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**Cases of Harm Involving Genetic Counseling Situations**

This document highlights instances of harm to consumers. Several of these cases have been documented in the literature or involve formal litigation. The examples illustrate the different types of harm that inadequate genetic counseling can cause including medical, economic, and psychological harm.

Many of the cases below are condensed for busy legislators and other stakeholders, but additional details are available upon request.  In addition to the cases of harm below, it is important for you to **collect cases of harm from your state.** Provide a brief description of the case and the harm to the patients, including whether the harm was the result of inadequate genetic counseling by a genetic counselor (licensed or non-licensed) or another medical profession.

Cases of harm committed by non-genetic counselors are common and illustrate the importance of having qualified practitioners provide genetic counseling services. Many of the peer-reviewed references below discuss such cases. It is equally important to include cases of harm that involve genetic counselors because genetic counselor licensure laws will not directly reduce the harm to patients that other medical providers practicing within their scope of practice cause.

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**Cases Involving Harm by Genetic Counselors**

* A woman was awarded $800,000 because she developed breast cancer after her genetic counselor failed to offer her an appropriate hereditary cancer genetic test.
* A woman was given a false negative result for an adult-onset neurological syndrome because the genetic counselor failed to follow proper testing procedures.
* A woman whose child was born with a limb defect after being consented for an invasive prenatal procedure by a genetic counselor but was not informed of the risk of limb defects.
* A couple was awarded a $7 million settlement because they were not offered amniocentesis due to the mother's advanced maternal age and their child was then born with a chromosomal abnormality.
* A couple conceived a child based on their inaccurate risk-assessment with a genetic counselor and the child was subsequently born with the hereditary skeletal dysplasia present in the family.
* A couple’s genetic counselor provided them with a false negative test result for Tay-Sachs and their child was born with Tay-Sachs disease.
* A Virginia woman’s whose genetic counselor gave her a false positive test result that the laboratory classified underwent an unnecessary colonoscopy and was recommended to have prophylactic colectomy before the counselor did standard-of-care research and learned of the incorrect classification.

**Cases Involving Harm by Inadequate Genetic Counseling Nationwide**

* A woman was diagnosed with breast cancer after a physician informed her that her paternal family history of breast cancer was not relevant. She was later found to carry a mutation in a breast cancer-causing gene.
* A woman’s physician declined to refer her for genetic counseling multiple times after she was diagnosed with early-onset breast cancer, despite her family history and ethnic risk factors. She was later found to have a BRCA1 mutation and died of ovarian cancer.
* A woman with a family history of Duchenne muscular dystrophy (DMD) who was never offered genetic counseling or diagnostic procedures terminated her pregnancy after assuming her male fetus was affected with DMD.
* A couple was never offered carrier screening despite the high chance that they were both carriers and their child was born with Tay-Sachs disease.
* A couple had a second child with polycystic kidney disease after being informed that their first affected child did not have a hereditary condition and their recurrence risk was practically zero.
* A couple was emotionally and financially drained after 10 years of infertility treatments, when their infertility was caused by a genetic rearrangement that would have been found if the couple had received a standard family history assessment and chromosome analysis.
* A couple was not offered maternal serum screening during pregnancy and their fetus was diagnosed at 38 weeks with Trisomy 18, giving this couple little time to prepare for the inevitable loss of their child.

**Cases of Harm Involving a Genetic Counselor that Resulted in Legal Action**

* 42 S.W.3d 16 (Missouri. 2001): The parents of a son born with spondyloepiphyseal dysplasia tarda, “SEDT”, took their medical team, including a genetic counselor, to court on the grounds of fraudulent misrepresentation. The wife had two relatives with SEDT and the couple wanted to know the risk to their pregnancy. The parents claim the report that they received assessed their risk lower than their actual risk. They conceived a child based on their risk assessment with the genetic counselor.
* Curlender v. Bio-Science Laboratories Medical Malpractice: Negligence—Wrongful Birth Court of Appeals of California 1980 (case), 1977 (failure to diagnose): Genetic counselors gave parents of the plaintiff (child with Tay Sachs disease) a false negative test result for Tay-Sachs. The court held that the child and the parents could recover the costs of the child's medical expenses and that the child could recover damages for her pain and suffering.
* A genetic counselor was the defendant in a case that resulted in an $800,000 settlement. The patient had undergone genetic testing for a hereditary cancer syndrome. The genetic counselor failed to recommend additional follow-up testing for the patient, and the patient subsequently developed breast cancer.
* A genetic counselor was a defendant in a malpractice lawsuit that resulted in a $7 million settlement. A couple claimed that they did not receive proper prenatal genetic counseling before having their baby. As a result, their child was born with a genetic syndrome referred to as “Cri-du-chat,” which results in severe mental and physical disabilities.
* The hospital employing a genetic counselor was sued by patients who claimed inadequate pre-test genetic counseling. During the procedural consent process for a diagnostic prenatal procedure, an unlicensed genetic counselor reportedly did not inform a pregnant patient of the risks of limb defects. The baby was born with a transverse limb defect.

**Peer-Reviewed Articles Addressing Harm**

* Annes JP, Giovanni MA, Murray MF. Risks of presymptomatic direct-to-consumer genetic testing. N Engl J Med. 2010 Sep 16;363(12):1100-1.
* Bensend TA, Veach PM, Niendorf KB.  What's the harm? Genetic counselor perceptions of adverse effects of genetics service provision by non-genetics professionals. J Genet Couns. 2014 Feb;23(1):48-63. doi: 10.1007/s10897-013-9605-3. Epub 2013 Jun 12.
* Brierley KL, Blouch E, Cogswell W, Homer JP, Pencarinha D, Stanislaw CL, Matloff ET. Adverse events in cancer genetic testing: medical, ethical, legal, and financial implications. Cancer J. 2012 Jul-Aug;18(4):303-9.
* Brierley KL, Campfield D, Ducaine W, Dohany L, Donenberg T, Shannon K, Schwartz RC, Matloff ET. Errors in delivery of cancer genetics services: implications for practice. Conn Med. 2010 Aug;74(7):413-23.
* Chitayat D, Langlois S, Wilson RD; Genetics Committee of the Society of Obstetricians and Gynaecologists of Canada; Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists. Prenatal screening for fetal aneuploidy in singleton pregnancies. J Obstet Gynaecol Can. 2011 Jul;33(7):736-50.
* Cohn, Gabriel, et al. The Importance of Genetic Counseling Before Amniocentesis.  Journal of Perinatology. 1996 16:5, p. 352-357.
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* Dickson D. British insurers continue with genetic tests. Nat Med. 1999 Sep;5(9):974.
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* Evans JP, Dale DC, Fomous C. Preparing for a consumer-driven genomic age. N Engl J Med. 2010 Sep 16;363(12):1099-103.
* Geller G, Holtzman NA. Implications of the human genome initiative for the primary care physician. Bioethics. 1991 Oct;5(4):318-25.
* Giardiello, Francis M., et al. The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis.  The New England Journal of Medicine. March 20, 1977 336:12, p. 823-828.
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* Gollust SE, Hull SC, Wilfond BS. Limitations of direct-to-consumer advertising for clinical genetic testing. JAMA. 2002 Oct 9;288(14):1762-7.
* Gollust SE, Wilfond BS, Hull SC. Direct-to-consumer sales of genetic services on the Internet. Genet Med. 2003 Jul-Aug;5(4):332-7.
* Lynch HT, Paulson J, Severin M, Lynch J, Lynch P. Failure to diagnose hereditary colorectal cancer and its medicolegal implications: a hereditary nonpolyposis colorectal cancer case. Dis Colon Rectum. 1999 Jan;42(1):31-5.

**Web Links to Articles Discussing Harm from Inadequate Genetic Counseling**

* Fumbled DNA tests add risk for victims.  By Robert Langreth, Washington Post, Herald-Tribune, Bloomberg News, October 4, 2012. Retrieved 5.18.14

<http://health.heraldtribune.com/2012/10/04/fumbled-dna-tests-put-victims-at-risk/>

* When Genetic Testing Can Be Dangerous to Your Health.  By Cheryl P. Weinstock, Oprah.com. Mar. 2013. Retrieved 5.18.14 <http://www.oprah.com/health/Genetic-Testing-Dangers-DNA-Research-Breakthroughs/>