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The Significance of Genetics Across Disciplines: Genetic Counseling & Testing

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HONORS PROJECT

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Genetics in general is a rapidly expanding and diversifying field. Genetic testing and genetic counseling are no exception to this. Genetic testing and counseling are relatively new concepts and their expansion has been greatly aided by the advent of the Human Genome Project. With the sequencing of the entire human genome (roughly 3 billion base pairs) complete, genetic research has proceeded in leaps and bounds. According to the National Institute of Health (NIH, 2013), the genetic basis of approximately 1800 genes has been discovered and there are over 2000 genetic tests available. With a greater wealth of knowledge available a need for professionals to administer, explain and counsel patients and families through genetic conditions/testing became apparent as well (Norrgard, 2008). Important considerations for this area of genetics includes a brief background on genetics and genetic testing (what it is, how it works and types of testing available), what genetic counselors are and their role and importance in health care, direct to consumer genetic testing, the Genetic Information Nondiscrimination Act of 2008 (GINA), and the ethics/obstacles surrounding testing. Ultimately, this research endeavors to showcase the importance of proper training, knowledge, commitment to making proper referrals when necessary, and experience with genetics for a variety of healthcare professionals in a variety of fields.

A brief background of genetics and how genetic testing works is an important foundation for understanding how the fields have grown and expanded over time. Genes are the basic unit of heredity and are comprised of short segments of deoxyribonucleic acid (DNA). DNA holds all genetic information and is stored in the nucleus of each cell as chromosomes. Chromosomes are DNA wrapped around proteins and condensed within the nucleus. There are 22 pairs of chromosomes in each cell along with a pair of sex chromosomes (XX for females and XY for males). Half of our chromosomes come from our mother while the other half comes from
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our father. There are roughly 25,000 genes in the human genome. DNA is made up of a long sequence of base pairs, the order of which determines structure and function of all genes and the eventual proteins made from those genes. There are four nitrogenous base pairs in the human genetic code: A (adenine), T (thymine), C (cytosine), and G (guanine). DNA is a double-stranded molecule so the A on one strand must pair with a T on the other strand while Cs and Gs also pair together. Genes are translated into proteins which direct our characteristics and assist in many processes in the body. Occasionally the genetic code undergoes a change during development and base pairs can be added, changed or deleted. These changes are known as mutations. Mutations can be either positive, negative or not have much of an effect at all, but in the terms of human disease they are negative. Some mutations are quite small (a change in a single base pair) but others are quite large, removing or adding entire chromosomes or portions of chromosomes. Scientists have been interested in the field of genetics for quite some time and have long utilized animal models to assist in understanding the genetic code and how human disease works. Some of the most important animal models include mice, rats, zebra fish and primates. The genetic code of many organisms is quite similar so by understanding how the code works in an animal model we can make fairly accurate hypotheses about how the code works in humans, allowing us to develop treatments, medications and detection methods for disease. The primary detection method for diseases controlled by genetics (genetic conditions) is genetic testing. In 1990, an international, cooperative project was undertaken to sequence the entire genetic code of humans (The Human Genome Project). This means all of the A’s, T’s, C’s, and G’s in human DNA was sequenced in its entirety. The project was completed in 2003, ahead of schedule and under budget. The results of this project were made available online to allow further collaboration throughout (NIH, 2013). As stated previously, the Human Genome Project (HGP) triggered a
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wave of genetic research and a multitude of discoveries. There are now over 1800 genes that have been studied and found to play a contributing role (or causal role) in the development of human disease, and over 2000 genetic tests have been developed to detect these conditions and others.

Genetic testing involves taking a sample of DNA, typically through a blood draw, and sequencing a portion of the genetic code that we are most interested in or feel that may play a contributing role to a disease that a patient has presented with. Genetic testing can look at large areas of DNA (like all of the basic chromosome structures) or very small areas (like a few base pairs in a single gene). Genetic conditions can affect very large or very small areas of DNA. Due in part to the HGP we now know what mutations or changes in the genetic code can cause some genetic conditions. Genetic testing can now be done for a variety of conditions in a variety of areas and patients have begun to seek out information about genetic conditions and ordering genetic testing (Norrgard, 2008). There is a huge variety of genetic testing that can be done for a variety of reasons. Some of these types of genetic testing include: carrier testing, diagnostic testing, prenatal testing, newborn screening, late-onset disease testing (determining risk for presymptomatic individuals), pharmacogenomic testing, preimplantation testing and forensic testing (Genetic Home Reference, 2008; Norrgard, 2008). Carrier testing is for individuals who do not have a genetic condition but may have a family history of a particular condition they could pass on to their children. Diagnostic testing determines the presence of a genetic condition (diagnose). Prenatal testing is done on developing fetuses to determine their genetic makeup and the possible presence of disease. Newborn screening is done postnatal for a variety of genetic conditions. Late-onset testing is for diseases that occur later in life but have at least a partial genetic basis. An example would be testing for breast cancer risks (BRCA 1 and 2 testing) or
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testing for Huntington’s disease which is a late-onset genetic condition. Pharmacogenomic testing can provide information about how a person may process a specific medication, allowing us to make personalized dosages or prescriptions. Preimplantation testing is done on a fertilized egg before it is placed back in the mother’s womb for development. Eggs and sperm from the mother and father can be combined and then resulting fertilizations can be tested for a specific genetic condition. Only fertilized eggs not affected by the genetic condition would be placed inside the mother for development. Forensic (or identity) testing can be for determining identity, paternity or making decisive conclusions in a criminal case (Genetic Home Reference, 2008; Norrgard, 2008). The amount of time necessary for the return of results varies on the depth and complexity of the testing, but anywhere from a few days to several months is normal.

Genetic conditions are often multifaceted and affect multiple areas of life. For example, genetic conditions like 22Q11.2 (a small chromosomal deletion on chromosome 22) can cause heart defects, cleft palate, immune deficiency, seizures, feeding problems, developmental delay and heightened risk of mental illness just to name a few (Genetic Home Reference, 2013). Several mental health issues like bipolar disorder have also been found to have an at least partial genetic basis. Genetic conditions can have a large range of severity as well, with some individuals having limited normal everyday function while others can have cases that go undetected for years. The multitude of symptoms also causes an overlap of multiple disorders/problems. If some symptoms have not presented themselves yet health care professionals may only focus on a small set of problems and miss the fact that there is a larger genetic condition at the root of the cause. With genetic testing we can diagnose earlier and prepare for the future. It is not too surprising to note that most genetic conditions require a whole team of health care professionals to assist families and patients throughout development.
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Genetic testing can provide much information about a person and family’s health. This information does not come without a price though. Genetic conditions can be life threatening or permanently alter how someone lives their life. A positive diagnosis or positive risk factor can be heartbreaking not only for the patient, but also for the family at large as genetic conditions can run in families, affecting carrier status and the health of future children. Because of these considerations and the fact that genetic information can often be complex or difficult to understand, genetic counseling has blossomed as a profession. According to the National Society of Genetic Counselors [NSGC], “genetic counseling is the process of helping people understand and adapt to the medical, psychological, and familial implications of genetic contributions to disease” (nsgc.org). The definition of genetic counseling has changed many times over the years, according to Charles J. Epstein in the foreword of a book by Seymour Kessler (published in 1979), “the principal purpose of genetic counseling is the prevention of genetically determined disorders. This is usually accomplished by the provision of information concerning risks of occurrence or recurrence” (Epstein, 1979). Clearly, these two definitions are quite different.

Overtime there has been a shift in focus from preventing disease to understanding and adapting to it. Genetic counseling at its core is helping patients and families to cope and make decisions. According to Kessler, “the basic processes on which genetic counseling rests, namely, communication and decision making, are both psychological in nature” (Kessler, 1979). Therefore, genetic counseling is like a blending of psychology and genetics. Genetic counselors help assess medical and family histories to determine risk of disease occurrence and reoccurrence, educate about genetic testing, inheritance, resources, and disease management and prevention, and counsel to facilitate informed decisions and adaptation to conditions (NSGC, 1983). Genetic counselors occupy a unique position in the healthcare field in that they have a
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strong background in genetics but are also training in the field of psychology and counseling patients. They are able to assist both patients and other healthcare professionals. According to Markens (2013), “genetic counselors constitute a key new profession situated between the ascendant complex genetic knowledge and the lay public, patients, and other medical professionals. In this sense, they occupy a space for ‘meso-level’ analysis, as they traverse between the formal knowledge arena and the situational practice arena” (Markens, 2013). The position of genetic counseling is great for the arena of genetic testing as well. Genetic testing without counseling can lead to many problems including emotional distress, inaccurate information/interpretation and inappropriate responses to information generated by testing. According to Arribas-Ayllon, Sarangi, and Clarke (2011), “by ‘genetic testing’, we do not mean simply the application of a laboratory process to a biological sample…we use the phrase ‘genetic testing’ to encompass not only the application of an ‘assay’…but also the interpretation of the laboratory findings within the clinical context, i.e., via genetic counselling” (Arribas-Ayllon et al., 2011). It is necessary that genetic testing be accompanied by genetic counseling to ensure proper interpretation of results that allows room for support, questions and counseling when needed. There is reason to worry that genetic testing and its interpretation could be done incorrectly and create problems. According to Arribas-Ayllon et al., “Attempts to develop a market for genetic tests of susceptibility to common diseases such as diabetes, cancer, coronary artery disease, hypertension and dementia are likely to gloss over the limited clinical applicability or benefits of such testing and to downplay the appropriate role for genetic counselling” (Arribas-Ayllon et al., 2011). This touches upon the advent of direct to consumer testing, which is genetic testing that can be ordered by consumers (via online or in stores) and
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then results are returned to the consumer directly (with varying levels of clinical interpretation and no counseling necessary).

Direct to consumer [DTC] testing presents a unique set of challenges to the genetic testing accompanied by genetic counseling paradigm. DTC testing grants easy access to genetic information to individuals and families, but this comes at a price. DTC testing cuts medical professionals from the process of genetics, which can be alarming considering the complexity of genetics and genetic testing. According to Irick (2012), “the traditional model for disseminating personal biological information depends solely on members of the medical professional. Today, however, the growing trend has been for individuals to make more choices independent of medical providers” (Irick, 2012). The article by Irick, entitled “Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach” is especially interesting because it covers concerns of both DTC testing and GINA. For instance, the article begins with the story of a woman who convinces her doctor to remove her ovaries based on a DTC test indicating that she may be at risk for ovarian cancer. The problem with this is that the test cannot say with certainty she will get cancer, only that there is a slight risk (Irick, 2012). This mishap shows a deficit in the explanation of results that were returned to the consumer. According to Irick, these kind of issues are not uncommon in the DTC testing industry, considering that the arena is “largely unregulated”, many large DTC testing companies (like 23andMe, deCODE Genetics, and 15 others) were sent warning letters by the FDA, and 23andMe announced a mix-up of 96 customer results in June 2010 (Irick, 2012). The FDA sent warning letters to DTC testing companies saying that their genetic tests are medical devices and therefore must be regulated by the FDA after Walgreens partnering with Pathway Genomics announced they would sell do-it-yourself genetic tests over the counter to customers.
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These findings are especially disconcerting for those wishing to enter the medical profession (especially genetic doctors and counselors). As the DTC market expands there will invariably be an inflation of potentially inaccurate information provided to customers and the media in general, which could create a façade of what genetic testing and genetic counseling really are. With information this sensitive, it is best to air on the side of caution to avoid a slew of legal issues. According to Irick, this onslaught may have already begun in the educational and legal sector, “the Government Accountability Office (GAO) conducted an investigation into the practices of some DTC genetic testing companies, and the investigation showed disturbing quality-control issues, inconsistent interpretive standards, and even fraud” (Irick, 2012). In the educational sector the University of California, Berkley launched a program for incoming freshman called, “Bring Your Genes to Cal”, a voluntary genetic testing program that tested genes related to alcohol and lactose metabolism and folate absorption and then would educate students about personalized medicine. Before individualized results could be given though a conflict between supporters and the opposition led to the California Senate Education Committee defended the ability to gather and use student DNA but the California Department of Health of Public Safety stepped in, saying the program constituted medical research and needed to be done in a licensed lab so results were returned in aggregate to all students who participated (Irick, 2012). Clearly, DTC genetic testing has expanded to many areas of life and has already created controversy in some circles. In order to curb so of the privacy issues created by genetic testing (and now DTC genetic testing), GINA was born. GINA seeks to protect individuals’ genetic information to prevent discrimination in the workplace and insurance coverage.

As genetic research and testing become able to answer questions about current and future disease risks, a new concern was raised in the general population. How will this
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Information be kept private and confidential? What if insurance companies find out about risk for a future disease and cancel or refuse my coverage? These questions and many more become viable considerations that necessitated federal legislation. These anxieties are accurately documented by Steck and Eggert (2011), “they fear that health insurers would either refuse to insure them or cancel existing health insurance if they are found to be predisposed to future onset of a genetic disease. Similarly, Americans fear that employers only would retain or hire individuals who are not predisposed to genetic disease” (Steck & Eggert, 2011). In 2008, GINA was finally passed and signed into law by George W. Bush, 13 years after it was first introduced in Congress. Under GINA, insurance companies cannot use genetic information to determine eligibility or cost, insurance companies cannot require or request genetic testing from their insured, employers cannot use any genetic information in regards to making employment decisions (hire, fire, promote, etc.), and employers cannot require, request or buy genetic testing results about individuals and their family members including test results of fetuses or embryos (Steck & Eggert, 2011). All of these are very good protections to have under a federal act. GINA places limitations on both insurance companies and employers. However, there are a few areas in which GINA falls short of full protection. For instance, an individual can still have their insurance canceled after being diagnosed with a disease (like breast cancer) and genetic testing identified the BRCA 1 or 2 mutation implicated in heightened risk for breast cancer (the individual can lose coverage because of the disease, but not because of the testing), insurance companies are not required to offer coverage for any genetic tests or treatment, employers can still request that employees undergo genetic testing, GINA does not prohibit genetic discrimination in disability, long-term care or life insurance, and GINA does not protect those in the military or veterans seeking services through Veteran’s Administration or Indian Health
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Service (Steck & Eggert, 2011). Unfortunately, these shortcomings leave GINA providing incomplete protection to a fair amount of America’s population. In order to fight against genetic discrimination the Coalition for Genetic Fairness was formed. The Coalition for Genetic Fairness is actually a partnership of many different organizations uniting as part of a common goal. They work to educate the public and Congress to fight for increased legislation against genetic discrimination (Steck & Eggert, 2011). Currently, the future of GINA and genetic discrimination risks are unclear. It is still quite easy for insurance companies and employers to get ahold of genetic information in one way or another and what they do with that information cannot be constantly regulated. Many groups and legislators continue to fight for better laws to protect against genetic discrimination but it will take time before real change is enacted. Until then, individuals and their families must tread carefully and be well versed in what GINA can and cannot do.

While genetic information is loosely protected under GINA, there are other obstacles to genetic testing that should be considered. For instance, there are still quite a few genetic conditions that cannot be detected by genetic testing yet. These conditions may simply be too rare or they are affected by many different genes in many different ways, making it difficult to provide accurate risk or diagnosis information. Additionally, some conditions are affected not only by genetic predispositions but also by environmental cues. Throughout development and growth, genes are turned on and off and contact with things in the environment may increase our risks to disease. An example would be carcinogens, which are things in the environment known to cause cancer like smoking, prolonged exposure to UVA and UVB rays, and a variety of organic and inorganic compounds, and many types of radiation. Other environmental cues can be things as simple as life experiences and certain illnesses. The dichotomy between genetic and
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Environmental factors make it difficult to give solid risk information in genetic testing for certain disorders. While some genes may indicate an increased risk for disease, that risk is rarely 100%. Finally, genetic tests are not foolproof. The sensitivity rate of testing is usually very close to perfect but it is not exactly perfect. Therefore, sometimes tests miss things. False negatives can happen (especially when risk is lower than normal but an individual still gets a disease like cancer). Some genetic tests and their results are difficult to translate into treatments as well. Some genetic tests show mutations that we aren’t quite sure what they mean yet. Some disorders are also difficult to care for beyond offering regular screening and the supports they need.

Outside of these obstacles, genetic testing also presents unique ethical considerations.

Some of the major ethical concerns with genetic testing are informed consent, incidental findings and children. Informed consent is the process of explaining to patients what will happen and what we can learn from a genetic test (as well as the risks and benefits) and having the patient sign a form that contains all of the necessary information. Informed consent is just like a liability form to protect healthcare professionals and explain necessary information to patients. Incidental findings are mutations or changes in the genetic code that we may find during a genetic test that are not related to what the actual test is for. If these changes correspond to a known disease or risk we are required to share that information along with the information that was ordered through the test. According to Green and Biesecker (2013), incidental findings are “unexpected positive findings...results of a deliberate search for pathogenic or likely pathogenic alterations in genes that are not apparently relevant to a diagnostic indication for which the sequencing test was ordered” (Green & Biesecker, 2013). It is important to note that in this paper, these incidental findings were deliberately searched for. This article was a list of recommendations made by the American College of Medical Genetics and Genomics (ACMG).
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about reporting incidental findings. The group of doctors and other healthcare professionals that made these recommendations felt that incidental findings were important because they could tell people about diseases that may not have worried about otherwise. They specifically wanted to search for diseases that could have confirmed diagnoses made, disorders where treatments or preventative measures were available, and diseases that would typically be late-onset (Green & Biesecker, 2013). The group making these recommendations developed a list of mutations/disorders they felt should be searched for as incidental findings. These mutations include BRCA 1 and 2 (heightened risk for breast and ovarian cancer), neurofibromatosis type 2 (growth of noncancerous tumors along nerve endings), and several other types of cancer risks and rare disorders. While most of the mutations and disorders on the list of incidental findings are quite rare, they are relatively well-known and can be treated in a way to reduce risks. This list was simply a recommendation but brings some interesting considerations to mind. Should we be searching for other disorders during genetic testing if we know we could prevent or cure those disorders by catching the mutation early? The answer to this question will certainly vary depending on who you ask.

A final ethical consideration of genetic testing is children. Whenever genetic testing is performed on children we must make sure that proper informed consent is obtained from the parents and the child when appropriate. Additionally, only certain kinds of genetic testing are recommended for children. The ACMG and the American Academy of Pediatrics (AAP) published a policy statement on genetic testing in children. According to their statement, “genetic testing is best offered in the context of genetic counseling” (Committee on Bioethics et al., 2013). They feel that diagnostic testing should be offered to children that show symptoms of a genetic condition (consent from parents must always be obtained first), newborn screening
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should be offered to all children, and carrier testing should not be done routinely in minors if it does not present direct benefits to their health in childhood. Additionally in their statement, “The AAP and ACMG advise against school-based testing or screening programs, because the school environment is unlikely to be conducive to voluntary participation, thoughtful consent, privacy, confidentiality, or appropriate counseling about test results” (Committee on Bioethics et al., 2013). This recommendation is of course referring to children that are still minors but does present a stark contrast from the genetic testing asked of all incoming freshman at University of California, Berkley mentioned in the section about DTC testing. The policy statement went on to say that predictive genetic testing may be approved by parents for children at risk of childhood conditions that they are currently asymptomatic for, but predictive testing for adult-onset conditions should typically be deferred until the child is an adult with few exceptions. Finally, the statement mentions adoption, “if a child has a known genetic risk, prospective adoptive parents must be made aware of this possibility” (Committee on Bioethics et al., 2013). They also feel that predictive genetic testing for known risks in the child may also be done to make sure the child is placed with a family willing to handle such challenges. These recommendations tend to make sense in terms of child autonomy and the types of genetic testing. Children cannot make medical decisions for themselves so much of these questions fall to the parents. Ethics can come into play when risks for serious disease are considered though. If a parent learns about a genetic condition their child has (or may develop) do they have to share that information with the child? And if so, when and how? These are some important considerations to think about in terms of genetic testing for children.

As previously demonstrated, genetic testing is much more complicated than a simple yes or no for a disease. Therefore, it is important that when people seek information about
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genetic testing and counseling that all healthcare professionals are able to provide adequate and accurate information. Patients typically do not seek out genetic counselors or doctors on their own right away, and typically rely on referrals from their primary physician or another healthcare professional who recognizes the overlap with genetics and refer them to obtain in-depth information and the appropriate supports (like genetic counseling or genetic testing).

Genetics professionals are not as widespread as one might expect, they are typically located in large cities with large hospitals and/or near colleges that offer advanced genetic degrees. Patients may have to travel many hours to reach the genetic counseling, testing and genetic doctors they need to meet with. Because of these difficulties, it is important that all healthcare professionals feel comfortable and have a satisfactory understanding of genetics, including the genetic basis of disease, genetic testing and genetic counseling. As Badzek, Henaghan, Turner and Monsen point out, “nurses need to recognize that their actions and those of others providing health care based on genomics are of significant concern since a single act may simultaneously benefit one person while harming another” (Badzek, Henaghan, Turner, & Monsen, 2012). Nurses can be certified in genetics but even nurses that are not play an important role in the health care process. Nurses often talk with patients in a less stressful environment from that experienced with doctors but what they say and how they interact is just as important to the patient. When it comes to genetic conditions/testing questions they should answer in a way that will benefit the patient and also provide necessary information if they know it. If the health care professional cannot answer the question effectively, they should have others answer the question or make an appropriate referral. Genetic doctors and counselors are often willing to answer questions by email or telephone as well as in person. All health care professionals need to understand how genetics affects health and other areas of life. According to Badzek et al., “recognizing the complexity of
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translating, interpreting, and delivering genetic information has been identified as a growing need for education and training across disciplines” (Badzek et al., 2012). If standards are put into place regarding educational and professional levels of knowledge for genetics, competency can be measured to a certain level. Nurses are especially important in communicating genetic information.

According to Skirton and Jackson (2013), there is evidence that patients respect the views of knowledgeable nurses when considering genetic tests…In the past, genetic testing was principally the domain of genetic specialists. However, because it is now being performed in many other specialties nurses are increasingly involved in preparing patients for genetic testing and/or supporting them to deal with the results of such tests (Skirton & Jackson, 2013).

As part of this recognition that nurses are important in the process of sharing genetic information, the US has a document known as the Essentials of Genetic and Genomic Nursing to help nurses stay informed. Many sources have highlighted the fact that genetic testing and counseling are things that multiple health care professionals will be involved with. Because this is such an important topic, as part of my Honors project I decided to host a talk about genetic testing, conditions and counseling.

This talk covered much of the topics covered throughout this literature review but in a condensed fashion. This project allowed me to explore an area that is highly relevant to my future career (I plan to pursue a Masters in genetic counseling) and also proved to be highly interesting and informative. The power point slides from my talk are included at the end at Appendix 1. Additionally, to advertise this talk I created fliers that I had approved by the Biological Sciences office and hung around the Life Sciences building. An email with
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information about the talk was also sent to all members of Beta Beta Beta (Honors organization for biology majors), and to pre-medical students under the advisement of Dr. Lee Meserve. Dr. Coombs, one of my advisors also emailed students completing research under her direction (I am one such student). Appendix 2 is one of the fliers I posted around the Life Science building. Finally, all attendees at the talk received a print out of the slides so they could refer back to them in the future. Appendix 3 is a copy of that print out. This talk was very important to me because I wanted to inform future health care professionals about the role genetics will play in their careers. Even if they have no intention of being a genetic counselor, it will still be important for them to have a basic understanding of genetics and genetic testing. As policies stand now, there is still much work to be done in the way of educating health care professionals about genetics. I want to help make a contribution, however minor it may be, to that cause. Genetics touch so many areas of our lives, and its significance will only continue to grow as research makes compelling discoveries on a regular basis.
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