The Miracles of Modern Medicine: A Double-Edged Sword for Insurers and Defense Counsel

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The healthcare space is constantly evolving, and as the insurers and counselors to healthcare providers we must do our best to stay abreast of the changes in the space. Genomic medicine, which is the study of a person's genes including the interaction of those genes with each other, is at the forefront of the changing medical space.[1] Healthcare providers are now using genomic medicine, which is the practice of using genomic information about an individual as part of their clinical care[2], in everyday care of their patients. Additionally, there are healthcare related providers and industries that are using tissue and DNA testing and other medical advancements for which insurers are being asked to write medical liability insurance and counsel are being asked to defend lawsuits that challenge the traditional norms of claims and defense handling. What follows is an examination how three branches of the medical liability system, namely claims departments, defense counsel and experts, are adapting to these new scenarios.

A Claims Perspective

Most claims professionals, defense counsel and experts involved in handling medical liability matters, better known as medical malpractice matters, have been in the space for decades and have a wealth of experience and knowledge. They have a knowledge base that includes medical terminology, potential outcomes, and the identities of the most known experts in the space. However, with changes in the healthcare space, the "typical" medical liability claim involving doctors practicing at a facility is becoming less frequent. Instead, those traditional claims have been replaced with all types of healthcare related and sometimes tangential claims.

The landscape of healthcare is being changed and challenged every day with constant advances and new healthcare services being offered. Now, families can test for certain genetic conditions and then try to ensure that any such genetic conditions are not passed down to their children. Additionally, the medical community is coming up with varying and fascinating ways to use almost any donor tissue to help those still living. Providers can also use genetic testing as a diagnostic tool to try and diagnose and help their patients. All of these types of medical treatments are fantastic advancements to our healthcare ecosystem, but they also open up potential liability scenarios that most professionals in the space have never seen before.

The first and most important consideration for a claims professional that is tasked with dealing with such a claim is to figure out exactly what healthcare services the insured offers. As a claims professional, the first knowledge of the claim generally comes from the demand received from a claimant or filed lawsuit and those can be vague as what exactly your insured does as a healthcare provider. It is important to

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[1] National Human Genome Research Institute, https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics

[2] National Human Genome Research Institute, https://www.genome.gov/health/Genomics-and-Medicine#:~:text=Genomic%20medicine%20is%20an%20emerging,implications%20of%20that%20clinical%20use.

review the policy and other underwriting documents to determine exactly what services the insured is providing to its patients/clients and how that falls within the coverage under their medical liability policy. In this ever-changing medical environment, it may be necessary to confirm with the insured the services they offer and your underwriting department that they intended to cover those services. Only once you have confirmed that the services in question were ones that fall with the coverage afforded by their medical liability policy, you can move to determine how to handle the claim.

Once it is confirmed that there is coverage for this type of claim, a claims professional might have to put in extra effort to make sure they secure the appropriate defense counsel. Finding a counsel with experience defending these types of can be difficult but is of the utmost importance. It will likely require extra effort by a claims professional to ask the right questions and perhaps asking around for recommendations of counsel that may have handled this specific type of case in the past. For instance, if the claim includes allegations of wrongful life in a jurisdiction that allows such, retaining a counsel who already is familiar with the statutory provisions that establish such a cause of action, the requirements of the plaintiff to bring such an action, and experts in the field can be of an immediate benefit. Counsel then does not have to spend time becoming acquainted with the nuisances of specific types of claims and applicable laws in the jurisdiction.

The claims professional should then rely on appointed defense counsel and any experts they may retain to help educate themselves on these new and differing types of claims. New and unique types of claims present a challenge for claims professionals to expand their knowledge base and re-imagine the claims and evaluation process.

Defense Counsel's Involvement

As the medical space is ever changing, it can be very difficult for anyone to keep up, much less counsel who is charged with defending medical providers against medical negligence claims. In many cases, they depend on experts to help educate on the theories and standards of care that would be applicable to the allegations that their clients face. As the medicine and technology is ever evolving, there can be no recognized standard or policy. Claims of inappropriate scope of testing can include not testing widely enough in scope or even testing too board and therefore leading to irrelevant or incorrect findings.[3] The challenge of liability falls most immediately on genetic professionals but also as testing evolves liability could attempted to be attributed to generalists.[1]

It can be a daunting task for counsel to quickly develop the knowledge base to develop a strong defense plan for the case and their client when the medical science is so new. Once counsel accepts the defense of a case involving these new types of medical care, they must quickly evaluate the case and determine if it is properly plead and the correct legal theories are being brought by the plaintiff.

A particularly instructive case was just decided in the Appellate Division, First Judicial Department of the Supreme Court of the State of New York. In that case, eggs were retrieved from a patient and fertilized with sperm which resulted in eight viable embryos.[4] Those embryos were then frozen and stored in a healthcare provider's storage tanks in 2008. In 2010, the embryos were retrieved and implantation was

[3] From Genetics to Genomics: Facing the Liability Implications in Clinical Care, The Journal of Law, Medicine & Ethics, April 28, 2020 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7433684/

[4] *Bledsoe, et al v. Center for Human Reproduction, et al.,* Case No. 2023-00146, Index No. 800212/11, Supreme Court of the State of New York, Appellate Division, First Judicial Department

attempted with two of the embryos as the other six were so degraded that they had to be discarded. Plaintiffs' complaint included causes of action for medical malpractice and ordinary negligence based on the theory that the defects in the storage of the embryos denied them the opportunity to bear children. The Appellate Court undertook an analysis of the actions of the healthcare provider and what aspects of the IVF process implicate ordinary negligence or medical malpractice. It was a case of first impression in New York according to the Court. The Court found that certain actions were acts of medical science and therefore the protections afforded such under New York medical malpractice law, including the statute of limitations, were applicable and that cause of action was dismissed. They went on to conclude that the acts of maintaining the storage of the embryos was administrative in nature and an ordinary negligence cause of action was properly brought by the plaintiffs. Ultimately, the Court found that based upon the testimony of the experts in the case, there was enough evidence for the plaintiffs to proceed on their negligence count against the fertility facility.

As this case clearly shows, all aspects of the legal system are being challenged by the advances in medicine. Defense counsel had to properly evaluate the law and the complaint and then reason that the treatment alleged by plaintiff did not fall within the bounds of medical malpractice. They then had to retain the proper experts to offer opinions and testimony specific to these medical services and that would be useful in advancing their attempts to have the case dismissed. Counsel also had to prepare two different tracts of defense for the medical negligence and general negligence causes of action. As the Court's opinion states, the changes in medicine are presenting new questions about which laws are applicable. This opinion will not be the last where the Court is being asked to determine how the law should be applied to new medical treatment.

As medicine changes and expands, we have seen that genomic experts can now provide guidance for counsel and potential input on many different types of cases and allegations that we would not have expected. Some of the theories or allegations that genomic experts may be able to provide opinions on are:

1. Failure to Test
2. Over-Testing and Incomplete Information
3. Choice of Specific Panels or Tests
4. Inappropriate Use of or Reliance on a Test
5. Incorrect Variant Calls
6. Failure to Communicate Results to Patients Accurately
7. Failure to Communicate Results and Share Data with Clinicians within a Heath Care System
8. Failure to Analyze and Offer Incidental Findings or Secondary Results
9. Failure to Update and Recontact
10. Failure to Warn Family Members
11. Error and Failures in Direct-to-Consumer (DTC) Testing[5]

It is important that counsel recognize these advances, not just so they can be prepared to defend healthcare providers in the space but also so that they can use the technology and advances to help in

[5] From Marchant G, Barnes M, Evans JP, LeRoy B, Wolf SM; LawSeq Liability Task Force. From Genetics to Genomics: Facing the Liability Implications in Clinical Care. J Law Med Ethics. 2020 Mar;48(1):11-43.

their defense of other types of healthcare matters. Once counsel has accumulated the information and knowledge they need for the particular type of healthcare, they can prepare a strong defense on behalf of their client.

An Expert's Perspective

Once an appropriate expert is selected and decides to review a case for potentially offering an opinion, they first must review the medical records to determine the appropriate and applicable standard of care. Then, especially in ever-changing fields such as genomic medicine, they must review the literature, online databases, and materials from the specialty clinical society that would have been available at the time of the treatment in question. They must also consider the relevant health plan, facility policies, and any differential diagnosis of causation. Once all that is done, they must also determine if genomic testing is indicated and viable in this case. They are also tasked with translating the genomic jargon and results into plain English to counsel and their clients.

There has been an explosion in the capacity and capabilities of genomic testing and science. The first human genome was tested and mapped in 2003 at a cost of over three billion dollars. There have been over ten thousand human genetic diseases cataloged and there are over thirty new pediatric genetic conditions found each month. Today, there are hundreds of centers that can do that work for under a thousand dollars and within twenty-four hours. It is estimated that over a million new medical journal articles will be published on this topic this year. The potential genomics tools that are available to experts in the field include, but are not limited to: microarrays, gene panels, exome sequencing, genome sequencing, long read genome sequencing, optical genome mapping, gene expression, methylation tests, spatial genetics, and single cell testing. Some of the capabilities and limitations for these tests are listed in the below chart.

Method	Types of Mutations Detected	Key Features	Limitations
Exome sequencing	SNVs CNVs mtDNA	• Frequently deeper coverage than genome sequencing methods at lower cost • Focus on functional areas-portion of the genome that we know the most about	• Uneven coverage, some exons missing entirely • Cannot read repetitive regions of the genome • Very limited detection of CNVs • No detection of SVs
Short-read genome sequencing	SNVs CNVs SVs STRs Mosaicism mtDNA	• Even coverage across all unique regions of the genome • Improved CNV calling over exome sequencing	• Unable to align to repetitive regions of the genome • Decreased read depth, lower allele fraction variants missed • Low sensitivity for SVs, STRs, and mosaicism
Long-read genome sequencing	SNVs CNVs SVs	• Even coverage across all regions of the genome, including repetitive regions	• Requires nonstandard DNA extraction • Lack of large cohorts of control samples to define expectations

	STRs Mosaicism mtDNA	• Improved CNV and SV calling over short-read genome sequencing	• Algorithms still being developed, therefore difficult to truly assess potential • Low sensitivity for mosaicism
Optical genome mapping	CNVs SVs STRs Aneuploidy Mosaicism	• Probably better CNV and SV calling than short-read genome sequencing • Higher resolution than microarray and karyotyping • Detection of mosaicism Unbiased screen across genome possible	• Requires nonstandard DNA extraction • Lack of large cohorts of control samples to define expectations • Limited resolution in some genomic regions. • Lower resolution than sequencing methods above • Low sensitivity for aneuploidy • Does not detect triploidies and higher-order polyploidies, as well as Robertsonian translocations and other whole-arm translocations

CNV=copy number variant; mtDNA= mitochondrial DNA; SNV= single nucleotide variant; STR= short tandem repeat; SV= structural variant; Table modified from Kernohan and Boycott Nature Reviews Genetics Jan 2024

After an expert is retained and has the ability to review the particular case, they can offer their insight and opinions to counsel. They can also help counsel understand how best to defend the care or medical technology involved in the case. They may be able to offer different testing or methods, like those above, to undertake that may offer supportive evidence or explain the reason for the claimed injury.

Conclusion

As the medical community evolves the legal system that supports it must change with it. All those involved need to put in the time and work together to effectively defend the healthcare providers and facilities. While these types of cases may require more effort than the traditional healthcare case, the opportunity presents itself to be better prepared and achieve a great result for the healthcare provider.