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CRS Report for Congress

Cloning: A Select Chronology, 1997-2004

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Prepared for Members and Committees of Congress

Summary

This is a selected chronology of the events surrounding and following the cloning of a sheep from a single adult sheep cell by Scottish scientists, which was announced in February 1997. The project was cosponsored by PPL Therapeutics, Edinburgh, Scotland, which has applied for patents for the techniques used. This chronology also addresses subsequent reports of other cloning experiments, including the first one using human cells. Information on presidential actions and legislative activities related to the ethical and moral issues surrounding cloning is provided, as well as relevant websites.

More information on cloning and on human embryo research can be found in CRS Report RL31015, *Stem Cell Research* and CRS Report RS21044, *Background and Legal Issues Related to Stem Cell Research.* This report will be updated as necessary.

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Chronology

1997

February 23, 1997. Dr. Ian Wilmut, a Scottish embryologist and his colleagues at the Roslin Institute, Edinburgh, Scotland, succeeded in cloning a sheep from a single adult sheep cell. *Dolly,* the sheep that was created in this manner, is genetically identical to the adult sheep from which she was cloned.

February 24, 1997. President Clinton asked the 18-member National Bioethics Advisory Commission to study the ethical and legal implications of cloning. Human cloning is not currently regulated by law in the United States.

March 2, 1997. Scientists at the Oregon Regional Primate Research Center in Beaverton, OR, reported cloning two monkeys. The monkeys, born in August 1996, were cloned from monkey embryo cells, not cells from an adult monkey. The cloned primates were not genetically identical to any adult monkey.

March 4, 1997. President Clinton issued a memorandum for the heads of executive departments and agencies entitled *Prohibition on Federal Funding for Cloning of Human Beings.* This memorandum may be accessed on the Internet at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1997_public_papers &docid=pap_text-144]. Also, the President issued remarks entitled *Remarks by the President on Cloning*, which may be accessed at [http://frwebgate.access.gpo.gov/ cgi-bin/getdoc.cgi?dbname=1997_public_papers&docid=pap_text-143].

The House Committee on Science's Subcommittee on Technology held a hearing entitled *Bio technology and the Ethics of Cloning: How Far Should We Go?*

March 12, 1997. A hearing entitled *Scientific Discoveries in Cloning: Challenges for Public Policy* was held by the Senate Labor and Human Resources Committee's Subcommittee on Public Health and Safety.

June 9, 1997. The National Bioethics Advisory Commission presented its report, *Cloning Human Beings*, to President Clinton. The report may be accessed on the Web at [http://www.georgetown.edu/research/nrcbl/nbac/pubs/cloning1/cloning.pdf].

President Clinton's remarks, entitled *Remarks by the President at Announcement of Cloning Legislation*, may be accessed at [http://frwebgate.access.gpo.gov/cgi-bin/ getdoc.cgi?dbname=1997_public_papers&docid=pap_text-418].

June 17, 1997. The Senate Labor and Human Resources Committee's Subcommittee on Public Health and Safety held a hearing entitled *Ethics and Theology: A Continuation of the National Discussion on Human Cloning.*

July 22, 1997. The House Committee on Science's Subcommittee on Technology held a hearing entitled *Legislative Hearing on the Prohibition of Federal Funding for Human Cloning Research.*

August 7, 1997. Researchers at ABS Global, Inc., DeForest, WI, announced that they had succeeded in cloning a Holstein bull from fetal stem cells. Stem cells are "blank slate" cells that have not yet specialized their function, such as a liver or muscle cell. The stem cell has the potential to be any part of the mature animal. Gene, the bull, was created in this manner. Dolly, the sheep, was cloned from the genetic material of an adult cell.

December 18, 1997. Roslin Institute scientists reported data showing the production of the world's first lambs that carry a human gene (transgenic lambs) created by nuclear transfer. To produce the lambs, they first exposed skin cells (fibroblast) to DNA that included a human gene and a marker gene. Then they took the cells that contained both the marker gene and the human gene and followed the same cloning technique they used to make Dolly. Both lambs contained the transgenic gene in their cells.

1998

January 7, 1998. Dr. Richard Seed, a physicist from Riverside, IL, on National Public Radio discussed his plans to open a clinic to clone humans before Congress outlawed the procedure. He stated he had already assembled a team of doctors, and four couples volunteered to participate. His objective was to provide childless couples with children. He first announced his intention on December 5, 1997, at a symposium on reproductive technologies in Chicago.

January 10, 1998. President Clinton, speaking in his weekly radio address, urged swift action by Congress to ban the cloning of humans. He reiterated his support for related areas of cloning research, which might lead to medical breakthroughs.

January 20, 1998. Michael A. Friedman, Acting Commissioner of the Food and Drug Administration (FDA), stated that the FDA has the authority under the Food, Drug, and Cosmetic Act to regulate human cloning, since it is a form of cellular or genetic therapy. Since such therapies require prior approval by FDA reviewers, anyone planning to legally attempt human cloning would have to file a formal application with the agency, which would then undertake a lengthy review of the proposal. Friedman also said the FDA would initiate legal action against anyone who failed to file such an application.

July 22, 1998. Researchers at the University of Hawaii announced that they had created dozens of mice by cloning, using a new technique in the most commonly-used laboratory animal. A paper detailing their method was published in the July 23 issue of the science journal *Nature.* The researchers were able to reprogram nuclei from cells taken from ovaries of adult mice. Known as cumulus cells, these

differentiated cells surround the eggs of mice, as well as humans, and are shed with eggs during ovulation. For the cloning experiment, nuclei from cumulus cells were inserted directly into egg cells whose nuclei had been removed. The combination was then activated with chemicals prompting the eggs to start dividing and form embryos. The embryos were transferred to the wombs of surrogate mice, and some resulted in the birth of mice clones (identical to mice from which the cumulus cells were taken). This was the first published documentation that adult animals could be cloned since researchers in Scotland announced the birth of a cloned sheep named Dolly in February 1997. Some scientists questioned the validity of that study. In the same issue of *Nature*, two other papers were published where researchers in England documented that Dolly is indeed a clone.

August 19, 1998. Scientists at the Ruakura Research Center in Hamilton, New Zealand, announced the cloning of the lone survivor of a rare breed of cow. The cloned cow is the last member of a herd which had lived in isolation on Enderby Island, a barren, subantarctic section of the Auckland Islands. From the cow's ovaries, the scientists took several granulosa cells, which nourish egg cells in the ovaries. The granulosa cells are similar to the cumulus cells that Hawaiian researchers used to clone mice. The nuclei from the granulosa cells were inserted directly into egg cells from which the nuclei had been removed. This combination was then activated with electrical shocks. The resulting fused cells divided and developed into embryos, which were transferred into the wombs of surrogate Angus cows. On July 31, 1998, the first clone was born, with slightly different markings than the adult cow. However, the results of a DNA fingerprinting test proved that the clone and the cloned cow were genetically identical.

December 11, 1998. Japanese scientists published data in the journal *Science* reporting the cloning of eight calves from an adult cow's oviduct and cumulus cells. The success rate was higher than that of any other group that cloned large mammals. Ten embryos, derived from differentiated (oviduct and cumulus) cells of one adult cow, resulted in the birth of eight calves, but four calves died at or soon after birth.

1999

April 26, 1999. An announcement was made that a collaboration of industry and academic researchers had successfully produced the world's first transgenic goats through cloning. The three goats are genetically identical copies of a goat embryo whose genetic material was modified to produce milk containing the human anticlotting protein known as antithrombin III (ATIII).

May 27, 1999. A study was published indicating that Dolly, the cloned sheep, may be susceptible to premature aging. Researchers in Scotland found that three-year-old Dolly, who was cloned from a six-year-old ewe, has cells that appear to be at least nine years old.

June 1, 1999. University of Hawaii researchers reported the first documented cloning of an adult male animal. Fibrio, a mouse, was cloned from cells clipped from the tip of a male mouse's tail. This was a different method than was used to produce Gene, the bull, who was cloned from fetal stem cells. Up to now, all animals cloned from adult cells had been female.

June 14, 1999. It was reported that two companies, Geron Corporation (Menlo Park, CA) and Advanced Cell Therapeutics (Worcester, MA) had started programs to grow their own embryos (human clones or human-cow hybrids) by cloning. The clones would be used as sources of embryonic stem cells, which may have potential in the treatment of a number of human conditions, including Parkinson's disease and diabetes.

2000

January 12, 2000. Dr. Gerald Schatten and his colleagues at the Oregon Regional Primate Center, Beaverton, OR, announced the first successful example of the cloning of a monkey called Tetra by using a technique called "embryo splitting." This technique splits an eight-cell embryo into four identical two-cell clones and then implants them in surrogate mothers. Clones made from split embryos are genetically identical.

This technique is different than the one used to clone Dolly the sheep, the first clone of an adult female animal. In that case, the clone was created by taking an adult animal's cell nucleus and implanting it in an unfertilized egg cell from which the original nucleus had been removed.

Some scientists hope that embryo splitting can be used to develop genetically identical laboratory animals better suited for testing therapies that may eventually be used to treat humans.

March 5, 2000. Researchers at the Blacksburg, VA, facility of PPL Therapeutics announced the production of the first cloned pigs — Millie, Christa, Alexis, Carrel, and Dotcom. The Scotland-based company, which also has a research facility in New Zealand, is the same firm that cloned the sheep Dolly. Basically, the pigs were created with the same technique used to create Dolly; but the researchers have not yet disclosed the "additional inventive steps" they said were used to create the pigs. Researchers hope that cloned pigs can eventually become a source of organ and cell transplants for humans.

July 21, 2000. Alexander Kind and his colleagues at PPL Therapeutics, the Edinburgh-based company that helped create Dolly, announced that they had successfully cloned Cupid, Diana, and a third unnamed transgenic lamb. The lambs were the first transgenic livestock to carry specifically chosen modifications in their genes.

The lambs were created using the same method applied for Dolly in 1997. DNA was taken from another sheep and transferred into unfertilized eggs. This time, however, the team picked a specific point on one of the sheep's chromosomes and inserted a new DNA gene sequence into it. This technique is called "gene targeting" and had previously only been possible in laboratory mice.

The inserted gene allowed the sheep to produce the human protein alpha 1-antitrypsin in their milk. This protein may someday be used to treat a variety of lung diseases, including cystic fibrosis; but the true significance of the feat lies in the wider application of gene-altering technology. Another potential application of this

technology is the development of animals that could supply organs for human patients.

2001

March 28, 2001. The House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations held a hearing on human cloning, entitled *Issues Raised by Human Cloning Research.*

April 13, 2001. PPL Therapeutics in Scotland announced the creation of the world's first five genetically-modified cloned pigs, a critical milestone towards producing spare part transplant organs for human patients. Inserted into the genetic make-up of the five clones was a marker gene, for fluorescence taken from a jellyfish. Tissue removed from the clones glowed under ultraviolet light, showing that the marker gene had been successfully integrated into their genetic blueprints.

Dr. Alan Colman of PPL Therapeutics stated that the same technique could allow scientists to create pigs whose organs would not be rejected by human patients' immune systems, since pigs have a gene which causes humans to reject their organs. The birth of the piglets suggested that the gene can be altered.

July 16, 2001. H.R. 2505, Human Cloning Prohibition Act of 2001, a bill to amend Title 18 of the *United States Code* to prohibit human cloning, was introduced. This bill passed in the House of Representatives by a 256-162 vote (roll call no. 303) on July 31, 2001. On August 1, 2001, it was received in the Senate, where it received no further action.

July 31, 2001. H.Amdt. 284 to H.R. 2505, was passed in the House of Representatives by voice vote. This amendment required the General Accounting Office to conduct a study to assess any need for the amendment of the prohibition on human cloning, as defined in Section 301 of Title 18, *United States Code,* as added by this Act and to transmit such study to Congress within four years.

November 25, 2001. Scientists at Advanced Cell Technology (ACT), a private company in Worcester, MA, announced that they had cloned the first human embryos. They said their aim was not to produce cloned human beings, but to create genetically matched stem cells to treat a wide range of diseases. However, the cloned embryos that they produced stopped developing after dividing into just a few cells — not enough to yield medically useful stem cells. ACT used two techniques to produce human embryos — cloning and a second process called parthenogenesis.

In cloning, the researchers obtained egg cells from seven female volunteers. They stripped the DNA from 19 egg cells and replaced it with genetic material from another person of unspecified gender. The new genetic material came from a skin cell or from ovarian material called a cumulus cell. Seven of the eggs began to divide and grow. These early embryos were clones, or offspring that carried genes from only one adult (the person who had donated the skin or cumulus cell). Two embryos divided into four cells each, and one embryo divided into six cells before the growth stopped. The growth occurred over a three-day period.

In parthenogenesis, an egg cell is treated with chemicals that cause it to start dividing into an embryo without being fertilized by sperm. ACT exposed 22 human eggs to those chemicals. After five days, six eggs had matured into larger masses of cells. Scientists believe embryos created this way could mature long enough to be useful in medical treatment but would be unable to grow to term.

Both the cloned and parthenogenetically produced embryos had significant shortcomings. None developed stem cells, which can grow into any type of body cell or tissue.

November 28, 2001. President Bush issued Executive Order 13237, establishing the President's Council on Bioethics. The Council is to advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology.

The executive order establishing the Council may be accessed on the Web at [http://www.whitehouse.gov/news/releases/2001/11/20011128-13.html].

December 31, 2001. The following legislation to prohibit cloning of humans in some manner was introduced in 2001 during the first session of the 107th Congress: H.Res. 214, H.R. 1260, H.R. 1372, H.R. 1608, H.R. 1644, H.R. 2172, H.R. 2608, H.R. 3495, S. 704, S. 790, S. 1758, and S. 1893. H.R. 2505 with H.Amdt. 284 passed in the House of Representatives (see July 16 and 31, 2001). No floor action was taken on the other measures.

2002

January 3, 2002. PPL Therapeutics in Scotland, the company that cloned Dolly, the sheep, announced that it had cloned another five genetically modified pigs — Noel, Angel, Star, Joy, and Mary. The pigs were born on Christmas Day 2001 at the firm's research facility in Blacksburg, VA. As a step toward producing pigs with organs and cells that could be safely transplanted into humans, the cloned pigs (all female) had a gene that was inactivated, or "knocked out." This is the pig gene that attaches sugar molecules to the surfaces of organs. When organs are transplanted into humans, the human immune system attaches to those sugars, recognizes the transplanted organs as foreign, and rejects them. Several other genetic modifications, including the addition of up to three human genes, would be needed to avoid rejection of the pig parts. The work was being funded by a $2 million grant from the National Institute of Standards and Technology.

January 24, 2002. The Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, and Education, held a hearing on human cloning. At this time, no hearing transcript is available.

January 24, 2002. S. 2893, Human Cloning Ban and Stem Cell Research Protection Act of 2002, a bill to ban human cloning while protecting stem sell research, was introduced. This bill was referred to the Senate Health, Education, Labor, and Pensions Committee.

January 28, 2002. S. 1899, Human Cloning Prohibition Act of 2001, a bill to amend Title 18 of the *United States Code* to prohibit human cloning, was introduced. This bill was referred to the Senate Judiciary Committee.

January 30, 2002. Researchers at Advanced Cell Technology in Worcester, MA, announced that they have used cells derived from cloned cow embryos to grow functioning kidney-like organs that were not rejected when implanted into adult cows, marking the first use of cloning technology to grow personalized, genetically-matched organs for transplantation.

This was the first time that cells taken from a cloned embryo had been used to grow an organ which, like kidneys, removes toxins from the body and produces urine. Researchers are still checking to see if it carries out all the functions of a kidney. For this work to be replicated in humans, the kidney would have to be created by using cloned human embryos. Cells taken from the human patient would be used to produce a cloned human embryo genetically identical to the patient. The experimental procedure would then harvest cells from the embryo to grow the organs needed for transplant, which theoretically would not be rejected by the patient because they would be genetically identical. Information on this work has not been published in a scientific journal, nor has the work been confirmed by others.

February 15, 2002. Researchers at Texas A&M's College of Veterinary Medicine announced that they had created the first cloned cat, a shorthaired calico named CC (short for "carbon copy" and "copy cat"). It was cloned with cells from a cat named Rainbow. Delivered by cesarean section on December 22, 2001, in a university laboratory, CC was the first household pet to be cloned.

Working first with an adult male cat, the researchers harvested cells from the animal's mouth and then fused them with cat donor eggs that had been emptied of genetic material. This created 82 cloned embryos that were transferred into the wombs of seven cats. The process yielded only a single fetal clone, and it died in utero.

In a second attempt, researchers used cumulus cells from the ovaries of the female cat named Rainbow and created five cloned embryos. They were implanted in Allie, another female cat. This time, an embryo took hold and grew. Sixty-six days later, CC arrived.

The kitten was anything but an exact copy of Rainbow. Although tests indicated that CC was a genetic duplicate of the cat that donated the original ovary cell, CC's markings were quite different from those of Rainbow. Calico markings such as those possessed by CC are the result of random molecular changes that occur during fetal development.

Mark Westhusin, the project's lead scientist, stated, "This is reproduction, not resurrection." He warned pet owners that cloning will never return their old pets, although the clones will probably resemble their predecessors in looks and temperament.

The work was funded by Arizona millionaire John Sperling, who gave Texas A&M about $3.7 million to develop technology to clone his pet dog Missy, an aging border collie-Siberian husky mix. Although several pregnancies have been achieved by using cells from Missy, none of the clones have survived to term. Parallel work on cats went faster, Westhusin said, in part because cat eggs grow and mature in culture dishes better than dog eggs.

To commercialize the work, two years ago, Sperling created a Texas company called Genetic Savings and Clone, which holds the licensing rights to any proprietary pet cloning techniques developed by Texas A&M's "Missyplicity Project."

March 29, 2002. French researchers reported that they had cloned rabbits by using genetic materials from adult cells. The four cloned rabbits, all females, were born a year earlier at the National Institute for Agronomical Research outside Paris. A team of developmental biologists led by Jean-Paul Renard did not report the achievement until the animals were mature and in good health. Neither these rabbits nor their parents (the adult females that provided the genes and eggs from which the cloned rabbits were made) were given names.

The French team is collaborating with other scientists to try to clone rabbits with the gene defect responsible for cystic fibrosis in human beings. The gene in the two species is very similar, Renard said, and the scientists hope cloned rabbits will provide a better model for studying the disease than other animals.

Robert Lanza, medical director at Advanced Cell Technology, said that since rabbits reach sexual maturity and breed very quickly, they provide offspring quickly as well, which is very important in cloning research. In contrast, a cow fetus spends nine months in the womb, and it is expensive to produce large numbers of them.

May 15, 2002. The House Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources held a hearing, entitled *Medical Science and Bioethics: Attack of the Clones.*

December 10, 2002. Stanford University announced plans to create a $120 million institute to study the overlapping biology of cancer and stem cells, including a plan to start cloning new stem cells from human embryos. An anonymous donor gave $12 million to seed a fund-raising campaign for the new center. The new Institute for Cancer/StemCell Biology and Medicine will be directed by Dr. Irving Weissman of Stanford. Researchers at the institute hope to use cloning techniques and stem cells to make genetically tailored material for transplants and to study the course of disease in specific types of human cells.

December 27, 2002. Brigitte Boiselier, a former university chemist who is the director of Clonaid, a company founded by the Raelians (a religious sect that believes humans are descended from space aliens) claimed that Clonaid had created the world's first human clone, a baby named Eve, who is allegedly a genetic carbon copy of her mother. Boiselier said the baby was born by cesarean section, but did not specify where the birth took place or identify the parents. No evidence was offered to back up the claim.

December 31, 2002. The following legislation to prohibit cloning of humans in some manner was introduced in 2002 during the second session of the 107th Congress: S. 2893, S. 1899, S. 2076, and S. 2439. No floor action was taken on these measures, and they died at the end of the 107th Congress.

2003

January 4, 2003. Clonaid announced the birth of a second human cloned baby born to a Dutch couple on January 3, 2003. No evidence was offered to back up the claim.

January 8, 2003. H.R. 234, Human Cloning Prohibition Act of 2003, a bill to amend Title 18 of the *United States Code* to prohibit human cloning, was introduced.

H.R. 246, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2003, was introduced. Section 510 includes human clones in its prohibition of funding research using human embryos.

January 29, 2003. S. 245, Human Cloning Prohibition Act of 2002, a bill to amend the Public Health Service Act to prohibit human cloning, was introduced.

February 5, 2003. H.R. 534, Human Cloning Prohibition Act of 2003, a bill to amend Title 18, *United States Code* to prohibit human cloning, was introduced. On February 25, 2003, the bill was reported to the Committee on Judiciary, H.Rept. 108-18. This bill passed in the House by a 241-155 vote (roll call no. 39) on February 27, 2003.

February 5, 2003. S. 303, Human Cloning Ban and Stem Cell Research Protection Act 2003, a bill to prohibit human cloning and protect stem cell research, was introduced.

February 13, 2003. H.R. 801, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the cloning of humans, and for other purposes, was introduced.

February 14, 2003. The Roslin Institute, Edinburgh, Scotland, announced that Dolly the sheep was euthanized, short of her normal lifespan after being diagnosed with a progressive lung disease. The decision to end the life of the six-year-old sheep was made afer a veterinary examination confirmed the lung disease.

February 20, 2003. The FY2003 Consolidated Appropriations Resolution P.L.108-7) was signed into law. One of the law's sections includes human cloning in its prohibition against funding any research that uses human embryos. This provision was originally part of H.R. 246, the FY2003 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, which was incorporated into P.L. 108-7.

February 25, 2003. H.R. 916, a bill to prohibit the expenditure of federal funds to conduct or support research on the cloning of humans, and to express the sense of Congress that other countries should establish substantially equivalent restrictions, was introduced.

February 26, 2003. H.R. 938, a bill to prohibit federal payments to any individual, business, institution, or organization that engages in human cloning, was introduced.

February 27, 2003. H.Amdt. 4 to H.R. 534 amendment, as modified, requiring the General Accounting Office, after consultation with the National Academy of Sciences, to conduct a study to assess the need (if any) for amendment to the prohibition on human cloning contained in the bill, was introduced and agreed to by voice vote.

H.Amdt. 5 to H.R. 534, an amendment in the nature of substitute sought to prohibit human somatic cell nuclear transfer technology to initiate a pregnancy and allow its use for medical research, was introduced and failed by recorded vote: 174-231, 1 Present (roll call no. 37).

May 29, 2003. The combined research team led by Gordon Woods and Dirk Vanderwall of the Northwest Equine Reproduction Laboratory at the University of Idaho and by Ken White of Utah State University announced the May 4, 2003, birth of a live cloned mule, the first successful cloning of an equid. Named Idaho Gem, after the state in which he was born, the foal is a sibling of Taz, a world champion racing mule. The researchers did not want to clone an adult animal because they "wanted to take the aging component out of the equation," said Woods. Some researchers suspect that the first cloned mammal, Dolly the sheep, aged prematurely because her DNA was derived from an adult cell. So the team rebred Taz's parents, took a somatic cell from the 45-day-old fetus, and fused it with an enucleated horse oocyte that was then implanted into a mare. Idaho Gem, born after a normal 346-day gestation, is not only the first member of the horse family but also the first sterile animal to be cloned. Mules, sired by donkeys and borne by horses, cannot reproduce.

June 11, 2003. Two weeks after announcing the birth of the first cloned mule, the same combined research team announced the June 9, 2003, birth of a second cloned mule, named Utah Pioneer.

June 26, 2003. S.1356, Department of Health and Human Services Appropriations Act 2004, Title V, General Provisions, Sec. 510, prohibits the use of funds made available in this Act for (1) the creation of a human embryo for research purposes; or (2) research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under specified federal regulations and the Public Health Service Act. Defines "human embryo or embryos" to include any organism, not protected as a human subject under specified federal regulations as of the date of enactment that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells

August 6, 2003. Italian scientists announced that they had created the first cloned horse. The horse is an Arabian thoroughbred born in the stables of the Laboratorio di Tecnologie della Riproduzione at Cremona, Italy, the work of a team led by Cesare Galli, director. The birth was a double first. Prometea, named after the Greek hero Prometheus (who stole fire from the gods), was born on May 28, 2003. This was the first time that a surrogate mother of any species has carried a genetically identical clone to term, since the Haflinger mare that provided Prometea's DNA was also her

surrogate mother. The foal was created by inserting the mother's skin cell into an egg and stimulating the egg to grow as if it had been fertilized. The scientists started by removing the DNA from 513 eggs. They got 328 eggs to fuse with skin cells from adult horses. Of these, 22 embryos developed, and the scientists transferred 17 of the embryos into the wombs of nine mares, resulting in four pregnancies. The mare that was implanted with an embryo for which she supplied the genetic material had the only one of the four pregnancies that succeeded.

August 13, 2003. Chinese researchers led by Huizhen Sheng, a U.S.-trained scientist now working at the Shanghai Second Medical University, say they have made human embryonic stem cells by combining skin cells with rabbit eggs. The breakthrough was published in the Chinese scientific journal *Cell Research*, a peer-reviewed bimonthly periodical affiliated with the Shanghai Institute of Cell Biology and the Chinese Academy of Sciences. The researchers used readily available rabbit eggs. After removing the eggs' DNA, the team injected human skin cells inside them. The manipulated eggs subsequently grew to form embryos containing human genetic material. After several days, the resulting embryos were dissected to extract their stem cells, which have the potential to form a wide array of different cell types.

Although just published, the work has been discussed and debated in scientific circles for more than 18 months. This type of experiment is controversial in the United States, where scientists question the validity of the findings. According to researchers familiar with the situation, the Chinese work was reviewed and turned down by Western journals, such as *Science* and the *Proceedings of the National Academy of Sciences*. If success is confirmed, this type of experiment would represent the first time that human embryonic stem cells have been generated by cloning.

September 25, 2003. Researchers at genOway, a French biotechnology company based in Lyon, France, and France's National Institute for Agricultural Research reported in the online edition of the journal *Science* that they had cloned rats. Rats are especially difficult to clone because their eggs start developing as soon as they are put in a petri dish — before the laboratory technicians can perform their DNA swapping task. As a result, the embryos die while they are tiny clusters of cells. The French team exposed the rat eggs to an inhibitor protein that slowed the activation of the eggs. This allowed time for the team to remove DNA from the eggs and replace it with DNA from an adult rat cell. The French scientists used fetal skin cells as a DNA source and conducted 876 procedures before producing Ralph and his three fellow clones, which have not been named.

The four new rat clones (two males and two females) have grown into fertile adults with no sign of abnormality or disease, said Alexandre Fraichard, chief executive officer of genOway.

Laboratory rats with special genetic changes can be used to test drugs and other therapies that may benefit humans. Genetically manipulated rats are highly prized by scientists because they provide an opportunity to explore biological processes that cannot be studied in humans.

2004

January 23, 2004. The FY2004 Consolidated Omnibus Appropriations Act P.L. 108-199) was signed into law. One of the law's sections includes human cloning in its prohibition against funding any research that uses human embryos. This provision was originally part of S. 1356, the FY2004 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, which was incorporated into P.L. 108-199.

February 11, 2004. A 15-member research team headed by Dr. Woo Suk Hwang and Dr. Shin Yong Moon of Seoul National University in South Korea reported in the online edition of the journal *Science* that they had cloned human embryonic cells. The researchers were able to create 30 early-stage cloned embryos using 242 eggs and donor cells from 16 female volunteers.

The 30 cloned embryos were grown in a laboratory for a few days to the blastocyst state, a ball of about 150 cells. Inner cell masses were isolated from 20 of the blastocysts. From those, one line of all-purpose stem cells was successfully derived. At the blastocyst state, the inner cell mass consists of indeterminate cells that are not yet committed to becoming any particular type of cell. These are the stem cells, which can theoretically develop into any of the body's tissues or organs. Stem cells from a clone would be genetically identical to those of the person who contributed the cells used to create the embryo.

The researchers attributed their cloning success to the use of extremely fresh donor eggs, precise timing protocols for reprogramming the egg, and a method for extruding (instead of suctioning) the DNA from the egg.

The scientists stated that the research was conducted in the laboratory in petri dishes. No embryos were implanted in the female volunteers, who were not paid for providing the unfertilized eggs needed to start the cloning process.

According to a February 29, 2004, *Washington Post* article, Dr. Hwang said, "We did it with private funding from Koreans who simply believed in our mission and believed that Korean scientists could pull it off."

Websites

President Clinton established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995. This executive order is in the *Federal Register,* October 5, 1995, p. 52063, and may be accessed online at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1995_register&docid=fr05oc95-126].

Information on the NBAC is at [http://bioethics.georgetown.edu/nbac/]. The NBAC charter expired on October 3, 2001.

Roslin Institute
[http://www.roslin.ac.uk]

PPL Therapeutics
[http://www.ppl-therapeutics.com/]

Oregon Regional Primate Research Center
[http://www.ohsu.edu/orprc/]

ABS Global, Inc.
[http://www.absglobal.com/]

Advanced Cell Technology
[http://www.advancedcell.com/]

Northwest Equine Reproduction Laboratory, University of Idaho
[http://www.avs.uidaho.edu/nerl/]

Utah State University, Department of Animal, Dairy, and Veterinary Science
[http://www.advs.usu.edu/]

genOway
[http://www.genoway.com]

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CRS Report for Congress

Relicensing of Non-Federal Hydroelectric Projects: Background and Procedural Reform Issues

Updated February 27, 2004

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Relicensing of Non-Federal Hydroelectric Projects: Background and Procedural Reform Issues

Summary

Hydroelectric facilities produce approximately 7% of all electricity generated in the United States and are an important source of power during periods of high demand. About half of these facilities are privately owned and operate under licenses issued by the Federal Energy Regulatory Commission (FERC). The remaining dams, which do not require FERC licenses, are owned and operated by federal, state, or local governments. In the next decade, 218 projects, or about 20% of the nation's total installed hydroelectric capacity, will undergo relicensing. New licenses for these facilities will establish their allowed generation capacity, operating parameters, and environmental protection requirements for the next 30 to 50 years. Given the multi-purpose nature of hydropower facilities and changes in river-management priorities since the 1950s and 1960s, it now can take more than six years and millions of dollars to relicense a hydroelectric project.

Since the mid-1980s, FERC has been working to improve the relicensing process. In 1985, FERC established a deadline-driven process known as the Traditional Licensing Process (TLP). In 1997, FERC developed a second, more flexible, process called the Alternative Licensing Process (ALP). The focus of recent FERC efforts, and of this report, is on the development of regulations, finalized in FERC's July 30, 2003 Rule (Docket No. RM02-16-000, Order No. 2002), to further modify the licensing process by establishing a third process. This process, called the Integrated Licensing Process (ILP), incorporates elements of the TLP (*e.g.,* deadlines for multiple steps) and the ALP (*e.g.,* focus on early stakeholder involvement). In addition, the ILP includes a new process for resolving study disputes and requires FERC to participate earlier in the licensing process. FERC indicates that these changes are intended to make the process shorter and more efficient without altering agencies' authorities under the Federal Power Act (16 U.S.C. 791 et al.) or the Clean Water Act (33 U.S.C. 1341) to develop license conditions that protect fish, federal reservations (*e.g.,* national forests, Indian reservations, etc.), or rivers' state-designated uses.

While FERC completed its rule establishing the ILP, both chambers of the 108th Congress passed legislation that could affect that rule. The House-passed and Senate-passed energy bills would change the way certain federal agencies establish license conditions under sections 18 and 4(e) of the Federal Power Act. Specifically, either version of H.R. 6 would allow license applicants to offer alternatives to proposed license conditions and would require agencies to accept them so long as the alternative conditions met certain environmental and economic requirements. However, there is concern that this legislation could reduce the effectiveness of the ILP by eroding federal resource agencies' conditioning authority.

The central issue for Congress may be whether FERC's licensing processes are adequate or whether new legislation is needed to increase relicensing efficiency. This report summarizes the two current processes, describes FERC's recent efforts to develop a third licensing process, and explains the debate regarding current legislation's effect on the ILP. This report will be updated as events warrant.