65, at 149.

Somatic cells include all cells in the body, except sperm and egg cells; whereas germ cells include only sperm and egg cells.[68]

Somatic cell gene therapy is the alteration of human somatic cells in order to treat a specific disorder.[69] As previously stated, somatic cells include all body cells, except sperm and egg cells. Although somatic cells are all inclusive, bone marrow stem cells seem to be the prime candidates for stem cell gene therapy.[70] Somatic cell gene therapy protocols are currently being tested for a number of disorders.[71] Below is a partial list of diseases for which somatic cell gene therapy is being tested:

Disease	Target Cell	Inserted Gene
ADA deficiency	Bone marrow stem cells	Adenosine deaminase
Hemophilia B	Hepatocytes	Factor IX
Cystic Fibrosis	Airway epithelial cells	CFTR
Malignant melanoma	Melanoma tumor cells	HLA-B7 gene
Duchenne Muscular Dystrophy	Myoblasts	Dystrophine
Lung cancer	Lung cancer cells	Normal p53
Brain tumors	Brain cells	Herpes thymine kinase
Ovarian cancer	Ovarian cancer cells	Herpes thymine kinase
AIDS	Helper T lymphocytes	Dominant negative retrovirus mutations [72]

The most commonly used technique in somatic cell gene therapy is gene replacement. Gene replacement therapy is the replacement of a missing gene product by inserting a normal gene product into the cell.[73] Geneticists insert the new genetic material into the cell through the use of a viral carrier.[74] This viral carrier enters the nucleus of the cell and deposits the normal gene product into the cell.[75] Researchers explain that even a partially effective gene therapy may provide significant health benefits.[76]

Focusing on diseases like hemophilia, cystic fibrosis, and phenylketonuria or PKU, researchers have developed a technique that prompts liver cells to change their own DNA sequences.[77] Scientists explain that genes are composed of nucleotides, and that missing even one nucleotide can cause drastic results.[78] For instance, hemophiliacs are missing the nucleotide responsible for directing liver cells to

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[68] *Id.*

[69] JORDE, *supra* note 5, at 283.

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] JORDE, *supra* note 5, at 283.

[75] *Id.*

[76] *Id.*.

[77] Laurence, *supra* note 6.

[78] *Id.*

produce an important blood-clotting protein.[79] Like hemophilia, many genetic disorders are caused by single nucleotide mutations.[80]

Dr. Clifford Steer of the University of Minnesota Medical School, determined that the mutation causing hemophilia occurs on the factor IX gene.[81] Relying on this information, Dr. Steer and his team designed a molecule that can travel into the liver cells of rats.[82] Once inside the nucleus of a liver cell, the molecule can direct the cell's internal mechanisms to correct the "clotting" nucleotide on the factor IX gene.[83] This special molecule is referred to as "chimeric RNA/DNA oligonucleotide."[84] Chimeric RNA/DNA oligonucleotide is composed of genetic material containing a "correction;" the correction mandates the cell to change its DNA.[85]

In simpler terms, this special molecule can be compared to a correction key on a typewriter.[86] The molecule alerts the cell to a mistake in its DNA sequence, then the cell corrects the mistake by "writing over" the incorrect nucleotide or nucleotides.[87] In hemophiliacs the factor IX gene has a cytosine, "C," in place of adenine, "A."[88] Chimeric RNA/DNA oligonucleotide instructs the cell to replace the "C" with an "A."[89] This molecule has the power to correct, insert, or delete up to three nucleotides.[90]

Dr. Steer and his team have also performed a similar procedure to correct the genetic mutation that causes the rodent equivalent of Crigler-Najjar syndrome.[91] Crigler-Najjar syndrome, like hemophilia, affects the liver.[92] Children born with this disease are unable to metabolize the protein billirubin.[93] Consequently, these children suffer from brain damage and will ultimately succumb to an early death.[94] The procedure developed by Dr. Steer and his team will assist researchers in creating therapies to cure and treat the most debilitating diseases, like Crigler-Najjar syndrome.

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[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] Laurence, *supra* note 6.

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] Laurence, *supra* note 6.

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] Laurence, *supra* note 6.

[93] *Id.*

[94] *Id.*

A major difference between Dr. Steer's method and traditional gene therapy is the use of a chimeric RNA/DNA oligonucleotide in the place of a viral carrier to deliver the genetic material to the target cell.[95] The procedure developed by Dr. Steer and his team is referred to as chimeraplasty.[96] Chimeraplasty is directed at somatic cells not germ cells, therefore the results are not heritable.[97] Dr. Steer and his team are confident that chimeraplasty will be used to cure liver-based diseases in the future.[98] Furthermore, Dr. Steer expects this method to be applicable not only to stem cells found in the liver, but also to those found in the bone marrow, nervous system, renal system, and the muscular system.[99]

Another type of gene therapy is germline therapy. Germline therapy involves the modification of all cells in the body, including those cells that produce gametes.[100] Germline therapy affects those cells involved in reproduction, therefore scientists can alter heritable traits.[101] Furthermore, because germline therapy involves gametes, the alterations made are inheritable.[102] Therefore, any changes made through germline therapy can be passed from the recipient to his offspring.[103]

The ability of scientists to alter future generations has been the root of much controversy surrounding gene therapy. Many argue that researchers should not be able to change the traits of an individual prior to birth, without his consent. Putting this controversy aside, germline therapy is essential to the early treatment of genetic disorders.[104]

Although no one has been cured by gene therapy as of yet, researchers explain that this genetic advancement has had some positive effects on individuals afflicted with many diseases.[105] Even though criticism surrounds the area of gene therapy, research illustrates that this procedure may be the most effective treatment available for many human diseases.[106]

C. Genetic Testing

There are three main types of genetic tests available today: screening tests, diagnostic tests, and predictive or pre-symptomatic tests.[107] With the increasingly

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[95]*Id.*

[96]*Id.*

[97]Laurence, *supra* note 6.

[98]*Id.*

[99]*Id.*

[100]JORDE, *supra* note 5, at 287. Gametes are sperm egg cells. *Id*.

[101]*Id.*; *see also* Walsh, *supra* note 65, at 149.

[102]Walsh, *supra* note 65, at 149.

[103]*Id.*

[104]*Id.*

[105]*Id.*

[106]*Id.*

[107]M. Warman & S. Schwartz, *Genetic Testing*, *at* syllabus.cwru.edu [hereinafter Warman III].

large number of diseases afflicting individuals today, genetic testing has become extremely important.

Genetic screening is used to classify seemingly healthy individuals who are at risk for the developing diseases.[108] Newborn screening is used to determine whether a newborn is afflicted with or is a carrier of a particular disease.[109] Normally this procedure is done within the first twenty-four to seventy-two hours of life.[110] Newborn screening allows physicians to begin treatment early, thereby, adding years and quality to an individual's life.

Newborn screening has proven to be extremely effective in treating many genetic disorders. Phenylketonuria is a genetic disorder that can be controlled through diet if caught early.[111] PKU causes mild to severe mental retardation in-patients afflicted with this disease.[112] The symptoms of PKU resemble developmental delay, therefore it is difficult for physicians to detect.[113] If a newborn is screened for PKU and tests positive, physicians can regulate the child's diet.[114] Research has shown that beginning a low phenyalanine diet, before four weeks of age, is highly effective in altering the course of this disease.[115] In fact, individuals on this diet can expect to develop normal intelligence.[116] Newborn screening is essential in the early detection and treatment of diseases, like PKU.

Carrier screening is used to determine what members of a population are carriers of genetic disorders.[117] Carrier screening gives physicians the ability to determine whether an individual is a carrier of a disease-causing gene. If an individual is found to be a carrier of a disease-causing gene, doctors can make counseling recommendations.[118] Furthermore, carrier screening can alert potential parents that they may pass a disease gene to their offspring.[119] Carrier screening is a tool that assists doctors in ensuring that dangerous disease causing genes are not passed into new generations.

Carrier screening also aids researchers in determining what populations are more susceptible to a particular disease. Through carrier screening, researchers have determined that one in twenty-five Caucasians carry the gene for cystic fibrosis,

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[108] *Id.* at 2-3.

[109] *Id.*

[110] *Id.*

[111] JORDE, *supra* note 5, at 268 (PKU affects approximately one in 10,000 to 15,000 Caucasian births).

[112] *Id.* (Approximately 95% of patients suffering from PKU who go untreatedwill develop mild to severe mental retardation.).

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] JORDE, *supra* note 5, at 268.

[117] *Id.*

[118] Milunsky, *supra* note 44, at 1310-11.

[119] *Id.*

about one in twelve people of Mediterranean decent carry the gene for thalassemia, about one in ten African Americans carry the gene for sickle-cell anemia, and about one in thirty Ashkenazi Jews carry the gene for Tay-Sacs disease.[120] Monitoring disease gene distribution over given populations will allow researchers to determine why certain individuals succumb to certain diseases.

Although genetic screening tests are medically and scientifically beneficial, they are not conclusive.[121] Once the presence of a disease-causing gene is suspected in an individual, physicians recommend diagnostic testing.[122] Diagnostic testing is used to confirm the presence of a disease-causing gene.[123]

In contrast, pre-symptomatic or predictive testing is used on healthy individuals who may have a family history of disease.[124] Pre-symptomatic or predictive testing is done before the individual presents any signs of a disease.[125] Consequently, results from this method of genetic testing can cause psychological or physical harm.[126] This method of testing raises concerns about privacy and confidentiality, in that it is a method of looking into the future.[127] Many fear that predictive or pre-symptomatic testing will make genetic information available for use by employers, insurance providers, and health care providers.[128] This is a prevalent concern because the genetic information can forecast the future; therefore insurance providers and employers can make decisions based on future events.

Many case studies establish that genetic testing can save thousands of lives. For example, early diagnosis of colon cancer can be life saving. Genetic testing for the disease-causing gene for colon cancer is now available.[129] Patients testing positive for one copy of the autosomal gene responsible for causing colon cancer can undergo life saving surgery.[130] Surgeons can perform a colonectomy or can remove colon adenomas before symptoms of the disease become present.[131] Both of these procedures effectively prevent colon cancer.[132] In addition to colon cancer, early diagnosis and treatment are successful tools in the prevention of many other diseases,

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[120] *Id.*

[121] Warman III, *supra* note 107, at 3.

[122] *Id.*

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] Warman III, *supra* note 107, at 3.

[127] Milunsky, *supra* note 44, at 1312.

[128] *Id.*

[129] *Id.*

[130] H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[131] *Id.*

[132] *Id.*

such as PKU.[133] Early diagnosis and treatment of disease can eliminate thousands of needless and painful deaths.

Even though genetic testing raises concerns over privacy, such as genetic information being disclosed to an unauthorized source, and the use of such test results by insurance providers and employers, the benefits outweigh the risks. Early diagnosis and treatment of disease prevents thousands of deaths; genetic testing assists physicians in this process. In response to the concerns, federal legislation has been developed to safeguard the privacy of genetic information and to ensure that employers and insurance providers do not misuse it.

IV. HUMAN EMBRYONIC RESEARCH

Human embryonic research is extremely important in the advancement of transplantation science. Findings show that in 1997 approximately 56,000 people in the United States were awaiting organ transplants.[134] The United Network for Organ Sharing explains that approximately 4000 of the 56,000 Americans awaiting organ transplants died because of the unavailability of organs.[135] The decreasing number of organs available for transplantation has caused bioethicists to suggest paying people for organ donations.[136] In some countries, organ shortages have lead to mandatory organ donation and the removal of organs from living persons.[137]

Presently, the problem in the United States has not lead to mandatory organ donation, but researchers predict that if families do not begin to donate organs of the deceased, drastic measures will need to be taken.[138] Researchers suggest that using isolated human embryonic stem cells to grow organs may solve this problem.[139] At the present time, researchers are not exactly sure how to create organs from isolated stem cells, but they expect to know in the near future.[140] Once scientists determine how to make organs from isolated stem cells, organs will be readily available for transplantation, and thousands of deaths will be prevented.[141]

A. Benefits of Human Embryonic Research

Although human embryonic research has sparked a significant amount of controversy, many positive scientific and medical advances have been made in the field. Possibly the most significant advancement is the isolation and growth of embryonic cells that are capable of developing into organs.[142] Human embryonic

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[133] *Id.*

[134] Wertz, *supra* note 11.

[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] Wertz, *supra* note 11.

[140] *Id.*

[141] *Id.*

[142] *Id.*

stem cells can develop into many different organs when given the proper genetic instructions.[143]

On November 6, 1998, the New York Times reported that two research groups, one headed by Dr. James A. Thomson of the University of Wisconsin, Madison and the other headed by Dr. John Gearhart of Johns Hopkins University, Baltimore, succeeded in growing human stem cells in a laboratory.[144] Many hope that researchers will be able to use these stem cells to generate human organs.[145]

The research groups isolated the human embryonic stem cells using two different procedures. Dr. Thomas' group removed stem cells from a fifteen to twenty cell "pre-embryo" called a blastocyst.[146] The stem cells were taken from the blastocysts approximately three days after fertilization.[147] At this stage, each stem cell has the potential to become many different parts of the body, and is referred to as pluripotent.[148] During the blastocyst stage these stem cells are identical, therefore it is impossible to determine whether a particular cell will become an embryo or a placenta.[149]

Dr. Gearhart and his research team isolated stem cells from the germ cells of aborted fetuses.[150] Unlike other embryonic cells, germ cells are not committed to becoming a particular organ.[151] Therefore, scientists can use genetic material to instruct the isolated stem cell to develop into any organ.[152] Regardless of the method of isolation, researchers believe that the isolated stem cells are identical, and will be extremely useful in advancement of transplantation science.[153]

B. Concerns Associated With Embryonic Stem Cell Research

A major concern associated with human embryonic stem cell research, involving the first method of isolation, is the destruction of potential life.[154] Responding to this argument, researchers remind critics that three-day old blastocysts used in the isolation process are not yet embryos.[155] At the blastocyst stage, the likelihood that a particular stem cell will become part of the placenta, which will be discarded at birth, is equivalent to the likelihood that the same stem cell will develop into part of a

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[143] *Id.*

[144] Wertz, *supra* note 11.

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] *Id.*

[149] Wertz, *supra* note 11.

[150] *Id.*

[151] *Id.*

[152] *Id.*

[153] *Id.*

[154] Wertz, *supra* note 11.

[155] *Id.*

potential person.[156] Many ethics committees, including those in the United States (the National Institutes of Health and the Human Embryo Research Panel), the United Kingdom, Australia, and Denmark, have referred to human embryos up to fourteen days old as "pre-embryos."[157] These committees recognize that before fourteen days there is absolutely no possible way to differentiate between the cells that will become part of the embryo and the cells that will become part of the placenta.[158] Therefore, these countries have approved human embryonic research on "pre-embryos" up to fourteen days old.[159]

Another major concern associated with human embryonic stem cell research centers around the second method of isolation. Critics of human embryonic stem cell research feel the second method of isolation will encourage women to have abortions.[160] This concern is completely unfounded. The request for the donation of an aborted fetus is made only after the abortion procedure has been completed.[161] Second, the woman does not receive any compensation for the donation of an aborted fetus.[162] The argument that this method of stem cell isolation causes abortion is as ridiculous and unfounded as arguing that organ transplantation causes murder.[163] Scientists and supporters of human embryonic stem cell research suggest that those who oppose such research should view it as saving a life rather than ending a life.[164]

Finally, the Supreme Court of the United States has determined that a fetus is not a "person" under the Constitution.[165] Therefore, a fetus is not afforded any Constitutional rights.[166] Additionally, in *Roe v. Wade*, the Supreme Court upheld a woman's right to receive an abortion.[167]

In 1995, due to enormous public pressure, Congress instituted a ban on the use of federal funds in human embryonic research.[168] On January 19, 1999, the Department of Health and Human Services ruled that embryonic stem cells do not fall under the 1995 Congressional ban on the use of federal funds in support of embryonic research.[169] Recognizing the tremendous scientific and medical importance of

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[156]*Id.*

[157]*Id.*

[158]*Id.*

[159]Wertz, *supra* note 11.

[160]*Id.*

[161]*Id.*

[162]*Id.*

[163]*Id.*

[164]Wertz, *supra* note 11.

[165]Roe v. Wade, 410 U.S. 113 (1973).

[166]*Id.*

[167]*Id.*

[168]Wertz, *supra* note 11.

[169]*Id.*

human embryonic stem cell research, Congress concluded that the benefits outweighed the concerns.[170] Consequently, Congress now permits federal funds to be used in support of human embryonic stem cell research projects.[171]

The importance of human embryonic stem cell research in the advancement of transplantation science is tremendous and clearly outweighs the concerns associated with this type of research. The isolation of stem cells has given scientists the ability to ensure that in the future persons in need of organ transplants will not die waiting for an organ. This discovery does not solve all the problems associated with organ transplants, although it has enabled scientists to look positively on the future of transplantation science. Additionally, researchers feel that human embryonic stem cell research will revolutionize the treatment of degenerative diseases like Parkinson's, Alzheimer's, diabetes, heart disease, stroke, arthritis, birth defects, osteoporosis, spinal cord injuries, burns, and most cancers.[172] Ultimately, over 140 million Americans stand to benefit from human embryonic stem cell research therefore scientists need the freedom to continue their research.[173]

V. ETHICAL AND LEGAL CONCERNS ASSOCIATED WITH GENETIC RESEARCH

The advances in genetic research are extremely important in the treatment and diagnosis of disease. However, genetic research has raised some ethical and legal concerns. The advances in the field of genetics have made vast amounts of personal genetic information available. The availability of genetic information is the center of the debate over restrictions on genetic research. Proponents of strict limitations on genetic research argue that the availability of genetic information can lead to breaches of privacy and fair employment and insurance practices. Although these concerns are prevalent in the minds of most people, the current legislation encompasses all of these concerns.

A. Privacy and Genetic Research

The most compelling concern associated with advances in genetic research is the effect on privacy rights. The purpose of the Human Genome Project is to gain access to information locked in an individual's genetic code.[174] Many people believe this information is so personal, it should stay locked.[175] Access to this personal genetic information will assist researchers in the detection, treatment, and prevention of disease.[176] Recognizing the highly personal and sensitive nature of this

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[170] *Id.*

[171] *Id.*

[172] *Id.* Glenn McGee, *Stem Cells the Goo of Life the Debate of the Century*, *at* http://www.msnbc.com/news/33631.asp (website expired) [hereinafter McGee II].

[173] *Id.*

[174] Annas, *supra* note 18; H.R. REP. NO. 102-601 at V (1994), *available at* 1994 WL 444748.

[175] *Id.*

[176] *Id.*

information, researchers agree it should be afforded special protection to ensure the individual donor's privacy interests are not compromised.[177]

People fear that once scientists unlock the genetic code, anyone will be able to gain access to this highly personal and sensitive genetic information.[178] Genetic information is the pathway into an individual's future, past, and present.[179] Genetic information discloses a person's traits, disease patterns and family history.[180] Consequently, if this information is not kept private, the wrong person could gain access into an individual's future, past, and present.[181]

Genetic information is considered to be highly sensitive and private for several reasons. First, the information contained in a genetic code is largely unknown by the person in whose genetic material it was found.[182] Therefore, if the wrong person gained access to this information, he would know more about the owner of the genetic material than the owner knows about himself.[183] Second, genetic information discloses probabilistic health information about the individual's family, especially parents, siblings, and children.[184] Finally, because the DNA molecule is stable, once stored, it can become an infinite source of genetic information.[185]

Because genetic material contains highly sensitive and personal genetic information, many fear that once it becomes available the donor's privacy rights will be violated. Although this is a valid concern, legislation has been developed to ensure that Americans do not have to sacrifice their Constitutionally protected right to privacy for advances in genetics. The Genetic Privacy Act and the ELSAI Program have been developed to protect this privacy interest.

B. Employment Practices and Genetic Research

Another issue raised by genetic research is the use of genetic information in employment practices. Critics of the availability of genetic information believe that genetic test results and information will be used unfairly in employment practices.[186] Some fear that a discouraging genetic makeup will eliminate them from the job market.[187] Furthermore, people fear that employers will begin to use genetic tests to screen employees for genetically desired or undesired traits.[188] Finally, many fear

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[177]*Id.*

[178]*Id.*

[179]Annas, *supra* note 18; H.R. REP. NO. 102-601 1994, at V (1994), *available at* 1994 WL 444748.

[180]*See supra* note 179.

[181]*Id.*

[182]*Id.*

[183]*Id.*

[184]*Id.*

[185]*See supra* note 179.

[186]Lawton, *supra* note 19, at 398-401.

[187]*Id.*

[188]H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

that negative genetic information will cause their employer to deny them insurance coverage.[189]

There is some evidence that genetic information has been the basis for denying corporate insurance coverage. For example, the father of an eight-year old girl suffering from PKU had a family group insurance plan through his employer.[190] The young girl's medical records indicated that she was on a low phenylalanine diet and was developing normally and healthy.[191] Subsequent to her diagnosis, her father changed jobs and was denied insurance coverage by his new employer, because of her condition.[192]

The issues associated with the use of genetic information in employment practices are significant; however, federal legislation has been developed to ensure that these issues are dealt with effectively. For instance, in 1995 the Equal Employment Opportunity Commission broadened the Americans with Disabilities Act to address concerns raised by the use of genetic information in employment practices.[193] Furthermore, many committees have been developed to ensure that employers do not abuse the availability of genetic information.[194]

C. Insurance Coverage

The availability of genetic information has fueled concerns that it will be used by insurance providers in making coverage decisions.[195] Insurance coverage is based on a theory of shared risks.[196] Therefore, prior to offering coverage, an insurance company will appraise all potential risks of the individual or the group.[197] Some of the risk factors used in coverage selection are age, present health, and the potential for future disease.[198] The presence of certain health conditions can result in higher premiums or complete denial of coverage.[199] Fortunately, most health conditions develop later in life; therefore people afflicted with these conditions can secure insurance coverage, at a reasonable rate, prior to the detection of the disease.[200]

The availability of genetic information has the potential to change the way in which insurance providers determine coverage.[201] First, genetic tests will enable

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[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] *Id.*

[193] Lawton, *supra* note 19, at 398-401.

[194] Mansoura, *supra* note 7, at 344.

[195] H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[196] *Id.*

[197] *Id.*

[198] *Id.*

[199] *Id.*

[200] H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[201] *Id.*

physicians to determine the presence of a disease prior to the onset of symptoms.[202] Insurance providers may see the presence of a potential disease as too great a risk.[203] Therefore, they may begin to deny coverage or charge extremely high premiums to people who are not sick and who may never become sick.[204]

There are several cases involving individuals who have been denied insurance coverage based on their genetic makeup. A woman who questioned her gynecologist about a family history of Huntington's Disease was denied coverage.[205] Likewise a salesman with a mild, stable, barely perceptible genetic characteristic was denied insurance coverage.[206] A family was excluded from coverage when their insurance provider discovered that the son suffered from a form of genetic mental retardation.[207] The insurance provider denied coverage to the entire family, even though it knew that the genetic disorder did not affect his health and was unlikely to be present in any of the female family members.[208] Although these cases are disturbing, evidence establishes that insurance providers rarely use genetic information to determine whether or not to provide an individual or group with insurance coverage.[209]

The concerns associated with the use of genetic information by insurance providers are significant; however, federal legislation has been developed to curb this problem. In 1996, the Health Insurance Portability and Accountability Act was passed to ensure that insurance providers do not make coverage decisions based on genetic information.[210] Focusing on the use of genetic information by insurance providers, the House of Representatives recently enacted the Genetic Privacy and Nondiscrimination Act. Additionally, the National Institute of Health, the Department of Energy Working Group, and the National Action Plan on Breast Cancer working jointly have made a series of policy recommendations on the use of genetic information and insurance coverage for federal and state legislatures.[211]

VI. FEDERAL LEGISLATION

In response to the aforementioned concerns, several pieces of legislation have been developed and amended. The Genetic Privacy Act was created to deal with the privacy issues associated with the availability of genetic information.[212] Congress recently enacted the Genetic Privacy and Nondiscrimination Act to restrict the use of

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[202] *Id.*

[203] *Id.*

[204] *Id.*

[205] H.R. REP. NO. 102-478 (1992), *available at* 1992 WL 74179.

[206] *Id.*

[207] *Id.*

[208] *Id.*

[209] *Id.*

[210] Mansoura, *supra* note 7, at 344.

[211] *Id.*

[212] *Genetic Privacy Legislation*, *at* <http://www.ornl.gov/hgmis/archive/laws.html>.

genetic information by insurance and health care providers and in employment practices.[213] The Equal Employment Opportunity Commission broadened the scope of the Americans with Disabilities Act, thereby prohibiting employers from misusing genetic information.[214] The Health Insurance Portability and Accountability Act was enacted to ensure the fair use of genetic information by insurance providers.[215] The present legislative restrictions on the use of genetic information are ample enough to overcome the current problems associated with genetic research.

A. The Genetic Privacy Act

The Genetic Privacy Act [hereinafter "GPA"] has three common goals. First, the GPA seeks to encourage a greater dissemination of information to patients and donors of genetic material.[216] Second, the GPA assures the protection of genetic information, while promoting continued research and experimentation in the field of genetics.[217] Finally, the GPA encourages individuals to supply genetic samples for analysis and research.[218]

The underlying goal of the GPA is to protect the sample source's[219] interest in his own genetic material and information.[220] The drafters of the GPA also realize the importance of continued genetic research in the discovery and treatment of disease.[221] Therefore, the GPA takes the proper steps to protect the sample source's interest in his genetic material without discouraging continued advancements in genetics.

1. The GPA Adequately Monitors the Collection, Analysis and Disclosure of Genetic Material.

Sections 101(a) and 102(a) of the GPA prohibit the collection and genetic analysis of an individually identifiable DNA sample without the written consent from the sample source or a representative of the sample source.[222] Section 103(a) of the GPA outlines the requirements for a valid written authorization for the collection and analysis of a DNA sample.[223] Pursuant to Section 103(a) of the GPA, a valid authorization contains the following: 1) a writing signed and dated by the sample source or the sample source's representative; 2) the identity of the individual

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[213]*Id.*

[214]*Id.*

[215]*Id.*

[216]Lin, *supra* note 18, at 129.

[217]*Id.*

[218]*Id.*

[219]Annas, *supra* note 18 (sample source is used in the GPA to refer to the individual who donated the DNA sample).

[220]Lin, *supra* note 18, at 129.

[221]*Id.*

[222]Annas, *supra* note 18.

[223]*Id.*

collecting or requesting the genetic sample; 3) the identity of the facility where the DNA sample will be analyzed and stored; 4) the manner in which the DNA will be collected; 5) a description of all authorized uses of the DNA sample; 6) a statement regarding storage of the DNA after completion of the genetic analysis; and, 7) a provision that permits the sample source or sample source's representative to prohibit the use of the DNA sample for research or commercial purposes.[224] The GPA provides for an extremely strict written authorization requirement for the collection and analysis of a DNA sample.[225] This written authorization requirement allows for enhanced dissemination of information from the researcher to the patient, sample source, or the sample source's representative.[226] Furthermore, §§ 101, 102, and 103 ensure that the sample source or the sample source's representative has complete control over the DNA sample.[227]

Section 111(a) of the GPA prohibits any person from communicating or disclosing private genetic information without written authorization from the sample source or a representative of the sample source.[228] Section 112(a) of the GPA provides that a valid disclosure authorization contains the following: 1) a writing signed and dated by the sample source or a representative of the sample source; 2) the identity of the individual granting the authorization and the individual's relationship to the sample source (if not sample source); 3) the identity of the person permitted to make the disclosure; 4) a description of the specific genetic material to be disclosed; 5) the identity of the person to whom the information is to be disclosed; 6) a description of the purpose for disclosure; 7) the date upon which the authorization expires (cannot be longer than thirty days after grant of authorization); and, 8) a statement that the sample source or sample source's representative can revoke the authorization at any time.[229]

Analogous to §§ 101(a) and 102(a) of the GPA, § 111(a) provides a stringent written requirement for the disclosure of genetic information. The written disclosure requirement ensures the privacy of the sample source by giving him complete control over the disclosure of his genetic information.[230] While protecting the privacy interest of the sample source, the GPA provides researchers with the flexibility they need to access a patient's genetic information.[231]

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[224] *Id.*

[225] *Id.*

[226] Lin, *supra* note 18, at 129.

[227] *Id.*

[228] Annas, *supra* note 18.

[229] *Id.*

[230] Lin, *supra* note 18, at 129.

[231] *Id.*

2. The GPA Confers a Federal Property Right in the DNA Sample to the Sample Source.

Pursuant to § 104(a) of the GPA, the sample source or the sample source's representative receives a federal property right in his DNA sample.[232] Because the sample source is the sole owner of his genetic material, he can order the destruction of the sample at any time.[233] The effect of this provision is two-fold. First, § 104(a) of the GPA protects the privacy interest the sample source has in his genetic material.[234] This privacy interest is protected because the sample source or owner has complete control over the how the sample will be used. Second, § 104(a) of the GPA promotes continued developments in genetic research.[235] The sample source's property right in his DNA sample gives those hesitant about participating in research projects the incentive to do so.[236]

3. Effectiveness of the GPA in Dealing with Issues Raised by Genetic Research.

The GPA adequately deals with the privacy concerns associated with advances in genetic research. The GPA provides a strict written authorization requirement for the collection, analysis, and disclosure of genetic material. The GPA confers a federal property right in the DNA sample to the sample source, thereby giving the sample source complete control over his genetic material. The Genetic Privacy Act effectively suppresses concerns raised by the advances in genetic research, while promoting continued research and development in the field of genetics.

B. Genetic Privacy and Nondiscrimination Act of 1999

The Genetic Privacy and Nondiscrimination Act of 1999 [hereinafter "GPNA"] was passed by the House of Representatives in the 106th Congress.[237] The purpose of the GPNA is to establish limitations on the disclosure and use of genetic information by insurance providers and employers.[238] By restricting the use and disclosure of genetic information, the GPNA safeguards an individual's Constitutionally protected right to privacy.

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[232]Annas, *supra* note 18.

[233]*Id.*

[234]Lin, *supra* note 18, at 129.

[235]*Id.*

[236]*Id.*

[237]H.R. REP. NO. 106-2555 (1999); S. REP. NO. 106-1322 (1999) (A similar bill, the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, was enacted in the Senate. This Act prohibits insurance discrimination based on genetic information. It limits the ability of employers to request or require employees to undergo genetic testing. Furthermore, this Act restricts the disclosure and collection of genetic information.).

[238]*See supra* note 237.

1. GPNA Prohibits Health Insurance Discrimination Based on an Individual's Genetic Information.

Section 2 of the GPNA amends the Public Health and Service Act [hereinafter "PHSA"] to prohibit insurance discrimination based on genetic information.[239] Additionally, § 2(B) of the GPNA prohibits the use and disclosure of genetic information without the individual owner's consent.[240] This section amends Subpart 2 of Part A of Title XXVII of the PHSA by adding an additional section. Section 2707 (section added by the GPNA) of the PHSA provides, in pertinent part:

> A group health plan, and a health insurer offering health insurance coverage in connection with a group health plan, may not use genetic information to reject, deny, limit, cancel, refuse to renew, establish differential rates on premium payments for, or otherwise affect benefits provided under the plan or health insurance coverage offered in connection with the plan.[241]

Additionally, § 2707 of the PHSA states that a health insurance provider may not disclose or be compelled to disclose (even through a subpoena) an individual's genetic information without specific authorization from the individual or a legal representative of the individual.[242] The authorization must be in writing and must contain the following: 1) a description of the information to be disclosed; 2) the name of the individual or entity to which the information is to be disclosed; and, 3) the purpose of the disclosure.[243] The same amendments were made to Subpart B of part 7 of Title I of the Employment Retirement Income Security Act of 1974.[244]

The GPNA effectively addresses issues raised about the use of genetic information by insurance providers. The GPNA does not permit insurance providers to make coverage decisions based on an individual's genetic information. Furthermore, the GPNA prohibits the disclosure of such information without the expressed written consent of the owner. The GPNA, in accordance with the GPA, ensures that advances in genetic information will not punish American citizens.

2. The GPNA prohibits the use of Genetic Information in Employment Practices.

Section 3 of the GPNA prohibits the use of genetic information in employment practices.[245] Section 3(a)(1)(A)(B) provides, in pertinent part:

> [I]t shall be unlawful employment practice for an employer (A) to attempt to acquire, to acquire, or to use the genetic information of an employee or applicant for employment, or (B) to require a genetic test of an employee or applicant for employment, for the purpose of distinguishing among

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[239] *Id.*

[240] *Id.*

[241] *Id.*

[242] *Id.*

[243] *See supra* note 237.

[244] *Id.*

[245] *Id.*

> employees or applicants for employment or for the purpose of discriminating against or restricting any right or benefit otherwise due or available to an employee or applicant for employment, in connection with any matter relating to employment or employment opportunities, including terms and conditions of employment, privileges and benefits for employees, and termination of employment.[246]

Section 3 of the GPNA also contains a provision making it unlawful for an employer to disclose or to allow an unauthorized individual to gain access to another's genetic information.[247] The GPNA further provides that § 3 of this act is enforceable under §§ 705-709 of the Civil Rights Act.[248]

The GPNA adequately addresses concerns regarding the use of genetic information in employment practices. For all intents and purposes, the GPNA prohibits the use of genetic information in employment practices.[249] In fact, the GPNA makes the use of genetic information in employment practices illegal.[250] The GPNA is an effective measure enacted by the House of Representatives to suppress concerns raised by advances in genetics.

C. The Americans With Disabilities Act

On March 14, 1995, the Equal Employment Opportunity Commission [hereinafter "EEOC"] determined that individuals who are subjected to discrimination based on genetic information relating to disease or other disorders are considered disabled.[251] Because the EEOC recognizes these individuals as disabled, they fall under the purview the Americans with Disabilities Act [hereinafter "ADA"].[252] Allowing employees who have been discriminated against based on their genetic information to bring a cause of action under the ADA will dissuade employers from misusing genetic information in employment practices.

D. The Health Insurance Portability and Accountability Act

Congress enacted the Health Insurance Portability and Accountability Act [hereinafter "HIPAA"] in order to address concerns associated with the use of genetic information by insurance providers.[253] HIPAA is codified in various sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.[254]

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[246] *Id.*

[247] *Id.*

[248] *See supra* note 237.

[249] *Id.*

[250] *Id.*

[251] Lawton, *supra* note 19, at 398, 401.

[252] *Id.*

[253] The Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, No. Stat. 1936 (1996).

[254] Lawton, *supra* note 19, at 418.

Section 1182(a)(1)(E), Title 29 of the United States Code prohibits a health insurer offering a group insurance plan from establishing rules of eligibility based on genetic information.[255] Section 1182(b)(1) states that an insurance provider offering a group plan is not permitted to require an individual to pay a higher premium than those similarly situated, based solely on the individual's health information.[256] Essentially, HIPAA prohibits insurers from using genetic information to deny or limit health insurance coverage.[257] Thus, HIPAA protects many Americans from losing health insurance coverage based on genetic information, whether it is gained from genetic testing or medical history.[258]

HIPAA, in connection with the GPNA, adequately addresses concerns associated with the use of genetic information by insurance providers. The benefits gained through genetic research clearly outweigh the concerns, thus the present limitations placed on the field are sufficient.

VII. PROGRAMS DEVELOPED TO DEAL WITH LEGAL AND ETHICAL CONCERNS

In addition to the federal legislation created to quell the ethical and legal artery associated with genetic research, several committees have been developed. The ELSIP and the National Institutes of Health and Department of Energy Working Groups are two programs that have been created to address the concerns raised by genetic research.

The United States Department of Energy [hereinafter "DOE"] and the National Institutes of Health [hereinafter "NIH"] have devoted three to five percent of the annual Human Genome Budget toward the study of ELSI raised by the availability of genetic information.[259] The main goals of the ELSI programs are to facilitate medical and scientific research in the field of genetics, while promoting education and the development of related medical and public policies.[260] The ELSI programs are in place to ensure that genetic information is not misused.[261] Specifically, the ELSI programs focus on maintaining privacy and fair employment and insurance practices.[262] Additionally, ELSI frequently joins with the NIH and the DOE to make policy recommendations on the importance of protecting genetic information to federal and state policy makers.[263] For example in 1995, the NIH-DOE ELSI Working Group and the National Action Plan on Breast Cancer developed a series of policy recommendations to prevent the unfair use of genetic information by

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[255]29 U.S.C. § 1182(a)(1)(E) (2000).

[256]§ 1182(b)(1).

[257]Mansoura, *supra* note 7, at 344.

[258]Lawton, *supra* note 19, at 404.

[259]*Human Genome Project Information: Ethical, Legal, and Social Issues* (Sept. 5, 2001), *at* <http://www.ornl.gov/hgmis/elsi/elsi.html>.

[260]*Id.*

[261]*Ethical Legal and Social Issues of Human Genome Project*, *at* <http://www/ornl.gov/hgmis/resume/elsi.html> [hereinafter "ELSI"].

[262]*Id.*

[263]Mansoura, *supra* note 7, at 344, 346.

insurance providers and employers.[264] These programs have been created to safeguard the interests of Americans, and to ensure that individuals do not have to exchange their rights to privacy, fair insurance and employment practices for advances in genetic research.

VIII. CONCLUSION

The advances being made in the field of genetics are miraculous. Furthermore, these advances are extremely beneficial to scientists in the study of disease. Researchers feel the completion of the Human Genome Project will unlock many mysteries in the study of human diseases. Although the completion of this project will lead scientists one step closer to the treatment of thousands of fatal and debilitating diseases, the project will also make genetic information completely accessible. Because of the personal and sensitive nature of this information, people fear that they will lose their right to privacy and to fair employment and insurance practices. Federal legislation is in place to suppress these concerns.[265] Additionally, programs are in place to make continued policy recommendations to state and federal policy makers.[266] This Note has established that the present limitations placed on genetic research are sufficient to suppress the concerns associated with this research. Furthermore, this Note has illustrated that the benefits of genetic research clearly outweigh those concerns thus scientists should be free to continue their research without further restrictions.

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[264] *Id.*

[265] Many states have also enacted legislation similar to that discussed in this Note.

[266] ELSI, *supra* note 261.

[267] The author received her Juris Doctor from the Cleveland-Marshall College of Law, Cleveland State University on May 19, 2001, and was admitted to the practice of law on November 13, 2001. The author would like to thank her family for their encouragement and support, Professor Kevin O'Neill for his helpful comments, and John Costin, fourth year student at the Case Western Reserve School of Medicine, for his assistance with some of the complex medical issues written about herein.