

# Attack of the Clones

As cloning technology marches forward, state legislatures are faced with some hard decisions.

By Alissa Johnson

First, it was sheep. Then, it was “CC,” the cloned house cat. If a cloned sheep spawned CC’s creator Genetic Savings and Clone, where pet owners can bank Fido’s DNA, then what could spring from cloned humans?

Cloning first hit the front page with the birth of Dolly in 1997, a lamb created using the nucleus of a cell from her mother’s body. Even before then, decision makers were debating the ethics of human cloning. In fact, researchers began laying the foundation for cloning technology more than 100 years ago. The clamor of debate, however, was fueled as never before by an announcement last December that an obscure religious sect had, indeed, cloned a human being.

“Cloning a baby is just the first step” toward human immortality, said former French journalist Claude Vorihon, who calls himself Rael and claims to be a direct descendant of extraterrestrials who created life on earth through genetic engineering.

In fact, the Raelian’s commercial offshoot, Clonaid, says they have cloned several human babies in recent months. Although Clonaid has not allowed scientists to conduct genetic tests to prove their contentions, the announcements have ignited an incendiary policy debate.

Clonaid’s claims, however, have not caught lawmakers by surprise. Since Dolly, the number of cloning bills introduced in state legislatures has grown each session. From 2001 to 2002 alone, the number of states taking on the issue quadrupled. The flurry of legislative activity has resulted in laws that restrict, prohibit or even encourage some forms of human cloning in seven states. The debate also has led lawmakers to examine the use of cloned embryos for stem cell research.

## CLONING 101

The process of human cloning begins with removal of the nucleus from a human cell, such as a skin cell and transferring it to a woman’s egg cell from which the nucleus has been removed. Through electrical stimulation, the egg cell then begins to divide. In reproductive cloning, the egg cell continues to develop into an embryo that is subsequently implanted into a woman’s uterus. If the procedure leads to a live birth, the resulting human primarily inherits the person’s genetic material from which the cell was taken. The clone also would carry traces of mitochondrial DNA found in the cytoplasm (the sub-

stance the surrounds the nucleus) of the egg cell.

Therapeutic cloning, or cloning for the purpose of research, begins in the same way, but development of the organism is typically halted during an early (blastocyst) stage when the original cell has divided into eight cells. Then, stem cells, which have the unique ability to generate specialized cells, such as liver cells or brain cells, are extracted for use in scientific research.

## FEDERAL REGULATIONS

Although the U.S. House of Representatives passed a measure to ban both therapeutic and reproductive cloning in February, the bill is waiting action in the Senate at press time. Several competing bills that would prohibit all or some forms of human cloning are also pending in Congress. Even so, federal regulations already restrict the activities of federally funded researchers.

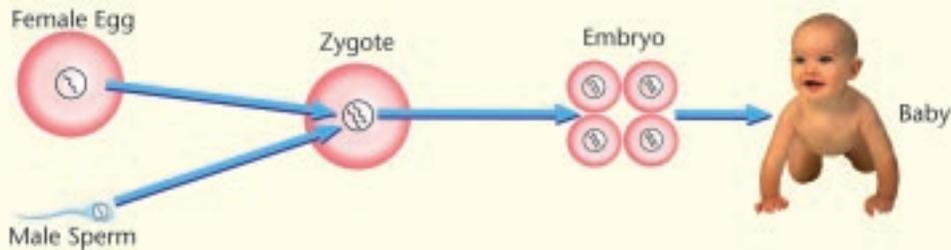
Former President Bill Clinton established the first federal policy to directly address reproductive and therapeutic cloning with an executive order that prohibited certain activities related to embryonic research, including human cloning, in federally funded projects. And President Bush addressed the nation in August 2001 to announce that researchers could not use federal money to harvest new cells from embryonic stem cells. Studies on cells already generated are permitted.

There is no federal law prohibiting reproductive or therapeutic cloning using private money. In a 1993 notice, the Food and Drug Administration (FDA) announced that it would regulate reproductive cloning. The agency requires researchers to submit an application to

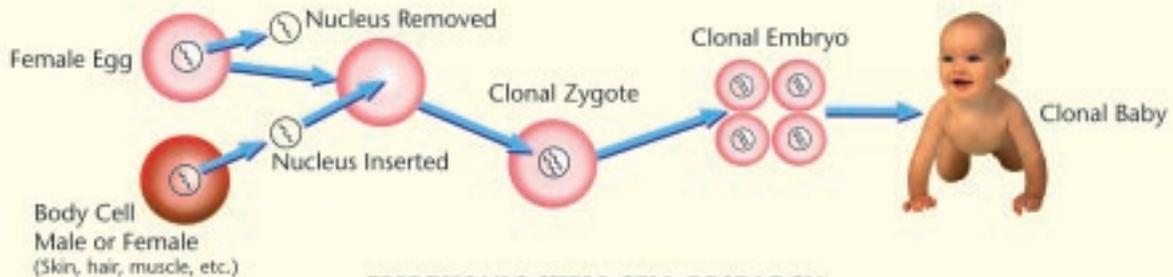
Alissa Johnson tracks genetics issues for NCSL.

STATE CLONING LAWS		
State	Prohibits Reproductive Cloning	Prohibits Therapeutic Cloning
California	Yes	
Iowa	Yes	Yes
Louisiana	Until July 2003	
Michigan	Yes	Yes
Missouri	Prohibits state funds	
Rhode Island	Until July 2010	
Virginia	Yes	Unclear

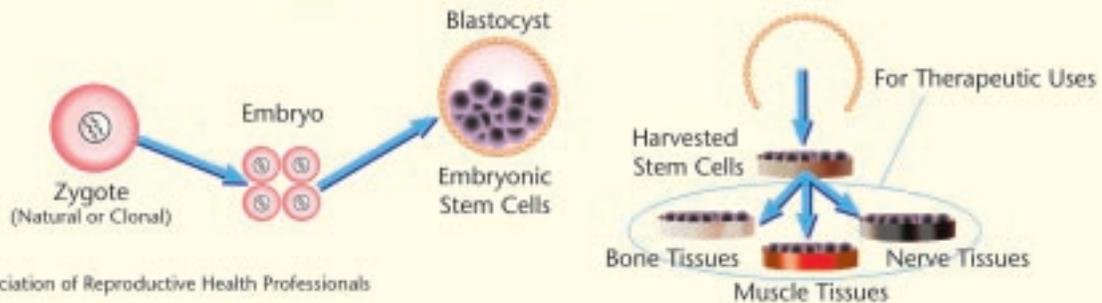
## SEXUAL REPRODUCTION



## REPRODUCTIVE CLONING



## EMBRYONIC STEM CELL RESEARCH



Source: Association of Reproductive Health Professionals

conduct studies involving biological products. Former director of the Center for Biologics Evaluation and Research (CBER) at the FDA Kathryn Zoon testified to Congress in 2001: "FDA believes that there are major, unresolved safety questions on the use of cloning technology to clone a human being and, therefore, would not permit any such investigation to proceed at this time." The FDA's position remains unchanged.



Senator  
Maggie Tinsman  
Iowa

### STATES ARE BUSY

In the absence of a federal law, states have taken on human cloning in increasing numbers. Most recently, Iowa banned all forms of human cloning in its 2002 session. "The federal government wasn't moving fast enough," says Senator Maggie Tinsman. "We were really concerned about human cloning."

Iowa legislators were not the first to worry. California established the earliest state law in 1997. Since then, Iowa, Louisiana, Michigan, Missouri, Rhode Island and Virginia have followed suit. This session, some 43 bills had been introduced in 19 states by the first of March. In Indiana, New Jersey and North Dakota bills had passed in one chamber.

Every state with a human cloning law has a ban or a moratorium on reproductive cloning with the exception of Missouri, which pro-

hibits only the use of state funds for reproductive cloning. California legislators revisited the state's law in 2002 and removed the sunset clause. Similarly, the Rhode Island General Assembly extended its moratorium on reproductive cloning until July 2010.

Human cloning prohibitions also apply to therapeutic cloning in Iowa and Michigan. In addition, Virginia's law also may forbid therapeutic cloning. The statute defines human cloning as the attempt to create a human being using nuclear transfer technology, but there is disagreement about whether "human being" covers embryos or blastocysts. Although these laws limit potential sources for research, they do not outlaw the use of embryonic stem cells altogether.

### STEM CELLS AND THE STATES

Four main sources exist for embryonic stem cells: stem cell lines that have already been developed, cloned embryos, germ cells—sperm or egg cells—from terminated pregnancies or miscarriages and unused in vitro fertilized embryos. Myriad state laws restrict or prohibit research on cells or tissue obtained from some or all of these sources. However, contrary to the president's position, the majority of states permit embryonic stem cell research using public and private funds on all four sources of stem cells. But the use of cloned embryos presents unique concerns.

The safety issues associated with reproductive cloning lead most people to quickly reject the idea. Many animal clones, for example, have suffered from genetic and other defects for reasons not yet

## CALIFORNIA MAGNET FOR MAJOR RESEARCH PROJECTS

Significant research developments transpired as SB 253 to support stem cell research moved through the California Legislature and, ultimately, was signed into law in September 2002:

◆ While the Assembly prepares to consider the bill, the University of California San Francisco (UCSF) announces a new stem cell initiative after the chairman of Intel, Andy Grove, presents UCSF with a \$5 million matching grant to start the UCSF Stem Cell Discovery Fund. For every contribution to the fund ranging from \$50,000 to \$500,000, Grove will match the donation.

◆ After receiving a \$12 million anonymous donation to start the project, Stanford University launches the Institute for Cancer/Stem Cell Biology and Medicine on Dec. 10, 2002. Dr. Irving Weissman leads the institute's efforts to find new therapies for cancer, diabetes, Parkinson's and other diseases using adult and embryonic stem cells.

◆ Renowned researcher Dr. Evan Snyder relocates to The Burnham Institute in La Jolla, Calif., from Harvard University on Jan. 1, 2003. Snyder says that the new law was a factor in his decision to move. He directs the institute's program on stem cells and regenerative medicine.

understood. Thomas Murray of the Hastings Center, a nonpartisan research institution, also notes that the failure rate for reproductive cloning is high, and although some embryos with abnormalities die early on, others continue to develop.

But when it comes to cloning for research, policymakers may take into account other complex ethical considerations. Murray explains that individuals who believe that a human embryo is a "morally sig-

nificant entity, but something other than a full-fledged entity" are more likely to weigh the ethical concerns about cloning for research vs. the potential to treat patients with serious ailments.

To the United States Conference of Catholic Bishops, cloned embryos deserve the same protections as other human research subjects. "In moral terms, we think that creating human lives solely to destroy them is more problematic than cloning for procreation," says spokesman Richard Doerflinger.

The cloning debate generates much interest. Legislators hear from religious organizations, medical centers, abortion groups, ethicists and individuals who suffer from diseases like Parkinson's or spinal cord injuries who might benefit from stem cell therapy.

Senator Tinsman says scientists from the University of Iowa came to testify and "admitted that they had not actually used embryos for stem cell research. But it was going to happen, and they wanted to be in on the ground floor."

When South Dakota legislators considered a bill to prohibit all embryonic research in 2000, however, researchers were not as involved. "The university did not play a major part in the debate because I think the majority of people thought it through and decided [research on embryos] is not the thing to do even though it might bring in research dollars," says Senator Jay L. Duenwald.

In the end, the South Dakota Legislature enacted the tightest restrictions on embryonic research in the United States. The law prohibited research on existing stem cell lines even before the president adopted his policy.

"We knew that we were taking a ground breaking approach," says Duenwald. "We were looking ahead to what might be coming down the road."

The South Dakota embryonic research ban also is unique in that it addresses stem cell



Senator Jay L. Duenwald South Dakota

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## CLONING TECHNOLOGY: OVER A HUNDRED YEARS IN THE MAKING

The cloning conundrum. A modern dilemma, right? Not so. Efforts to clone various creatures began in the 1800s.

In the beginning, scientists were trying to clone sea urchins and frogs. Early success was limited to embryos. The technology to clone mammal embryos surfaced in 1983. But the ability to clone adult mammals evaded scientists for another 14 years. That's why Dolly, a clone of an adult sheep, was a major achievement.

**1894** Hans Dreisch isolates cells of two- and four-cell embryos of sea urchins and observes development of cells into small but complete larvae.

**1901** Hans Spemann splits a two-cell newt embryo into two parts, successfully producing two larvae.

**1914** Spemann conducts early nuclear transfer. Using a strand of baby hair, he partially constricts a newly fertilized egg cell, forcing the nucleus to one side and only cytoplasm to the other. As the nucleus side of the cell divides successively to the 16-cell stage, a nucleus slips over to the cytoplasm on the other side. Cell division starts on this side also, and the hair knot is tightened, preventing further nuclear transfer. Twin larvae develop, one slightly older than the other.

**1940s - 1950s** Various species of mammalian embryos are cloned by embryo splitting, but success is limited to early stage embryos.

**1952** Robert Briggs and Thomas J. King transplant a nucleus of a frog embryo cell into an unfertilized egg cell with the nucleus removed. These injected eggs develop into tadpoles and many grow into juvenile frogs. This technique, nuclear transfer, becomes the prototype for

cloning of multicelled organisms.

**1964** F.C. Steward grows a complete carrot plant from a carrot root cell.

**1970s** Using nuclear transfer, researchers produce larvae from the nuclei of adult frog cells.

**1983** James McGrath and Davor Solter develop nuclear transfer technology for mammalian embryos.

**1986** Steen Willadsen clones lambs by fusing the nucleus of an eight-cell embryo to an egg cell with the nucleus removed. Other researchers subsequently succeed in producing full-term cattle, sheep, pigs, goats and rats using a similar approach.

**1997** Ian Wilmut and his colleagues from Scotland produce Dolly, the first mammal cloned from an adult cell.

**1998** A Honolulu group, led by Teruhiko Wakayama, reports the production of a large number of live mice by injecting nuclei taken from adult ovarian cells into egg cells with the nucleus removed. These investigators also report success in recloning the first clones. A Japanese group, led by Yoko Kato, produce eight calves from various cells derived from one adult donor.

**2001** Advanced Cell Technology of Worcester, Mass., reports the creation of the first cloned human embryos for stem cell research. None of the organisms develop past the six-cell stage.

**2002** Clonaid announces the birth of the first human clone, but scientists are skeptical. Clonaid does not allow its claims to be verified by genetic testing.

Source: "Cloning: Past, Present and Future," by Marie DiBerardino in *Breakthroughs in Bioscience* from the Federation of American Societies for Experimental Biology, 1999.

research while avoiding the cloning debate. Reproductive and therapeutic cloning are still permitted in the state. You cannot destroy an embryo for research purposes, but you can create one. The cloned embryo can be frozen, disposed of or implanted in a woman's uterus, but not used in experiments.

South Dakota legislators are not the only ones who have been creative. California Senator Deborah Ortiz sponsored seminal legislation enacted in 2002 to specifically permit research on stem cells, including cells from cloned embryos, embryonic germ cells and adult stem cells. For her, stem cell research struck a personal chord: "My interest in stem cells resulted from my work on cancer research when my mother was ill ... I was really searching for a cure to stop the cancer that ultimately took my mother's life." Through her ordeal, Ortiz says that she "became aware of the incredible potential for stem cell research to alleviate chronic and fatal diseases."



Senator  
Deborah Ortiz  
California

Although therapeutic cloning and embryonic stem cell research already were legal in the state, the bill gave legislators an opportunity to send a message to biomedical researchers that the state supports stem cell research. Senator Ortiz reports that since the law was passed, California has lured away researchers from other states. The law requires that an institutional review board, typically comprised of scientists, ethicists, consumer representatives and religious leaders, over-

see the work of stem cell scientists. In addition, fertility patients must be given the option to store unused frozen embryos, discard them, donate them to another individual or donate them to science.

This approach has sprouted a new branch of legislative activity. Before California, no state had specifically addressed stem cell research in legislation. Since then, several states have considered bills encouraging stem cell research.

In the end, it's too soon to tell what the role of this technology, which remains in its infancy, will be in our society. Broad-based acceptance of reproductive cloning, though, appears a long way off.

If cloning a baby was safe—what then? The Hastings Center's Murray remarks, "First of all, the idea that cloning will ever be safe is a heroic assumption. Let's say though, that it was true ... Cloning then would raise an additional set of questions. Why would people want to do it? The best argument against reproductive cloning is if someone does clone Michael Jordan, the kid might really want to be an accountant and could care less about playing basketball. Michael Jordan is so much more than just his physical being. He has a certain character, a certain drive, a certain personality. And you can't expect that you will achieve that."

As scientists deliberate if and when such a scenario might be possible, state legislators continue to grapple with the potential consequences. In a world of uncertainty, policymakers can rely on one sure thing: Just when legislators grasp the seemingly unanswerable questions surrounding human cloning, genetic technology will surely throw them a new curve.