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THE GROWTH OF DIRECT-TO-CONSUMER GENETIC TESTING AND ITS VALUE IN DISCOVERY

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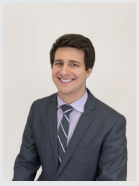

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I. Introduction

Genetic testing and the industries surrounding it are set to continue their enormous growth in the coming decade. Since the completion of the Human Genome Project in 2003, an international effort which mapped all of the genes of the human genome, scientists have continued to improve the speed and reduce the expense of decoding the genome, all the while making the results gleaned from decoding more informative and valuable. *See* National Human Genome Research Institute, *An Overview of the Human Genome Project*, available at http://www.genome.gov/12011238. Naturally, as genetic testing has made its way from a futuristic luxury good to a direct-to-consumer package costing approximately two hundred dollars ($200.00), defense counsel must begin to consider employing genetic testing in personal injury cases.

The genome is the code which makes up every single plaintiff against whom you defend and provides a bundle of invaluable medical information about a plaintiff. In fact, the genome may be the most accurate and specific medical information available. In any given case, genetic testing results may prove to be more valuable than traditional medical records or independent examinations. The genetic code can help unlock a plaintiff's pre-existing conditions, alternative sources for alleged injuries, and possibility of life-threatening diseases which could drastically affect and/or reduce quality-of-life and life expectancy. This article advocates for defense counsel in personal injury cases, and especially medical liability matters, to begin seeking discovery on a plaintiff's genetic code in an effort to provide causation defenses and reduce damages.

II. Genetics And Direct-To-Consumer Testing

Deoxyribonucleic Acid ("DNA"), a molecular substance that resides in the nucleus of every living cell, is the building block of life. DNA is structured as a twisted double helix, like two ladders twisting upwards beside each other. Between these twisting ladders rest nucleotides which are composed of one or more phosphate groups and a nitrogen-containing base attached to a five-carbon sugar. The sugar is deoxyribose, and the base may be either adenine ("A"), thymine ("T"), cytosine ("C"), and guanine ("G"). *See* Alberts B, Johnson A, Lewis J, et al., *Molecular Biology of the Cell*, 4th ed., New York: Garland Science (2002) (The Structure and Function of DNA), available at https://www.ncbi.nlm.nih.gov/books/NBK26821//. Nucleotide base pairs in DNA make up the code for life. These pairs, in short, are what makes every tree, reptile, flower, dog, and human. In humans, the genomic sequence is about three billion nucleotide base pairs long. The majority of these nucleotide base pairs have been linked to no particular function, and humans share about ninety-nine and 9/10ths percent (99.9%) of their nucleotide base pairs with each other. It is the few differences in the nucleotide base pairs that make every person unique.

Although the science behind analyzing DNA is far too complex for this article, there are two different variants of genetic results that the law can focus on:

- The first type of variant is the most useful, as it provides a simple "yes/no" output. These "monogenic" disorders are caused by a single gene "mistake." For example, a "T" may be where a "G" should be, and this genetic error can be linked directly to a disease or disorder. Monogenic disorders have been linked to many diseases, including cystic fibrosis and muscular dystrophies.

- The second type of variant is a more complicated, "multifactorial" or "polygenic" disease. Certain medical conditions are not controlled directly by one single gene, but may be affected by a number of variants down long stretches of the DNA. Evaluating a number of genes can help provide the likelihood of an individual suffering from certain medical conditions.

Currently, the primary use for genetic testing is for defendants to show alternative sources for injury.

In the last decade, DNA testing has emerged from the dusty corners of science to television commercials that appeal directly to consumers. There are a number of direct-to-consumer ("DTC") products available to average Americans, and these products offer the analysis of a person's genome for a continually dropping fee. The best known DTC product is a Google (Alphabet) backed product called 23andMe (a play on the number of human chromosomes). The 23andMe service product was launched in 2007 and offers consumers the opportunity to have their genome partially sequenced and analyzed for a variety of medical conditions and novelty markers. In recent years, 23andMe has been providing this genetic testing service with FDA approval.

For about two hundred dollars ($200.00), 23andMe will send a consumer a testing kit with instructions on how to collect and provide a saliva sample for testing. 23andMe analyzes the saliva sample and typically provides two major genetic testing results:

(1) the individual's ancestry; and

(2) a variety of "health" genetic marker results.

These "health" results are broken into four major sections:

- First, 23andMe provides the consumer with "Genetic Health Risk Reports," which include tests for monogenic variations that are known to cause diseases, such as Parkinson's Disease and late-onset Alzheimer's Disease.

- Second, 23andMe provides "Wellness Reports," which provide results for certain factors such as how a person responds to caffeine, lactose intolerance, or genetic predisposition for weight.

- Third, 23andMe provides some "novelty" results for "traits," such as whether the individual consumer is predisposed to have a unibrow, earwax type, eye color, hair curliness, and other non-medical traits.

- Finally, 23andMe informs the individual if he/ she is a carrier for a number of diseases, such as cystic fibrosis and sickle cell anemia, and thus has an increased risk of passing the disease to a child.

III. Discovery And Genetics

It does not take any stretch of the imagination to see why the new wave of DTC genetic testing may be valuable to personal injury defense counsel. Imagine a scenario where you are defending a physician in a personal injury death case in which the decedent died during surgery and the decedent's heirs claim the death was due to the surgeon's negligence. Further, suppose that the decedent was only thirty (30) years old and likely to continue as a high-income earner in the growing tech-field earning about $5,000,000 in his lifetime. What if the decedent had undergone DTC genetic testing via an FDA approved genome sequencing product which revealed that he tested positive for PI*Z and PI*S variants in the SERPINA1 gene causing Alpha-1 antitrypsin deficiency, a deficiency which can cause, among other things, liver and lung disease and greatly reduce life expectancy? Armed with knowledge of a diminished life expectancy, defense counsel may confidently argue for a much lower economic award. In addition to the possibility of cutting short loss of future earnings capacity, identifying genetic defects which reduce life expectancy may also support a reduction of other alleged damages, such as an alleged lifetime of pain and suffering and/or alleged damages on behalf of survivors.

Currently, the primary use for genetic information is for defendants to show alternative sources for an injury. For example, in cases where an infant is found to have certain neurological defects, the defense has sought to

argue that these neurological defects were not caused by any physician's negligence, but by genetic factors. *See e.g.*, *Vanslembrouck v. Halperin*, 2014 Mich. App. LEXIS 2089, 2014 WL 5462596 (Mich.Ct.App. 2014) (unpublished opinion)(In this medical malpractice case, defense experts opined that a genetic condition, not traumatic birth injuries, caused the plaintiff's debilitating neurological condition.); *Fisher v. Winding Waters Clinic*, 2017 U.S. Dist. LEXIS 19691, 2017 WL 574383 (D.Or. Feb. 13, 2017)(Defendants sought to compel genetic testing, including conducting nearly entire genome sequencing, to show plaintiff-infant's developmental delays were related to a genetic condition, not due to hypoxic-ischemic brain damage. The Court denied the motion on the grounds that Defendants failed to meet their burden of establishing (a) that the requested genetic testing would provide "in controversy" genetic information, and (b) the requisite "good cause.")

How does defense counsel get this genetic information? There are two potential methods that defense counsel should consider for obtaining a plaintiff's DNA information. The first, and most obvious, method is to simply submit a discovery request asking if plaintiff has undergone prior genetic testing. Alternatively, defense counsel may seek a court order compelling genetic testing for good cause. As this article focuses on the growing wave of DTC genetic testing, it will not detail the complicated matter of seeking a Rule 35 examination to obtain genetic testing; however, this is a worthwhile issue to consider in some cases.

In the context of civil tort hypotheticals where defendant sought to admit genetic testing in order to establish a causation defense, the majority of state and federal judges reported they would compel the testing. However, the majority of judges also reported they would not admit genetic testing to show shortened life expectancy in the damages phase of the case.

IV. Obtaining Existing Genetic Testing

While genetic testing is growing, the reality is that, as of today, most people have never been tested. However, the frequency of DTC genetic tests is growing and, going forward, discovery of this information will reap benefits to the defense. It is a question well worth asking in written discovery in cases where genetic information may show alternative causes for a disease or where life expectancy is a major issue.

If a plaintiff has previously undergone genetic testing, obtaining the genetic information should not be problematic. The information is reasonably calculated to lead to the discovery of admissible evidence. If confronted with resistance from opposing counsel, it is suggested that existing genetic results be postured as medical records. In essence, the genetic information is not significantly different from other medical information gleaned from plaintiff's medical records in a personal injury case. No plaintiff's counsel can argue in good faith that medical records are not discoverable.

This article also advocates for seeking ancestry-related genetic testing. 23andMe, Ancestry.com, and other products are available and show an individual what percentage of their genetic code is attributed to a particular type of ancestry. Though a fairly novel consideration, ancestry-related genetic information may complicate the process for providing race-specialized life expectancy tables by economists to the jury. Consider a descendant-plaintiff who physically appears and considers himself/herself of Asian descent (with a historically high life expectancy), but his/her genetics show that he/she is approximately fifty percent (50%) of African descent (with a historically low life expectancy). As individuals continue to learn about the mosaic of their ancestry, the race-based life expectancy tables may become murky and altogether useless in civil litigation.

V. Court Considerations And Admissibility Issues

Judges have had little opportunity to consider genetic evidence in civil litigation. In 2007, the University of Maryland set out to poll judges on how they consider, or would consider and evaluate, genetic evidence. Hoffman, Diane E. and Rothenberg, Karen H., *Article: Judging Genes: Implications Of The Second Generation Of Genetic Tests In The Courtroom*, 66 Md.L.Rev. 858 (2007). In this study, the authors surveyed Maryland state court and federal court judges. The study's results are based upon a response rate of one hundred and one (out of one hundred and forty) Maryland circuit court judges and sixteen (out of twenty-five) of Maryland's federal district court judges. Many judges had dealt with DNA testing for identification in the criminal context. However, only seven of the state court judges reported receiving a request to compel and only two of the state court judges had ever received a request to admit genetic testing for the purpose of identifying a genetic disease or predisposition. None of the federal court judges had received a request to compel or admit genetic testing in the context of determining health status. *Id*.

As a part of the survey, Maryland judges were given different hypothetical scenarios and asked if they would compel a test or admit existing tests, and if not, identify the factors that influenced the decision to reject the request. *Id.* at 873. Responses varied depending on the case context (criminal or civil case) and issue for which the evidence was being offered. In the context of civil tort hypotheticals where defendant sought to admit genetic testing in order to establish a causation defense, the majority of state and federal judges reported they would compel the testing. However, the majority of judges also reported they would not admit genetic testing to show shortened life expectancy in the damages phase of the case. Judges indicated that admitting genetic tests for life expectancy purposes only may be unfair to the plaintiff, effectively punishing an individual for his/her genetic lot in life. The survey results also showed that, as a general rule, judges were more hesitant to compel a test than to admit an already performed test. In addition to the "good cause" requirement under Rule 35, judges voiced concerns about forcing a plaintiff to undergo genetic testing to reveal potential unknown diseases against their wishes, possibly causing psychological harm. *Id*. at 880-883.

Skilled plaintiff's lawyers will undoubtedly come up with crafty arguments (both general and case specific arguments) opposing the admissibility of genetic information. Plaintiff's counsel may attack admission of genetic testing evidence on the grounds that making the information public may lead to ridicule and discrimination if the plaintiff does, in fact, have a genetic defect. In rebuttal to this particular point of attack, defense counsel should be aware of the Genetic Information Nondiscrimination Act of 2008, 122 Stat. 881, 110 P.L. 223 (enacted May 21, 2008), which makes discrimination based on genetic information illegal with respect to health insurance and employment. Plaintiff's counsel may also claim that genetic testing is "unreliable" or "novel." In response, defense counsel should emphasize that DTC testing is subject to FDA requirements and that DNA is frequently used for identification purposes in criminal trials where the stakes are an individual's liberty.

Addressing any resistance from courts or plaintiff's counsel in admitting genetic testing results should include equity-focused arguments. The tort system demands that we reach the most equitable result possible, regardless of the defendant's actions in any given case. If a plaintiff is predisposed to a short life or has a clear alternative cause for his injury or disease, it is inequitable to provide plaintiff a windfall by awarding damages in excess of the likely harm.

VI. Practice Pointers And Conclusion

Genetic information may not be useful in every case, so it is not necessary to add a genetic information request to every set of propounded discovery. It is important to consider when it is appropriate to seek this information. Discovery requests, including interrogatories and requests for production, should be broad and ask whether the plaintiff has ever undergone any genetic testing and, if so, where, when, and what were the testing results. Discovery requests should also seek both health and ancestry information. If plaintiff's counsel voices opposition during the discovery phase, defense counsel should emphasize that seeking genetic information is no different than seeking medical records. If plaintiff's counsel raises objections in the trial phase of the case, defense counsel should emphasize that the requested genetic testing information will only provide a more equitable result, as desired by our tort system. If you decide to seek discovery or compel disclosure of plaintiff's genetic testing information, case law primarily from the 1990's on HIV/AIDS, where defendants sought to compel blood tests to establish life-expectancy for individuals believed to carry this disease, may be instructive.

DTC genetic testing will continue to grow and, sooner than later, defense counsel will encounter a plaintiff who has undergone this type of testing. The results of these genetic tests can provide valuable information to diminish the value of a plaintiff's case, or even dispose of it altogether.