

## Introduction

Reproductive genetics – meaning the use of reproductive and genetic technologies to both provide prospective parents information about a future child and to avoid having a child with a genetic abnormality – is a rapidly evolving area of medicine. As with other reproductive technologies, courts have been called upon to resolve a variety of disputes arising from reproductive genetics, and more can be anticipated as these technologies continue to develop and their use becomes more widespread.

Reproductive genetic testing has been used for several decades to inform prospective parents about their risk of producing a child with a genetic disorder. Prospective parents can be screened to determine if they are carriers of a genetic disease (“carrier screening”) before they initiate pregnancy. Most of the time, however, carrier screening occurs once pregnancy has already begun. In addition, prenatal testing can be performed, in which the fetus’ DNA is tested for genetic defects using amniocentesis or chorionic villus sampling (CVS).

In past decades, the number of genetic tests available was fairly limited. Now, however, there are tests for more than 1400 genetic diseases available either clinically or as part of research,<sup>1</sup> and the availability of some of these tests has influenced standards of medical care. For example, in 2001, the American College of Obstetrics and Gynecology and the American College of Medical Genetics recommended that the genetic test for cystic fibrosis be made available to all couples seeking preconception or prenatal care, and offered to all couples in ethnic or racial groups considered at higher risk for carrying the CF gene.<sup>2</sup>

The advent of a procedure called preimplantation genetic diagnosis (PGD) in 1990 has allowed scientists to test embryos directly for genetic defects before they are implanted into a woman’s uterus. More recently, this technology has been extended to attempt to determine which embryos appear most likely to result in a pregnancy regardless of genetic abnormalities, for example in women of advanced maternal age or couples who have had repeated failed IVF cycles. This usage is more accurately described as pre-implantation genetic selection (PGS) since the intent is not to diagnose a genetic disorder. Recent scientific studies have raised questions and fostered a debate as to whether PGS results in a higher pregnancy rate or may even reduce it, and suggests that some early embryos may self-correct or otherwise develop so that an early microscopic ‘snapshot’ is not predictive.<sup>3</sup> In the future, scientists may even be able to correct genetic abnormalities before birth using germline gene therapy.

Both assisted reproduction (often referred to as assisted reproductive technology, or ART)<sup>4</sup> and genetics have raised novel issues for the courts over the past few decades. The combination of these technologies has increased the range and complexity of the decisions judges have been called upon to make, and has invited legislative efforts.

Assisted reproduction has raised a variety of legal issues including: (1) control and custody of embryos; (2) access to assisted reproduction services; (3) parentage of children conceived through donor gametes or mixed-up embryos; and (4) liability for misappropriation of gametes and embryos.

Genetic technologies have also raised many legal issues, such as: (1) ownership and control of genetic material and information; (2) misappropriation of genetic material; (3) discrimination based on genetic information, e.g., in employment or insurance; (4) liability for failure to detect or warn about a genetic disorder through genetic testing; and (5) privacy rights and compelled testing in the workplace and otherwise.

In considering legal questions in the context of novel reproductive genetic technologies, courts are likely to draw upon existing precedents (previously decided cases in relevant, if not identical, contexts) for guidance. For example, the legal theories of “wrongful birth” and “wrongful life,” discussed below, first arose before the advent of prenatal and preconception genetic testing, but have since been asserted in these contexts. This article will provide a discussion of the most relevant areas of the law and litigation that currently bear on reproductive genetics or that can be anticipated to do so in the future.

### **Court Cases Arising from Children Born with Genetic or Other Birth Defects**

Carrier screening and prenatal testing for some genetic conditions, such as Tay Sachs disease and Down syndrome, have been available for many years. And before prenatal genetic testing was available, doctors employed other tests to assess fetal health. There is thus a large body of case law in the United States arising from lawsuits against health care professionals following the birth of a child with an impairment that was either not discovered in the fetus through prenatal testing or not foreseen prior to conception by proper screening or diagnosis of the parents. Legal theories or “claims” supporting such lawsuits are generally referred to as “wrongful birth” and “wrongful life” claims, although various courts may characterize such theories simply as negligence, professional negligence, or medical malpractice.

“Wrongful birth” claims are those brought by parents alleging that, but for the defendant’s negligence, they would have aborted or never conceived the child.

“Wrongful life” claims are those brought by (or on behalf of) children alleging that, but for the defendant’s negligence, they would not have been born. Claims for wrongful birth and wrongful life are most often brought against the physicians who performed or failed to offer or perform prenatal testing or preconception genetic testing, hospitals or medical practices that employed such physicians, and genetics laboratories that provided or failed to provide the testing services.

There is also a large body of law involving children, healthy or otherwise, born following a failed sterilization, abortion, or pregnancy diagnosis. Courts throughout the U.S. differ widely in their terminology, characterizing these claims variably as “wrongful conception,” “wrongful pregnancy,” professional negligence, medical malpractice, or simply negligence. (For ease of reference, all such claims will be referred to here as “wrongful conception”). Some courts may also analyze such claims as a subset of “wrongful birth” claims. “Wrongful conception” claims are generally filed by parents against the physician (and the hospital or medical practice employing him or her) who performed the negligent sterilization or abortion or who failed to diagnose a pregnancy. These cases, and the analysis the courts apply, may provide relevant precedent for cases involving reproductive genetic testing, since parents will similarly claim that, “but for” the missed diagnosis, they would not have attempted a pregnancy. This theory may be an even stronger legal basis for such claims, since in almost every instance the pre-conception procedure will have been undertaken for the very purpose of avoiding the conception of a child with a genetic abnormality. Thus both causation and injury may be readily provable.

Before turning to particular cases, it should also be noted that the legal theories that a court will permit to support a lawsuit (called “claims” or “causes of action”) are typically governed by state law and therefore vary from state to state. Thus, this overview should be used as a guide rather than definitive evidence of the status of the law in a particular jurisdiction. Finally, this overview focuses primarily on court decisions from the highest state courts, since these provide precedent (rules or interpretations of law), which lower courts in that same state must follow. Some federal court decisions that have interpreted a state’s laws are also reviewed, since those interpretations are often given great weight within a state.

### Wrongful Birth Court Decisions

Thirty states have high state court or federal court decisions that recognize and uphold wrongful birth claims, although not all use that terminology.<sup>5</sup> These courts nearly universally allow recovery of damages for extraordinary expenses due to the child’s affliction but prohibit recovery of normal child-rearing expenses. The decisions differ regarding whether damages are recoverable for the parents’ emotional distress. Some of the courts characterize the claims as negligence or malpractice, rather than as “wrongful birth.”

Nineteen of these wrongful birth cases involved children with a genetic impairment, such as Down Syndrome, Tay Sachs disease, cystic fibrosis, or, in one 2007 case, the first discovery of partial Trisomy 9q.<sup>6</sup> Eight involved children with non-genetic congenital defects such as rubella syndrome or birth defects resulting from cytomegalovirus or medication prescribed to the mother during pregnancy.<sup>7</sup> Two cases involved spina bifida, whose causes are not clearly understood, and in two cases the courts did not discuss whether the impairment had a genetic component or not.<sup>8</sup> The nature of the

impairment (genetic or non-genetic) generally has no bearing on the legal outcome in wrongful birth actions.

A minority (seven) of state high courts or federal courts that have considered the issue have refused to recognize wrongful birth actions.<sup>9</sup> These courts rejected such claims either because of a specific statute prohibiting them, or based on the court's judgment that the existence of a human life, even with severe impairments, cannot constitute a cognizable legal injury, i.e., an injury that the law is willing to redress.

There are also a significant number of states (fifteen) that have no state high court or federal court case law addressing the validity of wrongful birth claims. The majority of these states have no intermediate appellate case law either. Those few states with intermediate appellate case law tend to follow trends similar to states with high court decisions. (Trial court decisions are not discussed here, because they do not carry the same precedential value as appellate cases.)

The advance of reproductive genetic technology in the absence of uniform state laws can lead to novel issues, as illustrated by a 2006 case whose outcome turned entirely on which state's law applied.<sup>10</sup> A Maryland couple parenting a child with cystic fibrosis underwent amniocentesis to avoid giving birth to another child with the same genetic abnormality. The test was performed on the pregnant wife in Maryland. The amniotic fluid was sent to North Carolina to be tested at a large, national lab that was headquartered in that state, and which returned a false negative result. Maryland recognizes wrongful birth, while North Carolina recognizes only wrongful conception. The defendant lab attempted to avoid liability and damages by claiming that North Carolina law should apply, since the laboratory was located there. The question was sent to the Maryland Court of Appeals (that state's highest court), which determined that Maryland law should apply, and the parents were subsequently awarded damages under Maryland's wrongful birth law.

Had the couple used PGD instead of amniocentesis, they would have claimed wrongful conception rather than wrongful birth, and the defendants would not have been able to attempt to exploit the differences between state laws to avoid liability. IVF, by separating the constituent parts of reproduction (union of egg and sperm and implantation into the uterus) raises a question legally of when conception occurs that courts may have to confront in the future.

A 2007 case demonstrates that genetic testing can still leave parents uncertain as to their child's outcome and that technology may outpace applicable standards of care.<sup>11</sup> A New Hampshire couple underwent ultrasound and amniocentesis, which revealed elevated but ambiguous risks of genetic anomalies for the fetus. After certain genetic risks (including Trisomy 18) were ruled out, the couple sought out additional testing and counseling at two different hospitals. Those tests revealed some, but not all, of the concerns noted by the first hospital, but did not provide definitive diagnosis or prognosis. The parents elected not to terminate the pregnancy and the child was born with severe impairments. Subsequent genetic testing of both the child and his parents

using more sophisticated techniques revealed the first reported case of partial Trisomy 9q, a chromosomal abnormality. The court rejected the parents' wrongful birth claims against both the first hospital where they had sought care and medical geneticist at that hospital. Although the parents claimed they would have terminated with better and earlier warnings or recommendations, the court found both insufficient evidence to support their claim and ruled that the parents had had adequate time to abort if they had so chosen.

In this case, it was possible to find the mutation, but not by using standard-of-care technologies and procedures, an illustration of how both advances in genetic testing and parental expectations may outpace applicable legal standards of liability.

### Wrongful Life Court Decisions

In contrast to wrongful birth claims, the vast majority (twenty-five) of states with state high court or federal court decisions have refused to recognize claims for wrongful life.<sup>12</sup> Of these, most (eighteen) involved children with genetic impairments;<sup>13</sup> a minority (seven) involved children with non-genetic congenital defects.<sup>14</sup> The overwhelming reason given for refusing to recognize wrongful life claims is the inability or unwillingness of courts or jurors to weigh the value of an impaired life against the value of nonexistence.

Only four states have high state court or federal court decisions that recognize wrongful life claims.<sup>15</sup> These decisions have generally allowed recovery of damages only for extraordinary expenses required to treat the child's ailment, and have not permitted recovery of general damages for having been born with an impairment.

As with wrongful birth, a significant number of states (nineteen) have no state high court or federal court case law addressing the validity of wrongful life claims.<sup>16</sup> Similarly, the majority of these states also have no intermediate appellate case law. Those relatively few states with decisions by an intermediate appellate court tend to vary in their analysis in the same manner as do the states with high court decisions.

### Wrongful Conception Court Decisions

The vast majority of states (thirty-five) have state high court or federal court decisions recognizing wrongful conception claims.<sup>17</sup> Only seven states reject such claims. Of the majority of states that recognize wrongful conception claims, most of the cases involved healthy children. Relatively few (nine)<sup>18</sup> involved impaired children (this includes one born prematurely who died at birth).

In cases involving the birth of healthy children that parents claim were "wrongly conceived" (i.e., conceived after measures were taken to prevent conception), most states (twenty-two) do not allow recovery for child-rearing expenses. These states do allow recovery for actual damages related to the failed sterilization or other procedure(s), as well as for costs related to the pregnancy and birth (e.g., medical

expenses, pain and suffering of the mother related to pregnancy and childbirth, lost wages of the mother, and “loss of consortium,” (typically loss of companionship for the woman’s spouse). A minority of states also allow recovery of the costs of child rearing, either in full<sup>19</sup> or offset by the benefit derived by the parents of raising a healthy child.<sup>20</sup>

In the nine cases involving children born with impairments, two states denied any recovery related to the birth defect because the birth defect was not a foreseeable consequence of the negligent sterilization;<sup>21</sup> five states allowed consideration of the defect in assessing other damages (such as emotional distress or special medical needs) but did not allow child-rearing expenses;<sup>22</sup> one state allowed recovery of the costs of raising the child without any offset for benefit to parents;<sup>23</sup> one case involved a child who died at birth;<sup>24</sup> and one state adopted a “case by case” approach where the court found the value of the benefit (of having a child) should mitigate or offset the damages to the extent equitable.<sup>25</sup>

A minority of states (six) have state high court or federal court cases rejecting wrongful conception claims.<sup>26</sup> Of those six states, all addressed claims involving healthy children; one, Texas, addressed claims involving both healthy children and children with congenital defects. In the five states involving only healthy children, four rejected the claims based on a lack of injury or damage to the parents, since the courts declined to consider the birth of a healthy child to be a legally cognizable injury.<sup>27</sup> The court in Iowa rejected such claims on the basis that the benefits of a healthy child outweigh the associated monetary burdens. Texas, the one state addressing both healthy children and children with birth defects, rejected all such claims and concluded that a birth defect makes no difference to the legal analysis because a birth defect is not a foreseeable consequence of a failed sterilization.

A relatively small number of states (thirteen) have no state high court or federal case law on wrongful conception.<sup>28</sup> The high court in one of those states (Colorado) decided a case involving a failed tubal ligation, but the mother sued, and lost, solely for a breach of contract and not as an issue of negligence, malpractice, or wrongful conception.

Defendants in wrongful conception or wrongful birth cases may seek to deny culpability on the basis that the plaintiff consented to the treatment or the procedure. While a court may examine a consent document to see whether it addresses the conduct at issue, generally courts have found that such documents do not remove or reduce a professional’s liability resulting from negligent conduct, such as medical malpractice. Courts have determined that, as a matter of public policy, professionals should not be able to protect themselves from liability for their own negligence — as opposed to any inherent risks of a procedure or condition — through disclaimers or waivers that attempt to transfer the risks to patients or non-professionals. Some courts have also noted that patients are not in an equal bargaining position with a medical professional and it would be unfair to enforce a waiver for that reason. The extent to which language in signed consent forms that outline risks may limit professional exposure is therefore unclear, particularly because state laws and courts vary regarding the degree to which they take such forms into account.

## State Statutes Addressing Wrongful Birth/Wrongful Life

A state's laws may derive from court decisions or statutes. In some instances, states develop a body of "common law" through court decisions over time, and the legislature then enacts a statute that essentially codifies that body of common law. Alternatively, the legislature may choose to override or modify the common law through statute. Once a statute is passed, courts will also develop a body of law interpreting it.

Eleven states have enacted wrongful life and/or wrongful birth statutes.<sup>29</sup> Seven prohibit both wrongful life and wrongful birth actions.<sup>30</sup> Two prohibit only wrongful life actions.<sup>31</sup> Maine limits damages for the birth of and to a child harmed as a result of professional negligence. At least three of the states that have enacted statutory bans on wrongful birth or wrongful life claims have done so in support of each state's stated public policies of respecting the right to life of all humans, born or unborn, healthy or unhealthy, and disfavoring abortion. The statutes in these states provide that a cause of action shall not arise based on a claim that, "but for" the act or omission of another, a person would have been aborted. Maine's legislative intent is reflected in its statutory language: "[i]t is the intent of the Legislature that the birth of a normal, healthy child does not constitute a legally recognizable injury and that it is contrary to public policy to award damages for the birth or rearing of a healthy child."<sup>32</sup> A few states, such as Maine and Michigan, have enacted statutes that prohibit recovery of child-rearing expenses in wrongful conception or negligent sterilization actions.<sup>33</sup>

## Wrongful Birth/Life Cases Arising From Assisted Reproductive Technologies

Wrongful birth and wrongful life issues have arisen in a small number of cases involving children born through the use of ART, donor gametes, and PGD.

### *Court Decisions Involving PGD*

PGD can result in the birth of genetically impaired children either if the testing is performed or reported incorrectly, or if an affected embryo is mistakenly implanted instead of an unaffected embryo. Either error can lead to litigation. "Wrongful life" issues were identified and rejected by a court in one of the only two cases reported to date involving PGD (both were trial level cases involving children born with cystic fibrosis after mistaken assurances that the tested embryo was not affected). A Massachusetts trial court rejected claims brought on behalf of an affected child and by his parents, and refused to recognize the injury based on a new legal claim of "preconception tort."<sup>34</sup> Instead the court characterized the claims as ones for "wrongful life," which it ruled were precluded by precedent in that state. The court further found that the defective gene itself, not the defendant physicians, had caused the defect, a distinction that also carries over to cases involving donor gametes with undetected or unreported genetic abnormalities, as discussed below. The court's opinion did not address whether the consent forms adequately outlined the risks of PGD or whether PGD was considered an experimental procedure. The second PGD case involved access to certain research

records and is discussed below in the context of breach of professional duty. A relatively small number of other alleged failures of PGD have resulted in lawsuits, but have settled and therefore no court decisions have been reported. In addition, insurance companies vary in their coverage for such procedures, with some reported denials of coverage based on the claimed experimental nature of the procedures or based on outright policy exclusions. In a number of cases, patients have challenged these denials with some success, often arguing that the cost of insuring a child with a serious genetic abnormality far outweighs the cost of covering the PGD procedure intended to prevent such births and affected lives.<sup>35</sup>

### *Court Decisions Involving Genetic Abnormalities in Donor Gametes*

At least two cases have been brought against professionals who failed to identify or inform intended parents of a genetic abnormality in their chosen sperm or egg donor, after which a child was born with a serious genetic abnormality. In one case, a California sperm bank failed to report a sperm donor's family history of kidney disease, although he had allegedly noted it on his donor intake form. The child was subsequently born with autosomal dominant polycystic kidney disease (APKD).<sup>36</sup> In the second, a New York ART medical program overlooked and therefore failed to notify the intended parents that their selected egg donor had tested positive as a carrier for cystic fibrosis.<sup>37</sup> They conceived and their child was born with the disease. Similarly, in the third case, patients sued a Colorado IVF program claiming it had recommended and provided them with an egg donor who had not been screened for cystic fibrosis. One of the twins born to the couple had cystic fibrosis and the couple claimed the physicians failed to perform genetic screening and misrepresented the quality of screening and the embryos.

In the California sperm bank case, multiple legal issues were raised and argued, including whether or not the bank was protected under state statutes designed to protect health care providers. The California trial court held that the sperm bank was exercising professional skills as a health care provider, even if not engaged in a physician-patient relationship, and therefore fell within that state's statutory protections. The court rejected the parents' arguments that the bank was operating solely as a commercial business selling sperm. As with the PGD cases, the court found that the donor's genes, and not the defendant sperm bank, caused the child's genetic abnormalities, and therefore the sperm bank could not be held legally responsible for the child's disease. Following California's established law, the court rejected the child's claim of wrongful life. The New York court also rejected arguments that the defendant professionals, rather than the donor, had caused the child's abnormalities. The New York trial court also characterized and rejected the claim as one for wrongful life, refusing to recognize either a tort of "negligent preconception or pre-implantation counseling."

### **Other Court Cases Involving Reproductive Genetics**

In addition to the extension of wrongful birth/wrongful life theories to encompass new reproductive technologies such as PGD, other issues are beginning to arise from

genetic testing, genetic information, and genetic material in the context of assisted reproduction. The remainder of this article provides a summary analysis of those relatively few cases, as well as of a limited number of recent cases that, although not directly involving reproductive genetics, present related issues and thus are helpful in understanding legal approaches that may be used to resolve conflicts involving reproductive genetics. Given the small number of cases and the fact that state laws differ, the cases are more illustrative of current approaches and trends than predictive of how specific future disputes may be resolved.

### Court Decisions Involving Failure to Warn Family Members

Cases involving reproductive genetics are likely to arise from a patient, a patient's parent, or a research subject claiming that a health professional caused harm by his or her negligent or intentional act or failure to act. In order to find a health professional liable, he or she must be found to have had a duty to the plaintiff(s) and to have breached that duty by falling below the applicable standard of care, and the breach has to have caused the alleged injury. Courts must, therefore, define the types of relationships that give rise to a duty, the scope of that duty, the standard of care owed as a result of that duty, and when the statute of limitations (the time during which the lawsuit may be initiated) for a breach of that duty begins to run. Where a child has resulted from the negligent act, some courts have followed their state's wrongful birth, wrongful life, or wrongful conception analyses, as discussed above, while others have analyzed the case under privacy, negligence and medical malpractice principles.

Failure to provide accurate genetic information has been the basis of claims against both treating physicians and researchers. Courts have frequently looked to whether or not the defendant had a relationship with, and thus a duty to, the plaintiff patient or family member. Researchers, as opposed to treating physicians, are generally held not to have a physician-patient relationship with their research subjects, and thus have been found not to have a duty to warn patients or family members as to a genetic vulnerability. For example, in a case involving a statewide randomized, blinded control study of newborns for cystic fibrosis, the researchers were found not liable to the parents or younger affected sibling for not learning of, or warning the parents about, the older child's positive test.<sup>38</sup> The plaintiffs had been part of a statewide cystic fibrosis research protocol in which excess blood was drawn from all newborns and used to test them for cystic fibrosis. Under the research protocol, the parents of half of the newborns were told of a positive test and those infants were put on a nutrition plan, while the test results of the second half were not revealed. The goal of the study was to ascertain whether nutritional supplements slowed the progression of CF. The plaintiffs were in the group who were not notified, and therefore did not learn of their child's diagnosis until age two and after they were expecting a second child. That child was also diagnosed with CF, and one of the parents' claims was that had they been given the newborn screening results, they would not have conceived their second child.

In a widely cited non-genetics research case, however, a Maryland appellate court came to the opposite conclusion.<sup>39</sup> That court found that a "special relationship" was

created between the researchers and their minor subjects and therefore negligence and breach of contract claims could be brought on behalf of minor plaintiffs against researchers who conducted an allegedly non-therapeutic research experiment (i.e., one that provided no benefit to the research subjects) and involved more than minimal risk. The court noted that minors were vulnerable research subjects, and that informed consent by parents on behalf of their children for nontherapeutic research raised serious legal, moral and ethical concerns.

In one of only two reported cases involving PGD,<sup>40</sup> where a child was born with cystic fibrosis after a mistaken assurance that the tested embryo was not affected, an Illinois intermediate appellate court refused to allow a plaintiff access to the IRB-approved research protocol documents, ruling they were privileged by state statute and not designed to facilitate truth seeking in private malpractice cases.<sup>41</sup> The couple had sought PGD (which the hospital treated as experimental at that time) to ensure their second child would not be born with the disorder after their first child was born with it.

Courts have come to different conclusions regarding a treating physician's duty to a patient's immediate family members. For example, in a few reported assisted reproduction cases a husband has sued his wife's physician for performing artificial insemination with donor sperm without the husband's consent. Two courts, based on their state's relevant statutes, have come to opposite conclusions on the question of whether or not the physician owed a duty to the patient's husband.<sup>42</sup>

Even when there is a duty to warn, it may not extend to all close relatives. For example, in a Minnesota case,<sup>43</sup> that state's high court found a duty to warn a biologically related parent in a case involving a child with Fragile X. After the child was born, her mother remarried, and the mother and new husband were falsely reassured, based on incorrectly read test results, that the child did not have Fragile X. The mother then proceeded, with her new husband, to conceive a child who was also affected with Fragile X. The court found a duty to warn family members about the first child's condition existed, which would be met by telling either biological parent. The court explicitly noted it did not need to rule on whether that duty extended beyond biological parents. In allowing the claim, the court framed the parents' claim as one for "wrongful conception," and not as wrongful birth or wrongful life (both of which had been prohibited by state statute). The court also addressed a statute of limitations issue, ruling that the statute began to run only upon the conception of the second child because only then had a harm occurred. The court recognized that in most circumstances, malpractice actions for failure to diagnose usually begin to run at the time of the failure; however, that rule could not apply where, without that knowledge, the mother did not get a tubal ligation and instead became pregnant. The court upheld the intermediate appellate court's decision in all respects; that court had noted that the ruling created the possibility that cases involving inherited genetic defects might not be discovered and therefore filed until years, and potentially decades, after the wrongful act.

In a case involving a misread amniocentesis which falsely assured a pregnant couple their fetus was not affected with cystic fibrosis (a condition their older child had and which they sought to avoid repeating in another child), the court found a duty to the husband as well as the wife. The court rejected the defendant company's argument that it did not owe a duty to the husband since only the wife could choose to abort or carry the child.<sup>44</sup>

Duty to warn cases involving genetic testing have also arisen outside the reproductive context, and demonstrate the lack of clarity that exists regarding physician duties to family members potentially affected by genetic information. In two cases involving adult-onset inherited genetic disorders, courts found a duty to warn family members, although the requirements the courts imposed for meeting that duty differed. First, in a Florida case<sup>45</sup> brought by a thyroid cancer patient's adult daughter, the court found the parent's treating physician had a duty to warn family members, but that such duty would be met by the physician warning only the patient. The court explicitly acknowledged that the disorder, medullary thyroid carcinoma, was a "genetically transferable disease." The court found that most patients would tell family members, and that any other requirements could compromise confidentiality and be unduly burdensome on a physician.

Second, in a New Jersey case,<sup>46</sup> an intermediate appellate court found a broader duty to warn the plaintiff. The case was brought by the adult child of a patient who had died (when the plaintiff was a child) of colon cancer resulting from multiple polyposis, an inherited syndrome that in virtually all untreated cases leads to colon cancer. Noting that it disagreed with the Florida court's ruling on how that duty could be met, the New Jersey court found that in some instances a duty to warn of a genetic risk might not be satisfied solely by informing the patient rather than his or her family members directly. Finding "a duty to warn of avertable risk from genetic causes" is "by definition a matter of familial concern," the court found a duty was owed to "members of the immediate family of the patient who may be adversely affected by a breach of that duty."

Both the Florida and New Jersey cases were brought by the child of a patient and neither court further defined the terms "immediate" or "family member." The Florida court did note that the prevailing standard of care, meaning the average degree of skill and care exercised by members of the medical profession in the same or similar locality given the present state of medicine, created a duty "that is obviously for the benefit of certain identified third parties" to whom a duty is therefore owed, including "a patient's children [who] fall within the zone of foreseeable risk." The court also noted that the standard of care, as in any malpractice case, is determined by a consideration of expert testimony on the question of the accepted or prevailing medical custom in and for that type of community.

Given the limited case law, the scope of a health care provider's duty to warn family members of genetic risks remains an unsettled area at this time.

## Conclusion

Legal issues surrounding reproductive genetics are still emerging and both statutory and case law are still developing. Law and policy makers will want to recognize both the many connections to existing areas of law and medicine, and those aspects that are novel. Legal developments are likely to continue to arise in a number of areas including liability for causation of genetic and chromosomal abnormalities, legal time limits for bringing claims once genetic abnormalities are discovered, the legal relevance of the scientific methods used to determine any abnormalities, and the limits of the standard of care and the scope of the physician's duty. Both cases and statutes addressing reproductive genetics and those that do not do so directly will continue to inform the legal disputes arising from reproductive genetics as these technologies advance and become more integral to patient care.

*Written by Susan L. Crockin, Esq. for the Genetics and Public Policy Center. Do not reprint without the permission of the Genetics and Public Policy Center.*

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<sup>1</sup> GeneTests, at <http://www.genetests.org>.

<sup>2</sup> W. Grody et al., *Laboratory standards and guidelines for population-based cystic fibrosis carrier screening*, 3(2) GENETICS IN MEDICINE 149-154 (March/April 2001).

<sup>3</sup> S. Mastenboek et al. *In vitro fertilization with preimplantation genetic screening*. 357(1) N. ENG. J. MED. 9-17 (2007); Cohen, J. *A Response to Mastenbroek PGD Study*, July 11, 2007, available at [www.ivf.net/ivf/index.php?page=out&id=2814](http://www.ivf.net/ivf/index.php?page=out&id=2814).

<sup>4</sup> Donor insemination, which predates most of the newer, more complicated technologies, is not routinely considered a form of ART from a medical perspective.

<sup>5</sup> These states are: Alabama, Arizona, Arkansas (as negligence claim), California, Colorado, Delaware, Washington, D.C., Florida, Idaho, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee (as negligence claim), Texas, Virginia, Washington, West Virginia, and Wisconsin.

<sup>6</sup> These cases were decided in the following states: Alabama, California, Colorado, Delaware, Washington, D.C., Florida, Illinois, Indiana, Maine, Massachusetts, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, South Carolina, Tennessee, Virginia, and West Virginia.

<sup>7</sup> These cases were decided in the following states: Arizona, Idaho, Louisiana, New Hampshire, Oklahoma, Texas, Washington, and Wisconsin.

<sup>8</sup> These cases took place in Arkansas, Kentucky, and Nevada.

<sup>9</sup> These cases were decided in Georgia, Idaho, Kentucky, Minnesota, Missouri, North Carolina, and Utah. All six such cases involved children with genetic impairments.

<sup>10</sup> *Hood v. Lab. Corp. of Am.*, 2006 U.S. Dist. LEXIS 36464 (D.Md. 2006)

<sup>11</sup> *Hall v. Dartmouth Hitchcock Medical Center*, 899 A.2d 240 (N.H. 2006).

<sup>12</sup> These states are: Arizona, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Utah, West Virginia, Wisconsin, and Wyoming.

<sup>13</sup> These cases were decided in: Colorado, Delaware, Florida, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Minnesota, Missouri, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Utah, and West Virginia.

<sup>14</sup> These cases were decided in: Arizona, Idaho, New Hampshire, Texas, Wisconsin, Wyoming, and Indiana.

<sup>15</sup> These states are: California, Louisiana, New Jersey, and Washington. All of these cases, except the Washington case, involved children with genetic impairments.

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<sup>16</sup> These states are: Alaska, Alabama, Arkansas, Connecticut, Washington, D.C., Hawaii, Iowa, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, and Virginia.

<sup>17</sup> These states are: Alabama, Alaska, Arizona, Arkansas, Connecticut, Washington, D.C., Florida, Georgia, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi (as negligence), Missouri, Nebraska, (as malpractice), New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. There are thirty-eight state high court or federal court opinions, thirty-five of which are negligent sterilization (or in one of these, failure to sterilize) cases, one is a failed abortion case (Pennsylvania), one is failure to diagnose a pregnancy case (Alaska), and one is a failure to diagnose cystic fibrosis in an older sibling (New Jersey).

<sup>18</sup> These cases were decided in: Connecticut (orthopedic abnormality), Florida (congenital defects), Georgia (club foot), Louisiana (albinism), Mississippi (baby born prematurely and died), New Jersey (cystic fibrosis), North Carolina (genetic defect), Ohio (birth defect), and Pennsylvania (neurofibromatosis).

<sup>19</sup> These states are: New Mexico, Oregon, and Wisconsin.

<sup>20</sup> These states are: Arizona, Connecticut, Maryland, Massachusetts, and Minnesota.

<sup>21</sup> These states are: Ohio and Louisiana.

<sup>22</sup> These states are: Florida, Georgia, Nebraska, New Jersey and Pennsylvania.

<sup>23</sup> This state is North Carolina.

<sup>24</sup> This state is Mississippi.

<sup>25</sup> This state is Connecticut.

<sup>26</sup> These states are: Iowa, Kentucky, New York, Oklahoma, and Texas. All of these cases were negligent sterilization cases, except for Iowa, which was a failed abortion case.

<sup>27</sup> These states are: New York, Oklahoma, Kentucky, and Nevada.

<sup>28</sup> These states are: California, Colorado, Delaware, Hawaii, Idaho, Michigan, Mississippi, Montana, Nebraska, New Jersey, North Dakota, South Carolina, and South Dakota. Included in this total of thirteen is a Hawaii State Supreme Court negligent sterilization opinion that addressed only civil procedure issues and did not rule on validity of underlying action.

<sup>29</sup> These states are: California, Idaho, Indiana, Maine, Michigan, Minnesota, Missouri, North Dakota, Pennsylvania, South Dakota, and Utah.

<sup>30</sup> These states are: Idaho, Michigan, Minnesota, Missouri, Pennsylvania, South Dakota, and Utah.

<sup>31</sup> These states are: Indiana and North Dakota.

<sup>32</sup> Me.Rev.Stat. Ann. tit. 24, § 2931(1) (2003).

<sup>33</sup> Me.Rev.Stat. Ann. tit. 24, § 2931 (2003); Mich.Comp.Laws §600.2971 (2004).

<sup>34</sup> Doolan v. IVF America, Inc., 12 Mass.L.Rep. 482 (Super.Ct. 2000).

<sup>35</sup> Author's and others professional representations; no reported decisions known to date.

<sup>36</sup> Johnson v. Superior Court, 124 Cal.Rptr.2d 650 (Cal.Ct.App. 2002).

<sup>37</sup> Paretta v. Med. Offices for Human Reprod., 760 N.Y.S.2d 639 (N.Y.Misc. 2003).

<sup>38</sup> Ande v. Rock, 647 N.W.2d 265 (Wis.Ct.App. 2002).

<sup>39</sup> Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807 (Md. 2001).

<sup>40</sup> A small number of such claims have reportedly been filed and settled without reported or published decisions (personal discussions with the author).

<sup>41</sup> Doe v. Ill. Masonic Med. Ctr., 696 N.E.2d 707 (Ill.App.Ct. 1998), *app.denied* 705 N.E.2d 436 (Ill. 1998).

<sup>42</sup> Cf. Shin v. Kong, 95 Cal.Rptr.2d 304 (Cal.Ct.App. 2000); Kerns v. Schmidt, 641 N.E.2d 280 (Ohio Ct.App. 1994).

<sup>43</sup> Molloy v. Meier, 679 N.W.2d 711 (Minn. 2004).

<sup>44</sup> Hood v. Lab. Corp. of Am., 2006 U.S.Dist.LEXIS 36464 (D.Md. 2006)

<sup>45</sup> Pate v. Threlkel, 661 So.2d 278 (Fla. 1995).

<sup>46</sup> Safer v. Estate of Pack, 677 A.2d 1188 (N.J.Super.Ct.App. Div. 1996).