

Legal Challenges to the Delivery of Genetic Services

Gregorio M. Garcia, J.D., Candidate for LL.M. in
Biotechnology and Genetics, Arizona State University

Overview

- Emerging challenges
- Foundation for legal obstacles
- Examples
- Discussion

Legal Challenges

- Negligence
 - Duty to inform of availability of tests
 - Duty to inform of results of tests
 - Misdiagnosis
- Informed consent

Foundation for Legal Obstacles

- Foundation for torts of negligence
 - Duty
 - Breach
 - Harm (Damages)
 - Causation
- Focus on Duty
 - Relationship
 - Formal law (e.g., statute)
 - Foreseeable harm

Duty and Medical Providers

- Negligence
 - Failure to inform of availability of tests
 - Failure to inform of results of tests
 - Patient
 - Potentially affected family members
 - Misdiagnosis

The Case of Genetic Testing

- Duty and Genetic Testing
 - Duty to inform of available testing
 - Relationship
 - Foreseeable harm
 - “The risk reasonably to be perceived defines the duty to be obeyed, and the risk imports relation; it is a risk to another or to others within a range of apprehension.”
 - *Palsgraf v. Long Island R.Co.*, 248 N.Y. 339, 162 N.E. 99, 100 (1928)
 - Duty to inform of results
 - Relationship
 - Foreseeable harm
 - Patient
 - Family members
 - Tension with privacy rights
 - How satisfied?

Wrongful Birth

- Two relevant classifications:
 - But for the negligence, the parents might have aborted
 - But for the negligence, the parents might not have conceived or might have taken precautionary measures
- Genomics driving third classification:
 - But for the negligence, the parents might have chosen alternative treatment

Duty: The Forseeable Harm

“The harm, if any, is not the birth itself but the effect of the defendant’s negligence on the [parents] resulting from the denial of the parents of their right, as the case may be, to decide whether to bear a child or whether to bear a child with a genetic or other defect.”

- *Reed v. Campagnolo*, 332 Md. 226, 237, 630 A.2d 1145, 1150 (App. 1993)(quoting *Viccaro v. Milunsky*, 406 Mass 777, 551 N.E.2d 8, 10 n.3 (1990))

Post-conception Diagnosis

- *Becker v. Schwartz*, 46 N.Y.2d 401, 386 N.E.2d 895 (1978)
 - 37 year old mother (parents) not informed of advanced risks due to age
 - Parents were not advised of testing (amniocentesis)
 - Child born with Down Syndrome
 - Companion case where parents of child who died of kidney condition shortly after birth inquired as to whether condition was genetic.
 - Doctor informed chance of conceiving second child with same condition was "practically nil."
 - Second child born with same condition and also died

Post-conception Diagnosis

- Duty continued...

- “The nature of the tort of wrongful birth has nothing to do with whether a defendant caused the injury or harm to the child, but, rather, with whether the defendant’s negligence was the proximate cause of the parents being deprived of the option of avoiding a conception or, in the case of pregnancy, making an informed and meaningful decision either to terminate the pregnancy or to give birth to a potentially defective child.”

- *Keel v. Banach*, 624 So.2d 1022 (Ala. 1993)

Pre-conception Diagnosis

- Two issues:
 - Identifying and informing of need for pre-conception testing
 - Accurate pre-conception testing
- Developments in genetic testing will drive both issues

Pre-conception Diagnosis

Lininger v. Eisenbaum, 764 P.2d 1202 (Colo. 1988)

- Parents of child born afflicted with blindness inquired as to whether condition was genetic in nature.
- Physicians informed that condition was not genetic – misdiagnosis.
- Condition was genetic.
- Parents chose to conceive second child, who also was born afflicted with blindness.
- Colorado Supreme Court held cause of action for negligence
- Misdiagnosis and failure to inform

Pre-conception Diagnosis

- *Molloy v. Meier*, 670 N.W.2d 711 (Minn. 2004)
 - Mother with mentally handicapped sibling gives birth to child with developmental delay.
 - Mother informs physician of family history and specifically asks for genetic tests on daughter to determine if daughter inherited genetic condition/abnormality.
 - Physician suspects Fragile X syndrome, but fails to ensure follow-up testing.
 - Testing performed, but not for Fragile X.
 - Negative test results reported to father (ex-husband), but not directly to mother and no mention of failure to test for Fragile X
 - Mother remarried and conceived.
 - Second child also had Fragile X; first child definitively diagnosed with Fragile X.

Pre-conception Diagnosis

- *Molloy* continued...
 - “Our decision today is informed by the practical reality of the field of genetic testing and counseling; genetic testing and diagnosis not only affect the patient. Both the patient and the family can benefit from accurate testing and diagnosis. And, conversely, both the patient and her family can be harmed by negligent testing and diagnosis... The standard of care thus acknowledges that families rely on physicians to communicate a diagnosis of the genetic disorder to the patient’s family. It is foreseeable that a negligent diagnosis of Fragile X will cause harm not only to the patient, but to the family of the patient as well. This is particularly true regarding parents who have consulted the physicians concerning the patients condition and have been advised of the need for genetic testing.”
 - *Molloy*, 679 N.W.2d at 719.

Other Health Related Genetic Tests

- Duty: Foreseeable harm
- Case Examples:
 - *Pate v. Threlkel*, 661 So.2d 278 (Fla. 1995)
 - Mother of adult female diagnosed with medullary thyroid carcinoma, a genetically transferable condition
 - Three years later, daughter also diagnosed.
 - Daughter sued mother's physician for failure to warn or inform of genetic nature
 - Daughter claimed she would have acted to test for condition and seek treatment
 - "...[W]hen the prevailing standard of care creates a duty that is obviously intended for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties."
 - *Pate*, 661 So.2d at 282.
 - Duty discharged by telling patient, not third parties.

Other Health Related Genetic Tests

- Case Examples continued..
 - *Safer v. Estate of Pack*, 677 A.2d 1188, 291 N.J.Super. 619 (1996).
 - Father diagnosed and treated for cancer by defendant (decedent) doctor in 1950's and 1960's.
 - Daughter subsequently developed same condition at young age (36).
 - "We see not impediment, legal or otherwise, to recognizing a physician's duty to warn those known to be at risk of avoidable harm from a genetically transmittable disease. In terms of foreseeability especially, there is no essential difference between the type of genetic threat at issue here or the menace of infection, contagion or a threat of physical harm... The individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning."
 - Failure to warn

Issues for Discussion

- How to balance the interplay between a duty to inform or warn and the right of privacy relating to medical information?
- How to address public discussion of moral interplay with right of family planning as it currently stands with medical provider's objection to outcome?
 - "Society has an interest in insuring that genetic testing is properly performed and interpreted... The recognition of a cause of action for negligence in the performance of genetic testing would encourage the accurate performance of such testing by penalizing physicians who fail to observe customary standards of medical practice."
 - *Gildiner v. Thomas Jefferson Univ. Hosp.*, 451 F.Supp. 692, 696 (E.D. Pa. 1978).
 - Is this subject to legislative input?
 - Conscience clause legislation

Issues for Discussion

- How to address scope of informed consent for testing?
 - Testing for all conditions, relevant to treatment?
 - Preconception testing for “birth defects” could also yield results for breast cancer
 - Postconception testing for “birth defects” could also yield results about paternity
- How will scientific/medical advancements affect legal challenges/obstacles to the delivery of genetic services?