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**TRIAL MAGAZINE
DRUGS AND DEVICES**

October 2002, Volume 38, No. 10

Can the law handle human cloning?

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As biotechnology races toward unraveling the mystery of life, the law and society seem unprepared for the coming legal, ethical, and moral issues. Technological advances are forcing us to address questions about the definition of life, when it begins, and what constitutes natural reproduction. What is the difference between human beings and other species? Today these questions have a certain "in your face" reality never before experienced.

Presidential edicts, committee recommendations, and a handful of state statutes have attempted to regulate cloning, but there is not yet a consistent body of law governing this burgeoning technology. Examining common law theories and extrapolating from case law developed in similar situations, such as assisted reproduction, can help lawyers prepare to face the legal challenges that lie ahead as cloning technology progresses.

In simple terms, cloning occurs when a female's donated egg is enucleated—stripped of its nucleus, which contains the deoxyribonucleic acid (DNA)—and injected with DNA generally obtained from another person's nonreproductive (somatic) cell. The egg is then exposed to a mixture of chemicals and growth factors that cause it to divide into the beginning stages of an embryo. This cloning process is called somatic cell nuclear transfer (SCNT).¹

Currently, the scientific community clearly distinguishes between cloning for human reproduction, which it does not view as viable or safe at this time, and nonreproductive cloning for stem-cell research, which it says may be one of the most innovative and promising areas for treating human diseases. For research, stem cells are harvested from the inner cell mass of early embryos. These unspecialized cells can self-renew indefinitely, and when exposed to growth factors, they can convert to more adult, differentiated cells—like muscle cells, neurons, and glandular cells. Science's challenge is to develop these stem-cell lines to the stage where they can help treat human disorders such as Parkinson's disease, muscular dystrophy, cancer, and genetic diseases.²

Cloning successes

In 1997, Dolly the sheep became the first mammalian clone successfully produced from an adult cell using SCNT. Since then, cattle, goats, pigs, mice, and one guar (an endangered wild ox native to South Asia) have been produced through cloning.³

In October 2001, Advance Cell Technology (ACT) announced it had cloned the first human cells and produced embryos. ACT's "success" was one embryo that progressed to a six-cell stage before it stopped dividing. The results did not reach the phase of a blastocyst consisting of about 100 cells, which could produce the starter stock for growing replacement nerve, muscle, and other tissues needed to treat various diseases. However, the company said the cloning had

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shown that the process might actually succeed.⁴ Other scientists criticized publication of this research and denied that it was the first cloning of human cells.⁵

In December 2001, Texas A&M University scientists—funded by a multimillion-dollar contract with a private company called Genetic Savings & Clone—produced a kitten clone, dubbed Copy Cat, from the cells of an adult cat. This raised concerns about the misguided use of technology to clone pets for money.⁶

In January 2002, Immerge BioTherapeutics and PPL Therapeutics announced that they had funded cloning research that produced litters of pigs whose organs lacked a genetic trait that would prompt the human body to reject them. This moved science one step closer to successfully using pig organs for human transplants.⁷

In early 2002, the Reproductive Genetics Institute announced that it used genetic screening to cull genes that cause Alzheimer's disease from a woman, allowing her to bear a child free of the family's susceptibility to an early-onset form of the disease. Critics called this a step toward producing "designer babies," noting that there is no bright line between "disease" and "undesirable trait."⁸

In June 2002, researchers demonstrated they could clone functional tissue that showed no signs of rejection when transplanted to cows. They cloned an embryo and implanted it in a surrogate-mother cow, where it grew for about six weeks. From the heart, skeletal, and renal cells of the growing embryo, they bioengineered tissue that was then transplanted back to the original DNA donor without rejection.⁹ This raised the possibility that a person's cells could be used to clone tissues that could be transplanted to the body without rejection.

Legal boundaries

These biotechnological advances have been made with or without the blessing of the law. Two presidents—Bill Clinton and George W. Bush—various committees, the FDA, and the states have weighed in on whether cloning research should be funded or pursued.

The announcement in 1997 that a sheep had been cloned set off an explosion of government concerns. Within days, Clinton requested a report on cloning from the National Bioethics Advisory Committee (NBAC). Without waiting for the report, he issued an executive order barring the use of federal funds for cloning research. The NBAC concluded on June 9, 1997, that concerns about safety and efficacy made any attempt at human cloning immoral and contrary to public policy.¹⁰

The National Academies and several scientific boards held a workshop in June 2001 to address the issue of using cloning to grow human embryos for stem-cell research. In findings published this year, the group recommended pursuing studies of embryonic human stem cells and establishing a national advisory group at the National Institutes of Health to oversee the research.¹¹

In August 2001, Bush issued an executive order prohibiting the use of federal funds for research involving stem cells derived from human embryos, including those generated from cloning. In published findings, the National Academies noted that the ban addresses only federally funded research and does not directly affect the private sector. Thus, for-profit biotech companies can continue to conduct stem-cell research.

The academies also pointed out that, over time, cells grown in tissue cultures in the laboratory change and typically accumulate harmful genetic mutations, making them potentially unusable. The existing stem-cell lines available for research may have these same problems.¹²

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In July 2001, the House of Representatives passed a bill banning all human cloning. The Human Cloning Prohibition Act mandates civil and criminal penalties for anyone "participating in, performing, or attempting to perform" human cloning.¹³ At press time, the legislation had stalled in the Senate, where it appears that a majority favors a bipartisan bill sponsored by Sen. Dianne Feinstein (D-Cal.) and Sen. Orrin Hatch (R-Utah), which bans human reproductive cloning but allows cloning for stem-cell research. This bill, however, does not have the support of 60 senators, which is needed to overcome a likely filibuster.¹⁴

One agency, the FDA, has announced its authority to regulate cloning of human cells. In early 1998, Acting Commissioner Michael Friedman warned that conducting the procedure without FDA approval would violate federal law and that the agency would initiate legal action against anyone who attempted it. However, the FDA has not previously asserted jurisdiction over similar procedures, such as assisted reproduction. For the agency to have jurisdiction over cloning, a clone of an embryo would have to be defined as a "product" for use in the treatment of a disease or condition.¹⁵

At the state level, California, Louisiana, Michigan, Rhode Island, and Virginia have passed statutes barring human cloning, and nine states have already banned all experiments conducted on human embryos. In 2002, more than 22 states introduced laws banning or restricting research with human embryos.¹⁶

Law before cloning

Aside from these edicts, recommendations, and state statutes, no laws currently regulate cloning. In the absence of clear legal guidelines, lawyers will need to study the existing law covering reproductive processes in light of their potential application to cloning technology.

Abortion law—when life begins. In 1973, the U.S. Supreme Court wrote in *Roe v. Wade*:

We need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer.¹⁷

The Court's decision in *Roe* was that the fetus does not gain the protection of the state until it becomes "viable," or able to live outside the mother's womb, at about seven months.¹⁸ This position has been retained and reaffirmed in more recent decisions by the Court, though with increasingly strong dissent.¹⁹ With human cloning imminent, the courts will no doubt be forced to make a more thorough analysis of when life begins.

In vitro fertilization (IVF), egg donors, and surrogate mothers—how life begins. To some extent, cloning may be seen as an extension of IVF because it involves human procreation outside the body—and it potentially creates similar injuries and victims. For a human to be cloned, there must be a woman to donate an egg and a surrogate mother to nurture and give birth to the cloned child.

The first live birth of a child conceived in vitro occurred in 1979 in Great Britain.²⁰ Since then, IVF and other fertility procedures have helped many infertile couples, same-sex partners, and single parents have their own children. The use of fertility procedures in the United States is on the rise, increasing by 27 percent between 1996 and 1998; a current estimate is that 50,000 IVF babies are born annually.²¹

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Some women who participated in the earliest use of IVF have since spoken out against it. They accuse the industry of using them wrongfully—without considering their health or emotional well-being—and criticize IVF technology because of its numerous complications and high failure rate.²² These same drawbacks will no doubt arise with the first attempts at cloning humans.

Women who are egg donors, for example, may put themselves at considerable risk for profit: There is a significant market for young women willing to provide eggs to fertility clinics. But what may seem like a straightforward procedure has many hidden pitfalls.

Normally, a woman produces only one or two eggs during her monthly cycle. To be useful as a donor, she must take medications that can cause ovarian hyperstimulation syndrome, which can result in thromboembolism, stroke, and death. Other serious complications of ovarian stimulation include liver damage, kidney failure, and heightened risk of ovarian cancer. Also, the surgery to harvest the eggs carries the danger of infection, hemorrhages, and pelvic scarring.²³

Money seems to be a motivating factor for women who voluntarily put themselves at risk for life-threatening complications. The amount offered to egg donors appears to be increasing as couples more openly seek women of high intelligence and other desirable attributes. For example, offers as high as \$80,000 have been advertised to entice women from the country's best schools to donate eggs.²⁴

Fertility clinics require donors to sign broad consent forms acknowledging the disclosure of various risks. There are significant questions about who covers the cost of related health problems, because most health insurance policies will not provide benefits for either egg donors or women undergoing IVF as a prospective parent. Apparently, one company now offers insurance to fertility clinics to cover donors' potential complications.²⁵

So far, it seems that no donors have filed suit for injuries. If cloning for stem-cell research is given the green light by Congress, the need for egg donors will increase. Women may begin filing suits for injuries they incur from taking potentially harmful drugs to stimulate their ovaries. Causes of action might include lack of informed consent, medical malpractice, fraud, and products liability. The first hurdle, however, will be the consent form that a donor signs, agreeing to increase her egg production by taking drugs with serious side effects in exchange for a few thousand dollars.

If human cloning is to be used for reproduction, surrogate mothers will be needed to carry the fetus and give birth. Even if cloning techniques progress to a level considered to be "safe," there will still be risks to the physical and emotional health of the surrogate.

The courts have recognized some of the IVF risks to both surrogate and child and have held fertility clinics liable for failing to screen prospective parents properly.

In 1992, a surrogate mother sued the broker who arranged the artificial insemination and surrogacy after the child she carried was born with an incurable sexually transmitted disease. She claimed she had been infected by the father's semen and that the broker had been negligent in not testing him. The Sixth Circuit found that the broker and other professionals who profited from the program had a "special relationship" with the surrogate mother that gave rise to affirmative duties to reduce the risk of harm to her and the child.²⁶

Five years later, another surrogate mother brought a case against the same fertility clinic for wrongful death on behalf of the child, who was shaken to death by the father within a month of his taking custody. The Pennsylvania Superior Court upheld claims based on negligence for the clinic's failure to screen the prospective parents, but it dismissed claims for negligent infliction of emotional distress, breach of fiduciary duty, and fraud.²⁷

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The duty imposed on the fertility clinics in these cases might also be applied to a cloning clinic for its duty to screen the egg donors, the DNA donors, and the parents of the prospective cloned child.

Embryos—after conception. The status of the embryo continues to be legally and ethically troubling. Much of the recent congressional debate surrounding stem-cell research centers on the question of why the embryos were created. Embryos are created at fertility clinics for implantation and birth; in stem-cell research, embryos are used to grow stem cells, and then they are destroyed. Whether researchers take unused embryos from fertility clinics or clone them directly, the final outcome for the embryo in stem-cell research is destruction.²⁸

Embryos do not have constitutional rights as people, and recent court decisions have treated frozen embryos as the property of those from whom they spring. In a 1989 case, a husband and wife sought to transfer their frozen embryos from a reproductive institute to a hospital in California. The doctors at the institute refused to consent to the transfer, and the court determined that the institute was a bailor of the plaintiffs' property and had an absolute obligation to return the property when asked.²⁹

In a recent case, the Rhode Island Superior Court shared this view. Three women whose frozen embryos had been lost or inadvertently destroyed during an IVF clinic's relocation claimed medical malpractice, bailment, breach of contract, loss of irreplaceable property, and severe emotional distress.³⁰

The court held that the embryos did not have a legal status and could not be victims of wrongful death, and that the plaintiffs did not witness the destruction of the embryos and therefore could not maintain a successful claim for negligent infliction of emotional distress. However, it did allow the plaintiffs to recover damages for emotional distress for the loss of irreplaceable property.³¹

Even with these decisions on the books, the law is inadequate, at this point, to decide the legal status of an embryo that was created through cloning. Some courts view embryos as property, but if the FDA's claim of jurisdiction over cloning is upheld, it will change embryos' status. The agency's jurisdiction claim is based on defining an embryo created through cloning as a product for use in the treatment of a disease or condition. Under this definition, lawyers may see the development of a new area of products liability law. As cloning technology reaches the stage of creating embryos for stem-cell research, someone who receives tissue generated from cloned stem cells could bring a defective product suit against the laboratory that did the cloning and grew the cells.

Other cloning considerations

The SCNT cloning process does not require a sperm donor. Instead, the egg is filled with DNA material from a nonreproductive cell, which is generally taken from a donor's skin. The skin biopsy to harvest the cells involves little risk other than possible infection at the site.³² However, if the resulting embryo has been created for reproduction and contains the DNA of the skin donor, the validity of any contract relinquishing the donor's parental rights could come into question.

In comparing DNA donors' potential rights with those of surrogate mothers in cases in which they have challenged the validity of their contracts relinquishing parenthood, the courts seem split over whether the contracts are valid. In *In re Baby M*, the New Jersey Supreme Court threw out the surrogacy contract as conflicting with the law.³³ Several years later, under somewhat different circumstances, the California Supreme Court upheld a challenged surrogacy contract.³⁴

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Although people might anticipate that the clone of a child would be a duplication of the original DNA donor, clones are likely to differ from their donors more than identical twins differ, because such a clone results from a different egg (with distinct mitochondrial DNA), gestates in a different womb, and grows up in a different environment.³⁵ This could cause emotional distress for parents who pay to clone a baby from a child of theirs who died—if the cloned child does not look or act like the child they were trying to replace. There would also be issues of informed consent and whether the family had been fully informed about the cloning process.

If human cloning ever becomes a reality, new areas of litigation will almost certainly emerge. For example, since a child clone was not a party to the cloning contract and had no legal status at that time, he or she could make valid claims against both the institution and his or her parents for the cloning process, which is experimental and known to result in a high percentage of deformity, early death, and premature aging.³⁶

Intended parents might also make claims for wrongful birth of a disabled child, or a child might file a claim for wrongful life. Most states, however, do not allow causes of action on behalf of a child for wrongful life—believing that life with a disability is better than no life at all—and only allow for special damages to cover the cost of treatment.³⁷

In recent years, in an attempt to increase the pool of organs available for transplant, researchers have conducted extensive experimentation on animal transplants. Transgenic pigs, which are genetically altered to include a human gene or genes, have been successfully cloned—a development that would decrease the risk of rejection if these animals' organs were transplanted to a human.³⁸ As one author points out, this raises new issues about how many human genes can be added to a pig before the pig enjoys the legal rights of a human being.³⁹

Cloning pigs and other animals for harvesting organs to transplant to humans raises the risk of cross-species diseases. Infections that might be transplanted with an animal's organ or tissue and cause illness in humans are referred to as zoonoses.⁴⁰

In 1998, James Thomson, a professor at the University of Wisconsin at Madison, developed the first human embryonic stem-cell cultures.⁴¹ They have the amazing ability to self-renew continuously, without differentiating, if they are grown in petri dishes on a layer of mouse embryonic fibroblasts (called "feeder cells") in a medium containing serum from cows. Once removed from the feeder cells and grown in suspension, the stem cells form embryonic bodies that give rise to many different cell types. Cells taken from these embryonic bodies have been shown to display genes associated with liver, pancreas, and blood cells.⁴²

The risk of zoonoses is associated with the mouse feeder cells used in this experiment. The cross-species danger affects not only the intended human recipient, but also the population at large. A recipient of cells grown on mouse feeder cells who develops a cross-species disease might sue the laboratory, doctors, or hospital for products liability, negligence, fraud, intentional infliction of emotional distress, and lack of informed consent. There might also be class actions formed on behalf of a general population for being exposed to and contracting a cross-species disease; these would involve issues of statute of limitations and insurance coverage.

The biotechnology revolution is changing what it means to be human. Medical technology expert Gregory Stock suggests, in his recent book *Redesigning Humans*, that the road to our eventual disappearance as humans might be paved by our success, not our failure. "Progressive self-transformation could change our descendants into something sufficiently different from our present selves to not be human in the sense we use the term now," he writes.⁴³

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Over the next decade, some lawyers may start seeing potential clients with grievances never before contemplated. Using common law theories and case law developed in IVF and similar areas, attorneys will have to be innovative and informed to vigorously represent clients through the chaotic changes that the biotechnological revolution is likely to bring.

Notes

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3. CAL. ST. REP., *supra* note 2, at I.B.1-3.
4. Cibelli et al., *supra* note 1 (noting that cloned early-stage human embryos put therapeutic cloning within reach).
5. *The Business of Cloning*, 359 LANCET 1 (2002).
6. Abate, *supra* note 1.
7. Jeremy Manier, *Pig Cloning Offers New Organ Hope*, CHI. TRIB., Jan. 4, 2002, at 1.
8. Brian Alexander, *The Remastered Race*, WIRED, May 2002, at 68.
9. *Cloning: Researchers Create Functional Tissue in Cows*, GENOMICS & GENETICS WKLY., June 21, 2002, at 2.
10. CAL. ST. REP., *supra* note 2, at I.A.
11. *STEM CELLS*, *supra* note 2, at 55-59.
12. *Id.* at 3-5; *see also The Business of Cloning*, *supra* note 5.
13. H.R. 2505, *available at <http://thomas.loc.gov/home/thomas.html>*.
14. Sheryl Gay Stolberg, *Total Ban on Cloning Research Appears Dead*, N.Y. TIMES, June 14, 2002, at A31. The opposing legislation sponsored by Sen. Sam Brownback (R-Kan.) is identical to the House bill.
15. CAL. ST. REP., *supra* note 2, at I.C.1.

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16. Sheryl Gay Stolberg, *States Pursue Cloning Laws as Congress Debates*, N.Y. TIMES, May 26, 2002, at 1; Heather Johnson Kukla, *Embryonic Stem Cell Research: An Ethical Justification*, 90 GEO. L.J. 503, 517 (2002).
17. 410 U.S. 113, 159 (1973).
18. *Id.* at 163-64.
19. See *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Stenberg v. Carhart*, 530 U.S. 914 (2000).
20. *Developments in the Law—Medical Technology and the Law*, 103 HARV. L. REV. 1519, 1537 (1990).
21. Erin McClam, *Fertility Procedures on the Rise—CDC Warns of Risks*, ASSOCIATED PRESS, Feb. 8, 2002.
22. For women's stories regarding their IVF experiences, see INFERTILITY, WOMEN SPEAK OUT ABOUT THEIR EXPERIENCES OF REPRODUCTIVE MEDICINE (Renate D. Klein ed., 1989) [hereinafter INFERTILITY].
23. Randy S. Morris, *Complications and Side Effects of Oocyte Donation*, in PRINCIPLES OF OOCYTE & EMBRYO DONATION 97-104 (Mark V. Sauer ed., 1998).
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25. Susan L. Crockin, *Statutory and Case Law Governing Oocyte and Embryo Donation*, in PRINCIPLES OF OOCYTE & EMBRYO DONATION, *supra* note 23, at 256. For a discussion of potential ERISA plan benefits for women participating in in vitro fertilization, see *Wald v. S.W. Bell Corp. Customcare Med. Plan*, 83 F.3d 1002 (8th Cir. 1996) and *Stumpf v. Med. Benefits Admin'r*, 179 F. Supp. 2d 1100 (D. Neb. 2001).
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27. *Huddleston v. Infertility Ctr. of Am., Inc.*, 700 A.2d 453 (Pa. Super. Ct. 1997).
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29. *York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989) (alleging causes of action for breach of contract, quasi-contract, detinue, and 42 U.S.C. §1983).
30. *Frisina v. Women & Infants Hosp.*, No. CIV. A. 95-4037, 2002 WL 1288784, at *2 (R.I. Super. Ct. May 30, 2002).
31. *Id.* at *8, *10.
32. *Cibelli et al.*, *supra* note 1, at 49-50.

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33. 537 A.2d 1227 (N.J. 1987).

34. Johnson v. Calvert, 851 P.2d 776 (Cal. 1993).

35. CAL. ST. REP., *supra* note 2, at I.B.2.a.

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40. *Id.* at 219.

41. STEM CELLS, *supra* note 2, at 7.

42. *Id.* at 32-34, 38.

43. GREGORY STOCK, REDESIGNING HU MANS: OUR INEVITABLE GENETIC FUTURE 4 (2002).

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