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THE EVOLUTION AND PRACTICAL APPLICATION OF GENETIC TESTING

BY TERESA FARISS MCCLAIN



Genetic testing had its origins in the 1950s when scientists discovered that an additional copy of chromosome 21 causes Trisomy 21, also known as Down syndrome. Methods for staining chromosomes were used to sort and count chromosomes, a process called karyotyping. That process, combined with the ability to collect fetal cells from a pregnant woman's amniotic fluid, provided scientists the ability to conduct genetic prenatal screening. Such testing revealed DNA-based diagnoses of genetic disorders caused by biologic irregularities such as too many chromosomes, too few, or clusters of chromosomes in the wrong places. As genetic testing became widespread, scientists began researching the substance of DNA, the chemical structure deciphered in 1953 by Rosalind Franklin, James Watson, and Francis Crick. Over the next several decades, it was discovered that helix-shaped patterns of paired chemical bases — adenine, thymine, cytosine, and guanine — provided a code that cells would decode into amino acids, the building blocks of protein. Scientists also discovered through research into the human genome that approximately 98% of DNA doesn't actually code for proteins, and was seen as "junk DNA."

APPLICATION IN OBSTETRICS

As science around genetics developed, the application and use in obstetrics medicine also expanded. Many diseases that affect humans have a genetic component. Some disorders are passed from parents to their children at conception. A change in DNA sequence away from the normal sequence can result in a genetic disorder. Such genetic disorders can arise through mutation in one gene (monogenic disorder), mutations in multiple genes (multifactorial inheritance disorder), a combination of gene mutations and environmental factors, or by damage to chromosomes (changes in the number or structure of entire chromosomes, the structures that carry genes).

Advances in genetic mapping and technology have increased the accessibility and affordability of preconception carrier screening for couples considering pregnancy. Given the advanced reproductive technologies now available, preconception carrier screening allows a woman and her reproductive partner to make informed reproductive decisions.

Systemic genetic screening has been available in the United States since the 1960s, when Dr. Robert Guthrie developed the newborn screening test for phenylketonuria, a metabolic disorder also known as PKU. Since 1964, the Minnesota Department of Health has coordinated the screening of all newborns for more than 50 inherited or congenital disorders via a blood draw between 24 and 48 hours of birth. In 2010, the Recommended Uniform Screening Panel (RUSP) was adopted as a national standard for newborn screening, consisting of five main categories: (1) hemoglobinopathies, (2) organic acid disorders, (3) amino acid disorders, (4) fatty acid oxidation disorders, and (5) miscellaneous disorders, such as cystic fibrosis and hypothyroidism. The newborn screening program is the largest genetic screening program, with approximately 4 million infants tested annually. While the advances in newborn genetic screening programs have improved the detection and early intervention for treatable genetic conditions, newborn testing cannot replace preconception or early prenatal carrier screening of the parents.

Beginning in 2017, obstetricians were advised to expand genetic screening offerings to their patients. Two committee opinions from the American College of Obstetricians and Gynecologists (ACOG), published in the March 2017 issue of *Obstetrics & Gynecology*, expanded guidelines on carrier screening for genetic disorders. These committee opinions were issued in response to the availability and affordability of expanded genetic testing that could screen for hundreds of conditions in one test, as well as in response to dilution of ethnic population concentrations that had previously guided genetic screening recommendations. ACOG Committee Opinion 690, "Carrier Screening in the Age of Genomic Medicine," includes general guidelines; and Committee Opinion 691, "Carrier Screening for Genetic Conditions," addresses testing for specific diseases.

The committee opinions distinguish three scopes of genetic screening:

- ethnic-specific, such as for Tay-Sachs disease among people of Ashkenazi Jewish descent;
- panethnic (for everyone), such as a test for cystic fibrosis, spinal muscular atrophy, and fragile X syndrome offered to all patients; and
- expanded carrier screening, which analyzes up to hundreds of conditions.

The general recommendation advises individual health care providers to "establish a standard approach" they offer consistently to patients, including counseling and informed consent. Counseling should include discussion of "residual risk" resulting from de novo mutations and mutations not included in test panels. At a minimum, the committee opinions advised that all patients should be offered screening for cystic fibrosis, spinal muscular atrophy, and hemoglobinopathies, because these are the more common recessive inherited conditions.

Advances in genetic science has led to the availability of preconception screening, offering couples seeking to become pregnant the opportunity to test for genetic changes that have little or no impact on their own health but can cause significant health problems for their children. ACOG defines carrier screening as "genetic testing performed on an asymptomatic individual to determine whether that person has a mutation or abnormal allele within a gene that is associated with a particular disorder." Genetic changes carried by both partners can cause a health condition if both copies of the genetic change are inherited by a child. These are known as autosomal recessive conditions. Genetic changes that are carried by the female partner and cause a health condition when a male child inherits the genetic change are known as X-linked conditions.

Carrier testing is particularly valuable for consanguineous couples, whose offspring are at elevated risk of inheriting recessive mutations from shared ancestors. Prenatal carrier testing provides information for diagnostic testing of the fetus or newborn, for termination, or for arranging care.

Ideally, carrier screening should occur prior to pregnancy. If both partners are carriers for the same genetic condition, genetic counselling is recommended to help couples understand the meaning of the test results and the available reproductive options, such as in vitro fertilization (IVF) with prenatal diagnosis and preimplantation genetic testing of embryos, or the use of donor gametes.

Current guidelines by ACOG are that women's health care providers offer carrier screening to all individuals who express an interest in becoming pregnant, regardless of ethnicity or family history. Recent progress in genetic testing technology with next-generation sequencing makes expanded carrier screening readily accessible for most couples. Where couples present themselves for preconception health evaluations, a provider has a duty to inform of the availability and offer carrier screening. When genetic screening isn't offered to individuals seeking preconception evaluation, it is a deviation from accepted standards of care and could give rise under certain circumstances to a claim for wrongful conception.

With the added scientific knowledge gained through the National Institutes of Health Human Genome Project and spin-off research, we can expect to see continual expansion in applications for genetic science.

MASS TORT, MEDICAL MALPRACTICE, PERSONAL INJURY, AND CIVIL RIGHTS GROUPS WELCOME SIX NEW ATTORNEYS

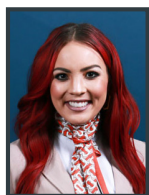
Since 2020, the Mass Tort, Medical Malpractice, Personal Injury, and Civil Rights practice groups at Robins Kaplan have added six new attorneys. The breadth of talent and experience these attorneys bring to the firm is truly exceptional. Their experience and past roles include federal clerkships, a Minnesota Court of Appeals clerkship, a former United States Attorney, working for the British Parliament, serving other Minnesota firms in the areas of employment and personal injury, and more.

“We are thrilled with the addition of this talented group of attorneys,” said Holly Dolejsi, deputy practice group leader for associate development. “Each brings their unique perspectives and experience to the group, and we expect great things from this next generation of lawyers in the firm.”

“Robins Kaplan is always looking to push the envelope, and this dynamic group of lawyers will do just that,” added Peter Schmit, chair of the National Personal Injury and Medical Malpractice Group.



RASHANDA BRUCE is part of Robins Kaplan’s Mass Tort and Personal Injury practice groups. Prior to joining the firm, she worked in the Minneapolis office of a national law firm. She was also a judicial extern for the Honorable Kate Menendez and the Honorable Sara Grewing. Rashanda has coached cheerleading for over 15 years and currently serves as the program director and head cheerleading coach for the Apple Valley Elementary and Middle School teams, where she instills and builds confidence in young girls. She is also a co-founder of LOCUS, a meeting ground that provides space and opportunities for authentic community building, identity-driven leadership, and resource sharing by and for people of color and indigenous peoples.



CASEY MATTHIESEN is the third enrolled member of the Yankton Sioux Tribe in South Dakota to become an attorney. She practices in Robins Kaplan’s Personal Injury, Medical Malpractice and Business Litigation groups. Her law practice focuses on taking difficult medical malpractice, personal injury, and tribal law cases. Casey represented the Standing Rock Sioux Tribe in state court relating to subpoenas issued in response to the Dakota Access Pipeline protests and the Mandan, Hidatsa, and Arikara Nation in federal court on energy extraction litigation. She was recently named president of the Minnesota American Indian Bar Association. Prior to joining Robins Kaplan, Casey worked for a highly regarded South Dakota lobbyist, a member of the House of Commons for the British Parliament, and was a law clerk for the Hennepin County Attorney’s Office.



ESTHER SORIA MIGNANELLI is a former federal prosecutor with experience as both a civil and criminal trial attorney. She focuses her practice on civil rights, health care litigation, and government and internal investigations. Prior to joining Robins Kaplan, Esther was an assistant U.S. attorney in Chicago, where she worked in the criminal division of the U.S. Attorney’s Office. She once orchestrated the charging and arrest of over 20 suspected leaders of the Black Disciples street gang in a single round-up. In her free time, Esther enjoys board games, traveling, and spending time with her family – including her 14-month-old daughter and 12 year-old fur daughter.



CAROLINE MOOS has dedicated her legal career to serving as a fierce advocate for the underdog. In the Mass Tort Practice Group, she represents clients who have been harmed by pharmaceutical drugs and medical devices. Caroline is a graduate of Mitchell Hamline School of Law, where she served as president of the Student Bar Association, editor-in-chief of the Mitchell Hamline Law Journal of Public Policy and Practice, and competed at the National Native American Law Student Association Moot Court Competition. After law school, Caroline clerked for the Honorable Judge Lucinda E. Jesson at the Minnesota Court of Appeals.



MORGAN VOIGHT has dedicated her career to protecting the rights of patients who have been harmed by medical malpractice. Prior to joining Robins Kaplan, she worked for the Matonich Law Firm, assisting with medical malpractice cases while completing her law degree at Mitchell Hamline School of Law, where she graduated summa cum laude in 2019. She also spent six years working as a paralegal at a medical malpractice law firm. Morgan's hobbies include beekeeping, preserving jams, and decorating cookies.



GRETA WIESSNER became a lawyer to fight for justice. In the Civil Rights and Mass Tort practice groups, Greta advocates for those who have been injured or have had their rights violated by police, the prison system, pharmaceutical companies, and more. Greta joined Robins Kaplan following two federal clerkships, one on the U.S. Court of Appeals for the Third Circuit and the other on the U.S. District Court of the Eastern District of Pennsylvania.

"My clerkships were a master class in legal research and writing on cases of all types, in all stages of litigation," Wiessner said. "I also appreciated the insight into judicial decision-making I gained from working so closely with two remarkable legal minds."

MASS TORT INVESTIGATIONS

Robins Kaplan LLP is currently investigating many new potential cases. Please contact our Mass Tort Group if you have any questions or know of any individuals whose case should be evaluated.

ELMIRON: The painful bladder syndrome drug Elmiron updated its labeling to warn that pigmentary changes in the retina have been identified with long-term use of the drug,¹ nearly two years after the journal of the American Academy of Ophthalmology published an article linking Elmiron to pigmentary maculopathy² (which may cause permanent vision changes, such as difficulty reading, slow adjustment to changes in lighting, and blurred vision).

INJECTAFER: This intravenous iron supplement prescribed to patients with iron deficiency anemia has been linked to severe hypophosphatemia — a dangerously low level of phosphorus in the blood that can cause life-threatening complications.

KEYBOARD DUSTING SPRAYS: After huffing keyboard dusting spray, drivers have lost control of their vehicle, resulting in deaths and injuries to innocent bystanders.

PREMATURE HIP IMPLANT FAILURES: Stryker Rejuvenate and Stryker LFIT COCR V40 implants, among others, have been involved in premature hip failure cases the Mass Tort attorneys may litigate.³

TRIBAL OPIOID CLAIMS: The firm is litigating claims on behalf of Native American tribes against the manufacturers and distributors of prescription opioids for their alleged role in creating the opioid epidemic.

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1. U.S. Food and Drug Administration, June 16, 2020 Supplemental Elmiron Package Insert. DRUGS@FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020193s014lbl.pdf.
 2. William A. Pearce et al., Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium. OPTHALMOLOGY. E. Pub. May 22, 2018, available at <https://doi.org/10.1016/j.ophtha.2018.04.026>.
 3. Concerns about Metal-on-Metal Implants, available at www.fda.gov.



CASE RESULTS

\$26.5 MILLION JURY VERDICT AGAINST PERPETRATORS OF HEALTH CARE FRAUD

Health care fraud affects everyone but mostly consumers who ultimately see increased premiums due to health care fraud. Robins Kaplan is on the forefront of holding those who commit health care fraud accountable. Recently Robins Kaplan partners Munir Meghjee and Jeff Gleason represented a client in litigation against defendants who conspired to defraud health care insurers through utilization of a laboratory pass-through billing scheme. Munir, Jeff and their team secured a \$25.6 million jury verdict against the defrauders. The verdict included both compensatory and punitive damages.

\$9 MILLION SETTLEMENT IN PRECONCEPTION NEGLIGENCE CLAIM

Teresa Fariss McClain confidentially settled a wrongful conception claim with a Twin Cities health provider for \$9 million. The claim involved preconception negligence and the subsequent birth of a child with a genetic disorder.

\$2.6 MILLION SETTLEMENT IN DELAY OF DIAGNOSIS CASE OF 72-YEAR-OLD

Teresa Fariss McClain confidentially settled a case on behalf of a 72-year-old married male for \$2.6 million. It involved a delay in diagnosis and treatment of colon cancer by a Twin Cities Clinic, resulting in lowered life expectancy and decreased quality of life.

MINNESOTA SUPREME COURT REVIVES WRONGFUL DEATH CASE OF FOUR-YEAR-OLD BOY AGAINST COUNTY AND CHILD PROTECTION WORKERS

Jason DePauw served as amicus author on behalf of Minnesota Association for Justice in support of the plaintiff's successful bid at the Minnesota Supreme Court to reverse the dismissal of a wrongful death case of four-year-old Eric Dean against child protection workers and the county child protection agency.

\$300,000 SETTLEMENT IN UNDERINSURED MOTORIST CASE

Phil Sieff and Brandon Vaughn negotiated a \$300,000 settlement on behalf of a client who was involved in a motor vehicle crash with an underinsured motorist, resulting in shoulder injuries and traumatic brain injury to our client.

\$300,000 SETTLEMENT IN PERSONAL INJURY CASE RESULTING FROM A DOG BITE

Phil Sieff and Brandon Vaughn negotiated a \$300,000 settlement on behalf of a client who suffered serious injuries to her face and eye after being attacked by a friend's dog.

FAILURE TO DETECT TUMOR CASE

Mark Hallberg confidentially settled a case arising out of a radiologist's failure to detect and report a small bowel tumor. Two months later, the patient developed severe abdominal pain and had a second CT scan which revealed a small bowel tumor with rupture of the bowel. An expert offered an opinion and a detailed report that the two-month delay was significant because the rupture likely spread cancer cells throughout the abdomen, increasing the likelihood of recurrence and a reduced life expectancy.

The Robins Kaplan Civil Rights team, which includes Bob Bennett, Andrew Noel, Katie Bennett, Marc Betinsky, Esther Mignanelli, and Greta Wiessner, have recently secured two important victories on behalf of their clients:

CAROL BUNKER AS TRUSTEE FOR THE NEXT OF KIN IN *STEPHANIE BUNKER V. MEND CORRECTIONAL CARE AND BELTRAMI COUNTY*: \$2.25 MILLION SETTLEMENT AUGUST 2021

Robins Kaplan's civil rights lawyers settled a jail suicide case at mediation with Retired United States Magistrate Judge Arthur J. Boylan. The settlement calls for a \$1.25 million payment from MENd Correctional Care and \$1 million from Beltrami County. Carol Bunker is a lifelong resident of the White Earth Reservation. Her daughter, Stephanie Bunker, committed suicide at the Beltrami County Jail. 42 U.S.C. § 1983 claims were filed against the defendants and some of their employees. Carol asserted that the defendants ignored Stephanie's medical and mental health needs, including suicidality.

MYLES REGENOLD V. TONY HIGGINS: \$550,000 SETTLEMENT AUGUST 2021

The civil rights team also secured a settlement of \$550,000 for a client who was shot in the arm by an Iowa police officer employed by the City of Ankeny. The shooting happened in the middle of the night when Myles was burglarizing a car wash. The shooting itself was not captured on video, but there was some video and audio from the defendant officer's body-worn camera establishing certain critical facts. The case was mediated by Retired United States District Judge Mark Bennett.



**MUNIR
MEGHJEE**



**JEFF
GLEASON**



**TERESA
FARISS
MCCLAIN**



**JASON
DEPAUW**



**PHIL
SIEFF**



**BRANDON
VAUGHN**



**MARK
HALLBERG**



**BOB
BENNETT**



**ANDREW
NOEL**



**KATIE
BENNETT**



**MARC
BETINSKY**



**ESTHER
MIGNANELLI**



**GRETA
WIESSNER**

AWARDS AND RECOGNITION

THREE ROBINS KAPLAN PARTNERS SELECTED TO RECEIVE 2021 MINNESOTA ICON AWARD

K. Craig Wildfang, Teresa Fariss McClain, and Robert Bennett have been selected to receive the 2021 Minnesota ICON award by *Finance & Commerce* and *Minnesota Lawyer*. The award recognizes attorneys or business leaders who have exhibited distinctive excellence that puts them at the top of Minnesota's legal and business communities.

BRANDON VAUGHN RECEIVES MINNESOTA LAWYER'S DIVERSITY AND INCLUSION AWARD

Brandon Vaughn has been selected to receive *Minnesota Lawyer's* 2021 Diversity & Inclusion Award. This award recognizes organizations and individuals who are significantly advancing diversity, inclusion, and justice for all within Minnesota's legal community.

BRENDAN JOHNSON NAMED A LITIGATION TRAILBLAZER BY THE NATIONAL LAW JOURNAL

Brendan Johnson has been recognized as a 2021 Litigation Trailblazer by *The National Law Journal*. This annual list recognizes attorneys who have moved the needle with innovative legal strategies and out-of-the-box thinking that is changing the practice of law.

ROBINS KAPLAN CIVIL RIGHTS PRACTICE GROUP NAMED ELITE TRIAL LAWYERS

Robins Kaplan recently received *The National Law Journal's* 2021 Elite Trial Lawyers Award for Civil Rights. This award recognizes law firms that have provided cutting-edge representation and achieved major wins on behalf of civil rights plaintiffs.

KATE JAYCOX NAMED CHAIR OF THE AMERICAN ASSOCIATION FOR JUSTICE'S WOMEN TRIAL LAWYERS CAUCUS

Kate Jaycox has been appointed chair of the Women Trial Lawyers Caucus (WTLC). This networking group focuses on membership, fundraising, education and public service projects.

CASEY MATTHIESEN ELECTED PRESIDENT OF THE MINNESOTA AMERICAN INDIAN BAR ASSOCIATION

Casey Matthiesen has been elected president of the Minnesota American Indian Bar Association (MAIBA). MAIBA is a nonprofit organization with the mission of promoting unity, cooperation, and the interchange of ideas among persons associated with Indian law.

TRIAL AD POSTPONEMENT

In light of the recent rise in COVID-19 cases, we have unfortunately once again made the difficult decision to postpone our annual Trial Advocacy Seminar. This seminar is a pinnacle event for our firm and the broader plaintiff legal community to come together and share ideas. As we've all found, there are no guarantees about what the world will look like in a year, but we hope to return to an in-person event in 2022. We intend to preserve the purpose and format for our guests.

As we head toward the end of the year, we're reminded how thankful we are for our relationship with you. If we can be of service to you in any way, please reach out to any of our attorneys.

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