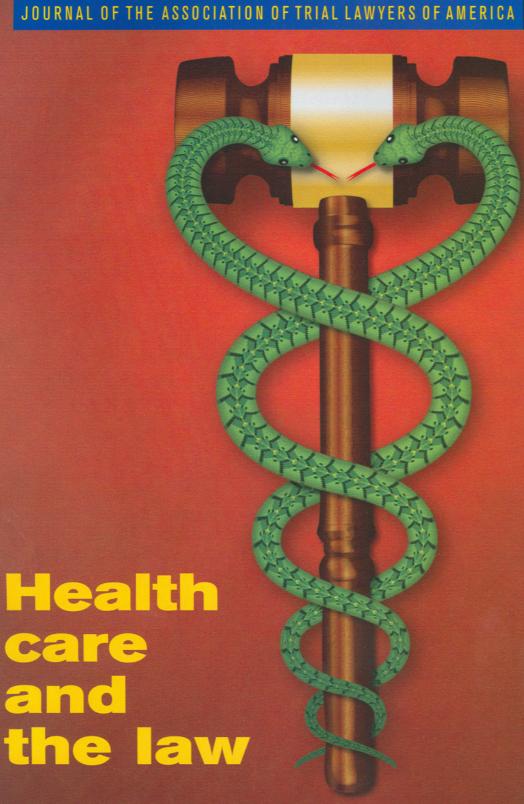
Body parts for sale

Enforcing patient safety 38

When genetic tests fail 44

OCTOBER 2006



and

www.atla.org

Genetic tests are testing the law

The fast-growing field of genetic testing has raised new legal questions: Who is responsible when a child is born with a severe genetic defect? And what theories, standards, and choice of law apply to these new technologies?

SUSAN L. CROCKIN, GAIL H. JAVITT, SUSANNAH BARUCH, AND ELIZABETH M. BLOOM

odern genetic testing is routinely used to determine whether prospective parents are at risk for passing on genetic diseases to children, to find out whether a fetus has a genetic disorder, and to identify certain genetic conditions in newborns. Recently, genetic testing has been used to screen embryos created through in-vitro fertilization (IVF) to select the ones that will be implanted.

This rapidly evolving area of medicine increasingly pushes the limits of both science and the law. With little regulation of genetic testing or IVF practice in the United States and few professional guidelines for health care providers, legal standards about proper use and interpretation of these tests are just emerging.

Genetic testing gives would-be parents more hope, more information, and more choices than ever. At the same time, testing, testers, or communicators of test results can fail—with sometimes tragic consequences. Plaintiff lawyers, who are more and more likely to handle a case involving these tests, need to know

how genetic testing works and what legal precedents for such claims exist.

Understanding the science

A genetic test is a laboratory analysis of a tissue sample that detects DNA or chromosomal alterations, or proteins or other metabolites indicative of a genetic disorder. Today, it can be done directly on a tissue sample taken from a cheek swab, blood cells, amniotic fluid (through amniocentesis), placental cells (through chorionic villus sampling, or CVS), or a single cell of an embryo created through IVF technology.

While genetic testing can be performed at any time, it is often used by couples thinking about starting a family. "Carrier testing" screens the prospective parents either before or during a pregnancy for potential genetic mutations. Certain types of carrier testing are offered depending on racial or ethnic background: For example, professional guidelines recommend cystic fibrosis (CF) screening for all white couples and say it should

be available to all populations.1

Testing of a developing fetus during pregnancy can identify a genetic alteration linked to current or future disease. Cytogenic testing detects changes in chromosomal number or structure (which could indicate, for instance, Down syndrome); biochemical genetic testing measures proteins and metabolites (which could signal, for example, phenylketonuria, or PKU); molecular genetic testing uses nucleic acid probes to identify alterations in DNA sequences that can predict early-onset diseases such as CF and late-onset illnesses such as Huntington's disease.

Recently, IVF, along with advances in genetic testing, has made it possible to test an early-stage embryo through preimplantation genetic diagnosis (PGD). Developed a little over a decade ago and still not routinely performed, PGD allows physicians or embryologists to identify embryos carrying specific genetic alterations that can cause disease. A couple can then choose to transfer to the woman's uterus only those embryos that don't show these alterations.

PGD has most frequently been used by couples with known genetic risks, who may already have an affected child. Worldwide, at least 2,000 babies have been born after PGD testing discovered that the embryos they developed from had no disorders like cystic fibrosis, Tay-Sachs disease, Marfan syndrome, muscular dystrophy, sickle cell and Fanconi anemia, and thalassemia.2

The use of PGD for other purposes such as to test the embryo's sex, to create a child to be a tissue match for a sibling, to detect late-onset disorders such as Alzheimer's disease, or to discover genetic susceptibility to diseases like hereditary breast cancer-is controversial.3

Today, genetic tests are clinically available for 1,000 diseases; several hundred more are available in a research setting.4 More than a hundred have been used in prenatal testing and PGD, and there is no technological barrier to any of these genetic tests being used in these contexts.

Mistakes in testing, failure to test, or failure to accurately convey test results are inevitable, and as options have multiplied, so have the chances of error. For anyone seeking a legal remedy to these new "reproductive wrongs," the challenge has been to try to fit them into, or find ways to expand, existing legal theories.

Reproductive wrongs

Legal theories of "wrongful birth," "wrongful life," "wrongful conception," and tort principles of negligence, professional malpractice, and fraud have all been applied to cases involving children whose births-or medical conditions discovered at birth-are either unanticipated or unwelcome. While these theories are not novel, plaintiff attorneys have attempted to extend or redefine them to fit these high-technology cases, with varying results.

■ Wrongful birth is recognized by most jurisdictions and usually involves a claim by parents that their child's birth would not have occurred "but for" the actions or inactions of one or more medical professionals. In other words, if the parents had only been given certain information-such as the results of a key genetic test-they would never have conceived or brought the pregnancy to term. The resulting child may or may not have genetic abnormalities. (If parents took steps to avoid having children, such as having a vasectomy, even the birth of a healthy child may be unwanted and they may seek child-rearing costs.)

■ Wrongful conception claims are less common. They typically involve claims by parents that they would never life is better than none and on the rationale that public policy frowns on assigning damages for a life.5

Wrongful birth and wrongful conception cases, however, are often allowed on the theory that parents who face extraordinary costs in rearing a child with a severe medical condition they did not anticipate should be permitted to recover those costs. Recent court cases highlight some of the novel

In California, a sperm donor passed on a serious kidney disease to a baby girl. The donor noted on his intake form a family history of kidney disease, but the sperm bank failed to act on that knowledge.

have conceived but for a professional's negligent or intentional actions, such as a failed sterilization or a misdiagnosis or miscommunication relating to a parent's or donor's health or that of a preimplantation embryo. While many such cases are also, or alternatively, brought as wrongful birth cases, wrongful conception can be an alternative liability theory in jurisdictions that do not recognize wrongful birth claims. Here, too, the child may or may not have genetic abnormalities.

- Wrongful life claims, in contrast, are brought on behalf of the child and allege that but for the defendant's actions or inactions, the child would not have been born. Often, the child plaintiff has a serious impairment that significantly affects the quality or length of his or her life.
- Negligence, medical malpractice, and fraud and other tort claims are frequently brought as alternative theories of liability.

Claims for wrongful birth, conception, or life are most often brought against the doctors who performed, or failed to perform, prenatal or preconception genetic testing; the hospitals or medical practices that employed the physicians; and genetics laboratories that provided, or failed to provide, the testing services. Most states refuse to recognize a child's wrongful life claim on the theory that any legal challenges created by these fastmoving technologies.

Testing the tests

Diagnostic mistakes can occur in genetic testing performed on embryos, gametes and gamete donors, fetuses, and parents. Most litigation (outside of criminal forensics) claims that children were born with genetic abnormalities because of faulty testing-either because the parents weren't offered testing or because the tests were incorrectly administered. Most, but not all, states that allow wrongful birth cases also allow damages for extraordinary child care costs but not for normal child-rearing expenses. The states vary widely on whether parents can recover emotional distress damages.6

At least two courts have confronted the tragic consequences of a failure to screen gamete donors for genetic abnormalities.7 In Johnson v. Superior Court of Los Angeles County, a California sperm

SUSAN L. CROCKIN is principal and ELIZABETH M. BLOOM is an associate with Crockin Law and Policy Group in Newton, Massachusetts. GAIL H. JAVITT is law and policy director and SUSANNAH BARUCH is director of reproductive genetics at the Genetics and Public Policy Center, Berman Bioethics Institute, Johns Hopkins University.

donor passed on a serious genetic condition, autosomal-dominant polycystic kidney disease (APKD), to a baby girl. The donor had noted on his intake form that he had a family history of kidney disease, but the sperm bank failed to act on that knowledge or inform the prospec-

tive parents of the risk.8

In the second case, *Paretta v. Medical Offices for Human Reproduction*, a New York medical program failed to report that an egg donor had tested positive as a carrier for cystic fibrosis. The couple who selected her as a donor then con-

ceived a child with the disease, presumably because the father was also a carrier (albeit untested and undetected).⁹

In *Johnson*, the parents and child sued the commercial sperm bank and two of its physicians, alleging professional negligence, fraud, and breach of

Consider juror emotions, politics in wrongful birth cases

E. DREW BRITCHER, ARMAND LEONE, AND JESSICA CHOPER

Courts respond to wrongful birth claims in a wide variety of ways, largely because these cases require judges to evaluate not just the law, but also questions of morality, medicine, and society.

The Rhode Island Superior Court, in an unpublished opinion, observed that these cases are essentially about abortion. (*Schloss v. Miriam Hosp.*, 1999 WL 41875 (R.I. Super. Jan. 11, 1999).) Those who can accept the legality of abortion have no difficulty finding room in the common law tort of negligence for a claim of wrongful birth. Those who cannot accept it think no one should be compensated for being unable to have an abortion.

This observation highlights the way wrongful birth actions are intertwined with politically and emotionally charged views that jurors may hold. Plaintiff lawyers must keep this context in mind when handling a case.

Case evaluation. Be realistic in your evaluation. First, you should be comfortable with a woman's right to elect an abortion, for any reason, through the end of the second trimester. If you are not, you will not be an effective advocate for your client's rights. Remember, most of the findings that lead to these abortions are discovered after the 15th week of gestation.

Second, you must feel that the average pro-abortion-rights juror would understand your client's decision. For example, one case that we chose not to handle involved a couple whose child was born without one hand but was otherwise healthy. The absence of the hand could

be seen on the ultrasound printout, and it was clear that someone at the hospital had simply missed it. Nevertheless, we thought that even a juror who favored abortion rights would have a hard time believing that the parents would have terminated the pregnancy for that reason.

Third, recognize the significance of religion. Evaluate your client's commitment to her right to choose. Always remember: Questions should focus on what the client would have done *at that time*, not now that the child is born.

Thanks to an adversary who asked a Catholic client of ours at deposition some rather aggressive questions, assuming that she would be troubled by them, we learned one of the most important questions to ask—and a common response. He asked our client, "Who did you ever tell of your views on abortion?" She answered that she had told her mother that she believed women had the right to choose abortion. She also provided the time and place of the conversation, which took place long before not only the deposition and the conception, but also before my client's marriage.

Since then, we ask every potential wrongful birth client, "Who can verify that you would have made the decision to terminate?" Surprisingly, perhaps, it is often the woman's mother.

Jury selection. This step is everything. You must argue that your clients have a right to a jury that fully accepts the legality of abortion. Try to get a written jury questionnaire that delves into each potential juror's views. You must convince the trial judge that you have the

same right to screen potential jurors as someone trying a capital case. The argument is straightforward: There are no two issues on which most jurors have a more developed, embedded, and ardent conviction than the death penalty and abortion.

In our trials, we provide a 50-question screening questionnaire that asks potential jurors for their views on certain issues, to make sure every juror can confirm his or her acceptance of the right to a lawful abortion. Any juror who does not is challenged for cause. Individual voir dire in chambers is essential, because an entire panel could be voided by one overzealous member.

Trial. Focus the testimony on the severity of the child's anomalies. This helps the jurors understand the devastating consequences of your client's loss of the power to make her own decisions. Be sure you are comfortable with the language of abortion as a medical procedure and terms that distinguish a fetus from a child.

With careful selection and proper planning, these can be rewarding cases to pursue. Many of the families involved face heavy financial, emotional, and physical difficulties because of their children's special needs. These cases are a wonderful opportunity to ease these burdens and improve the child's life as well as that of his or her parents.

E. Drew Britcher, Armand Leone, and Jessica Choper are partners at Britcher, Leone & Roth in Glen Rock, New Jersey.

contract. While certain issues were specific to California law—including the court's conclusion that the defendants were acting as medical providers and were therefore protected by state malpractice statutes—others are of more general applicability.

Stating that "we recognize the harshness" of the rules, the court nevertheless characterized the child's action as a wrongful life claim and denied her general damages, damages for pain and suffering, and lost earnings. ¹⁰ It left open the possibility of the lower court rein-

allow the former to recover damages but not the latter. The court also denied the parents' claim for emotional distress and loss of services but allowed their claim for punitive damages, based on allegations of the defendants' grossly negligent or reckless conduct, to go forward.

Both courts found that the gamete donor, not the sperm bank or medical facility, had caused the children's disease, and each rejected the children's claims of wrongful life.

Prenatal genetic testing that does not

Today, tests are available for almost 1,000 genetic diseases. Mistakes in testing or failure to accurately convey test results are inevitable, and as options have multiplied, so have the chances of error.

stating a dismissed fraud count brought by the parents.

In Paretta, the couple followed their medical program's recommendation to use the ova of a prescreened donor, with disastrous results. Although the program's "custom and practice" was to screen donors for CF, among other diseases, it failed to notify the couple that the donor had been screened for and found to be a carrier of cystic fibrosis or to test the husband, and their child was born severely impaired.

The couple and the child sued the program, alleging it had failed to properly screen the egg donor, inform the parents, or test the father. The complaint alleged "negligent preconception and preimplantation counseling" and lack of informed consent, and the parties filed cross-motions to dismiss and for summary judgment.

The court rejected the plaintiffs' theory that "by combining the sperm and egg, the doctors had a role in [the child's] genetic composition." The court found that a baby "does not have a protected right to be born free of genetic defects" and concluded that the law does not recognize a distinction between IVF children and children born without medical assistance that would

involve donors has also been the subject of recent litigation. Two recent cases from Ohio and New Hampshire illustrate the novelty of these issues and the creative legal work that can result.

In Schirmer v. Mt. Auburn Obstetrical and Gynecological Associates, Inc., prenatal testing failed to pick up a Trisomy 22 (three copies of chromosome 22 instead of two) in the fetus. The child was born with severe permanent disabilities. The court limited the parents' recovery to the costs of pregnancy and birth.¹²

Genetic carrier testing of the mother had indicated she had a "balanced translocation" of chromosomes 11 and 22, which meant that while she was unaffected, there was a risk that her children could have an abnormal number of chromosomes. During the pregnancy, a CVS revealed a normally developing female infant with the same balanced translocation as the mother. The birth of an affected son suggests that the CVS sample had included some of the mother's DNA.

On appeal, the Ohio Supreme Court approached the case as a wrongful life claim, rejecting all claims for consequential economic and noneconomic damages and saying that the "crux of this case is a comparison of nonexistence versus existence, albeit impaired."¹³ A clearly divided court issued four separate opinions and a strongly worded dissent. One justice, concurring in part and dissenting in part, noted disapprovingly that the decision would make Ohio the only state to recognize a cause of action for negligent prenatal counseling while disallowing recovery for the extraordinary costs of raising the child.¹⁴

The court also found—as had the California and New York courts—that the defendants had not caused the child's genetic condition. Since the plaintiffs argued that they would have terminated the pregnancy had they known of the child's impairment, the court did find them entitled to the costs of the continued pregnancy and delivery.

An unrecognized distinction between this case and the donor and PGD cases is that in the latter, someone—a physician, embryologist, or parent—selected a particular gamete or embryo from other available ones, and the resulting child had the abnormality. Whether that distinction will blossom into a future basis for a viable legal claim remains to be explored.

Another recent decision, Hall v. Dartmouth Hitchcock Medical Center, 15 highlights both the limits of medical science and the challenges for parents, professionals, and courts when, despite extraordinary efforts, things go tragically wrong. After a couple's initial prenatal screening showed an elevated risk of Trisomy 18 in their developing fetus, they underwent more tests.

These tests ruled out Trisomy 18 and other severe genetic abnormalities but raised some questions about the fetus's health. Further testing at the end of the second trimester continued to raise concerns, and with very little time left to terminate the pregnancy, the parents arranged for additional testing and counseling at two Boston teaching hospitals. Ultrasounds showed the fetus had clenched hands and a small lower jaw, but not the other problems detected by the defendants.

The couple continued the pregnancy, and their child was born with severe impairments. After the birth, more ex-

tensive genetic testing of the child and his parents revealed a rare chromosomal abnormality, partial Trisomy 9q, which, the court noted, was the first reported case of this abnormality.16

The Halls' suit against the hospital and medical geneticist alleged negligence for failing to inform them of an increased possibility of serious birth defects, to disclose the results earlier, and to recommend additional testing. The plaintiffs said that with better information, they would have terminated the pregnancy.

The jury found for the plaintiffs, but the New Hampshire Supreme Court reversed, saying the Halls' experts had failed to show that the test results could have been disclosed sooner or that there wasn't time to get an abortion.17 Given the extreme rarity of the child's disorder, it is unlikely any court would have found liability. But the case raises challenging questions about the impact of expert witnesses in this stillemerging area of litigation.

It also illustrates that even tremendous advances in genetic testing may be outpaced by parental expectations, as test results often will not be definitive. Moreover, given the pace of technological changes, standards of care will likely always lag behind what is technologically feasible. In this case, it was possible to find the mutation, but not by using standard-of-care technologies and procedures. For plaintiff lawyers, this means needing to be particularly attentive to changes in technology and practices. For plaintiffs, it may mean that mistakes with dramatic, and perhaps tragic, human consequences for their families may nonetheless not result in legal liability.

As this article was in press, a novel question involving conflicts of law, with significant impact on the application and outcome of wrongful birth and conception claims, was reported to the Maryland Court of Appeals. That court has been asked to decide whether the state law where the test was administered, or where the family resides, applies, with recovery turning in large part-at least under one of the state's laws-on whether the test was administered before or after

Pre-Settlement Funding

Non-recourse funding solutions for Plaintiffs and Plaintiff lawyers. We offer quick service and reasonable rates while respecting your ethics and need for confidentiality. We fund case and client living expenses. Call today for case evaluation and funding proposal.

EXPRESS

Lawsuit Funding LLC

t: (866) 688-2900 f: (248) 645-1222 www.expresslawsuitfunding.com info@expresslawsuitfunding.com



Imagine your next trial... the jury hangs on your every word. Your organized, insightful presentation has never been better. You're using TrialDirector! Winning litigators use TrialDirector to organize exhibits and depositions, prepare their cases for trial, and enhance their presentations.

To get your FREE evaluation software, visit www.indatacorp.com or call 800-828-8292.



Need Direction With Your Marketing?



Use Our Proven Marketing System

The System That Built The Largest Plaintiffs Firm In The Country.



Call 877-PMP-MARK • (877-767-6275) pmpmarketing.net

HEALTH CARE

conception. This distinction would have serious implications for these developing technologies.¹⁸

Embryonic litigation

With PGD testing of IVF embryos becoming more widely available, more errors are inevitable. In one of the few reported cases, *Doolan v. IVF America, Inc.*, a couple's child was born with CF even though their 10 embryos had been PGD-tested. They sued the IVF clinic and the doctor who performed the test for failing to properly detect the condition. 20

The trial court rejected the parents' attempt to characterize their claim as a novel "preconception tort." Applying established and disfavored wrongful life principles, the court also noted that the genetic mutation, and not the physician or clinic, actually caused the child's disease, and the defendants could not be held liable for it.

As more prospective parents use PGD testing, more courts will have to address the unique dimensions of this technology and reconsider traditional legal theories. Although medical professionals do not "cause" a genetic disorder in a gamete or embryo, they are frequently responsible for selecting or excluding specific gametes or embryos, presumably to create a particular type of child-that is, one who is healthy or has particular genetic characteristics. Yet patients, physicians, lawyers, and the courts may know little about PGD and how often the test should be performed, for what reasons, and with what degree of success. Until experts create a reliable and comprehensive database of PGD testing and outcomes, we won't know these things.21

Bringing the tests home

Direct-to-consumer (DTC) genetic tests are now available over the counter (or more accurately, over the Internet). ²² A test called the BabyGenderMentor recently received press attention after failing to deliver on its promise to determine within 99.9 percent accuracy the sex of a fetus at as early as five weeks of pregnancy. ²³ Despite numerous com-

plaints filed with the Federal Trade Commission, that agency has not taken any action. Nor has the FDA (which regulates home pregnancy tests) or the Centers for Medicare and Medicaid Services (CMS) (which regulates clinical laboratories).24

Although the FDA and CMS each has potential oversight of home-based genetic-testing kits, both claim a lack of jurisdiction because the testing is for a non-health-related purpose and is not performed by a clinical laboratory. A class action suit was filed on behalf of thousands of women against both the lab doing the testing for the Baby-GenderMentor and the company distributing it.25

At least a dozen Web sites offer DTC genetic tests for everything from Alzheimer's disease to nutritional guidance based on one's genetic profile, all without government review to ensure they provide accurate health information.26

Litigation is likely to make inroads into the ways courts characterize and resolve claims resulting from failure to provide genetic counseling, failure to perform genetic tests, or failure to accurately report test results. Skillful lawyers and sympathetic plaintiffs may move courts to shift their views of these claims. As preconception genetic testing of and information about donors, gametes, and IVF embryos become more prevalent, courts are likely to become more accepting of claims for wrongful conception and wrongful preconception counseling, and judges may expand their views of what types of claims are appropriately seen as wrongful birth and professional negligence.

These new technologies will test both statutes of limitations and standards of care. The time limit for bringing claims after genetic abnormalities are discovered is likely to stretch, potentially into future generations. The standard of care that courts apply to the performance of genetic testing services is also evolving. While precedent will continue to be relevant, new reproductive wrongs will doubtless lead to new legal theories and more evolution in the case law.

- 1. Am. College of Obstetricians and Gynecologists, Am. College of Med. Genetics, Preconception and Prenatal Carrier Screening for Cystic Fibrosis: Clinical and Laboratory Guidelines 1-32 (ACOG 2001).
- 2. Susannah Baruch et al., Genetic Testing of Embryos: A Critical Need for Data, 11 Reprod. BioMedicine Online 667, www.dnapolicy.org/ resources/GeneticTestingOfEmbryos.pdf (last accessed Aug. 31, 2006).
- 3. See generally Kathy Hudson et al., Genetic Testing of Human Embryos: Ethical Challenges and Policy Choices, in Expanding Horizons in Bioethics 103 (Arthur Galston & Christiana Peppard eds., Dordrecht: Springer 2005).
 - 4. See GeneTests, www.genetests.org (see box

recognizes the tort of wrongful birth and allows damages for the cost of rearing an affected child, whereas North Carolina recognizes the tort of wrongful conception, but not wrongful birth, and thus disallows all damages for extraordinary child-rearing costs. The outcome of the litigation will thus turn on which law governs: the jurisdiction where the lab is located and where it administered the test-which would allow recovery only if the test had been performed preconception-or where the results and the child were delivered and the fam-

19. See Doe v. Ill. Masonic Med. Ctr., 696 N.E.2d 707 (Ill. App. 1998), appeal denied, 705 N.E.2d 436 (Ill. 1998) (refusing plaintiff access to research protocol documents in malpractice

Government agencies claim a lack of jurisdiction over home-based genetic-testing kits because the testing is for a non-health-related purpose and is not performed by a clinical laboratory.

at left of page) (last accessed Aug. 31, 2006).

- 5. For a review of the jurisdictions with precedent involving these theories, see Susan Crockin, Reproduction, Genetics and the Law, 10 Reprod. BioMedicine Online 692 (2005); Susan Crockin, Reproductive Genetics: Conceiving New Wrongs? 3 Sexuality, Reproduction, & Menopause 37 (2005).
 - 6. Id.
- 7. Voluntary professional guidelines recommend certain screening tests for donors. See Am. Socy. for Reprod. Med., Guidelines for Gamete and Embryo Donation: Guidelines and Minimum Standards, and Guidelines for Cryopreserved Embryo Donation, 77 Fertility & Sterility (Supp. 5) S1 & S9 (2002).
 - 8. 124 Cal. Rptr. 2d 650 (2002).
 - 9. 760 N.Y.S.2d 639 (2003).
 - 10. 124 Cal. Rptr. 2d at 666.
 - 11. 760 N.Y.S.2d at 646. 12. 844 N.E.2d 1160 (Ohio 2006).
 - 13. Id. at 1166.
 - 14. Id. at 1173.
 - 15. 899 A.2d 240 (N.H. 2006).
 - 16. Id. at 244.
 - 17. Id. at 249.
- 18. Hood v. Lab Corps. of America, No. CCB-04-3870 (Md. memorandum and order filed June 1, 2006). This case involved a North Carolina-based lab's mistaken negative amniocentesis report done for a Maryland couple whose first child had been born with cystic fibrosis. The couple had tested and aborted their second pregnancy, and sent out tests on their third pregnancy to ensure they would not have another affected child. Relying on the erroneous negative report, they carried the pregnancy to term and delivered an affected child. Maryland

- case). A few PGD lawsuits have been settled without reported court decisions (in private consultations).
 - 20. 12 Mass. L. Rep. 482 (Super. Ct. 2000).
- 21. Led by the Genetics and Public Policy Center, the PGD Database Working Group, comprising the leadership of both the Society for Assisted Reproductive Technology and the Preimplantation Genetic Diagnosis International Society, has started this work-which should offer valuable information about current practices, error rates, and outcomes-with an eye to establishing a standard of care in this area. Baruch et al., supra n. 2.
- 22. Gail H. Javitt et al., Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can't) Do to Protect the Public's Health, 57 Okla. L. Rev. 251 (2004).
- 23. Carey Goldberg, Gender Test's Accuracy Is Questioned, Boston Globe C1 (Oct. 17, 2005); Nell Boyce, Critics Question Accuracy of Fetus Sex Test, National Public Radio (Morning Edition), Sept.
- 24. Gail H. Javitt, Pink or Blue? The Need for Regulation Is Black and White, 86 Fertility & Sterility 13 (2006).
- 25. Blumer v. Acu-Gen Biolabs, Inc., No. 06 CA 10359 RCL (D. Mass. filed Feb. 27, 2006). Information about the lawsuit is available at www. babygenderinvestigation.com (last accessed Aug. 31,
- 26. See e.g. Sandra Boodman, Too Much Information; Results of Home DNA Tests Can Shock, Misinform Some Users, Wash. Post F1 (June 13, 2006); Madeline Drexler, Your Genetic Test Is in the Mail, Good Housekeeping 205 (May 28, 2006).