

# Genetic Cloning, Testing, and Research

## BACKGROUND

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### GLOSSARY

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#### Biotechnology

The use of living organisms, cells, or substances from living organisms to make products, improve plants or animals, or develop microorganisms.

#### Chromosome

The structure in the nucleus of a cell, composed of DNA, that contains genes.

#### Clone

An exact genetic copy of an organism.

#### Deoxyribonucleic acid (DNA)

A chemical, found in the nucleus of a cell, that carries genetic information—that is, the instructions for making all the structures and materials the body needs to function.

#### Embryo

The prefetal product of conception from implantation through the eighth week of development. An embryo conceived through sexual reproduction receives half its genes from each sexual parent; that is, half from the sperm and half from the egg. A cloned embryo receives all its genes from one parent—the DNA donor.

#### Gene

A component passed from one generation to the next that occupies a specific location on a chromosome and helps determine a particular characteristic in an organism.

Recent advances in the field of genetics have expanded with dazzling speed, bringing with them the challenge of wide-ranging and often unknown consequences. Over the years, genetic manipulation has been used for purposes such as improving crop yields and accelerating animal growth. Cloning an animal from embryonic cells and, more recently, from adult cells, vaulted genetics into the daily headlines, then, in 2001, there came the announcement that a very early human embryo had been produced.

#### Genetic Cloning

The birth of Dolly, the sheep cloned in 1997, generated both anticipation and fear that human cloning would not be far behind. At the federal level, an executive order immediately banned the use of federal funds for human cloning. Extensive discussion ensued in Congress about the ethics of cloning, and numerous bills were introduced in an effort to prohibit human cloning without restricting promising research. Cloning began to be discussed in terms of *therapeutic cloning* (to create an embryo for a supply of stem cells for research or therapy, thus destroying the embryo) and *reproductive cloning* (to produce a human being). Currently, Congress is considering legislation to ban all cloning, including therapeutic cloning, and alternatively, legislation to ban only reproductive cloning.

Michigan enacted laws in 1998 making human cloning a felony, setting penalties for cloning, and prohibiting state funds from being used for it. California, Louisiana, and Rhode Island also have such a ban, and other states have similar legislation pending.

Related controversy surrounds research using embryonic stem cells, which are believed to hold potential for leading to treatment for diseases such as Alzheimer's, Parkinson's, diabetes, and heart disease. The president announced in August 2001 that he would allow the award of government funds for research that uses embryonic stem cells being cultured in laboratories around the world but would prohibit funding to develop new lines that involve creating and destroying additional embryos.

In early 2002 two biotechnology companies announced that they had cloned pigs that do not have a specific gene that appears to cause the human body to reject pig organ transplants; the breakthrough is thought to be an important step in the field of *xenotransplantation*—animal-to-human transplants. In addition, human embryonic stem cells have been developed into tiny blood vessels, a crucial step in someday using such cells to repair blocked arteries.

#### Genetic Testing and Profiling

Genetic testing is the process of examining human chromosomes for genetic markers that may indicate the presence or likelihood of diseases or conditions that sometimes can be treated. Hundreds of genetic tests are available, and seven are required of newborns in Michigan. Similarly, genetic profiling records an individual's DNA makeup and can be used to identify a person with near certainty.

**Legislation**

In 1999 the report of the Michigan Commission on Genetic Privacy and Progress recommended ways to protect genetic data, prevent discrimination, and maximize the beneficial uses of new genetic medical knowledge. Legislation followed in 2000 that

- prohibits health insurance companies from requiring genetic information before issuing coverage,
- requires a person's informed consent before undergoing genetic testing, and
- prohibits the use of genetic tests as a condition for obtaining employment.

Pending Michigan legislation (HB 4936) would require separate written consent from the patient for disclosure of genetic information to another party, except as allowed by law or Medicaid policy. Another bill (SB 1214) would set conditions under which DNA test results may be considered as the basis for a new trial of someone convicted of a felony.

Effective January 2002, Michigan law expanded DNA profiling to the entire felon population, including those convicted of specific sex-related misdemeanors.

Although considerable federal legislation has been introduced regarding genetic testing, none has been enacted to date. In 2000 the president issued an executive order prohibiting federal agencies from using genetic information in making employment or promotion decisions and declaring genetic information subject to the same privacy protections as other medical information. The president has urged Congress to pass legislation extending these protections to all citizens.

**Biotechnology**

Biotechnology is the practice of using living organisms, cells, or substances from living organisms to make products, improve plants or animals, or develop microorganisms other than human cloning. Nearly 300 "biotech" businesses in Michigan generate \$2 billion in annual revenue and employ more than 16,000 workers.

In July 1999 the state agreed to invest \$1 billion over 20 years in a "life sciences corridor" designed to make Michigan a leading state in developing biotechnology applications. The lead Michigan research institutions—Michigan State University, the University of Michigan, Wayne State University, and the Van Andel Institute—have been joined in proposing biotech projects by other institutions and universities. The initial investment was \$100 million, which, along with all future monies awarded under the program, is allocated in three areas: 40 percent on basic research; 50 percent on collaborative research, with emphasis on developing emerging discoveries; and 10 percent on commercializing developments through start-up companies. The proposals are awarded competitively after peer review by a third party, most recently the American Association for the Advancement of Science.

The awards, administered by the Michigan Economic Development Corporation, are intended as a catalyst for bringing health-related products to the consumer while also building companies that create high-technology jobs. The funds are augmented by substantial private money, and 21 new life-science companies were formed in or attracted to Michigan in 2001. Interest from public and private researchers generated nearly 300 project proposals for \$45 million to be awarded in 2002. While some proposals are in the field of genetics/genomics, 40 focus on bio-defense.

**Genetic marker**

*A known DNA sequence associated with a particular gene or trait; some are associated with certain diseases and conditions.*

**Genetic profile**

*The record of a person's genetic makeup.*

**Genome**

*The complete collection of an organism's chromosomes. Except for red blood cells, all human cells contain a complete genome.*

**Genome sequencing**

*Determining the order of the chemical bases that make up DNA; that is, "reading" the genetic makeup of an organism. This order spells out the exact instructions required to create a particular organism with its own unique genetic traits.*

**Stem cell**

*A cell that has the ability to divide for indefinite periods in culture and to give rise to specialized cells such as skin or heart cells; embryonic stem cells are undifferentiated and thus more capable of being nurtured into various types of tissue than are non-embryonic stem cells.*

**Stem cell line**

*The continuing division of a particular stem cell; as cell lines age, they lose their capacity to differentiate into various kinds of tissue.*

## GENETIC CLONING, TESTING, AND RESEARCH

At the international level, the massive, ongoing Human Genome Project is designed to identify and sequence the genes in human DNA and develop tools for analyzing the resulting data. A feature of the U.S. government's part in the project is transferring technology to the private sector through licensing and awards for innovative research. In 2000 the government and a private company announced that a first draft of the entire human genome had been sequenced, and, more recently, three chromosomes of the total 24 in the human genome have been decoded to a high scientific standard.

### DISCUSSION

Stem cell research and cloning pit doubts about the morality of embryo experiments against the promise of treating disease. Some people believe that harvesting stem cells from human embryos is tantamount to homicide and any benefits derived from such research are morally tainted. Others counter that stem cells offer staggering potential to treat disease, and research should not be limited, as the president has decreed, to existing stem cell lines.

The National Academy of Sciences and the Institute of Medicine assert that public funding of research on human stem cells derived from both adults and embryos will provide the most efficient and responsible means to fulfill the promise of stem cells for achieving medical breakthroughs. The academy notes that new stem cell lines will be needed in the future to replace existing lines compromised by age and to address concerns about cultures using animal cells and serum that could result in health risks for humans. The academy report continues,

Although stem cell research is on the cutting edge of science today, it is still in its infancy, and an enormous amount of basic research remains to be done before it can result in medical treatments . . . Public sponsorship of basic research would help ensure that many more scientists could pursue a variety of research questions and that their results are made widely accessible . . . In addition, public funding offers greater opportunities for regulatory oversight and scrutiny of research . . . [However] Human reproductive cloning should not now be practiced. It is dangerous and likely to fail.

Opposition to cloning a human being is nearly universal. Advanced Cell Technology, the private company that produced a very early, six-cell human embryo, denies interest in cloning a human; its stated goal is to produce stem cells for research. While a very few scientists have expressed interest in cloning a human, most believe that apart from moral or ethical issues, it is simply too dangerous at the current level of knowledge.

In 2001 the U.S. House of Representatives passed a measure to prohibit human cloning. A few months later, during consideration of an unrelated bill, the Senate defeated an amendment that would have placed a six-month moratorium on all cloning, but it has not acted on the cloning-prohibition bill itself. The Council of Catholic Bishops condemns this inaction as "morally irresponsible," and asserts that the successful early-stage cloning of human embryos has dangerous implications of playing God and devaluing human life. Right to Life of Michigan also deplores the Senate's inaction. At this writing, debate continues on the prohibition bill and on a second Senate bill that would ban reproductive cloning but allow continued cloning for medical research. The president has affirmed his intention to sign a bill banning human cloning if it comes to his desk.

Current policy of the American Medical Association directs its member physicians not to participate in human cloning "at this time because further investigation and discussion regarding the harms and benefits of human cloning are required."

The final report of the National Bioethics Advisory Commission (its charter expired in October 2001) concludes that the federal oversight system should protect the rights and welfare of human research participants, regardless of whether the research is publicly or privately sponsored. Since no current entity has the authority to develop federal policy for all research involving human participants, the commission called for legislation creating a single federal office.

Three to five percent of the U.S. Human Genome Project budget is devoted to studying the ethical, legal, and social issues surrounding the availability of genetic information; this is the largest bioethics program in the world. Among the issues under study are the following:

- Fairness in the use of genetic information by insurers, courts, schools, adoption agencies, and the military: Who should have access and how will it be used?
- Privacy and confidentiality of genetic information: Who owns and controls it?
- Stigmatization due to an individual's genetic differences: How does personal genetic information affect society's perceptions of that person?
- Reproductive issues such as adequate informed consent for complex procedures and reproductive rights: How reliable is fetal genetic testing? What larger issues are raised by new reproductive techniques?

- Clinical issues, including the education of professionals and the public, and the implementation of standards in testing procedures: How will genetic tests be evaluated and regulated for accuracy? How do we balance limitations and social risk with long-term benefits?
- Uncertainties associated with gene tests for susceptibilities and complex conditions: Should testing be performed when no treatment is available?
- Philosophical implications regarding human responsibility, free will versus genetic determinism, and concepts of health and disease: Do people's genes make them behave in a particular way? Where is the line between medical treatment and enhancement?
- Health and environmental issues concerning genetically modified foods and microbes: Are such foods safe to humans and the environment?
- Commercialization of products, including property rights such as patents and copyrights and accessibility of products: Who owns genes and other pieces of DNA? Will patenting DNA sequences limit their accessibility and development into useful products?

The questions surrounding genetic cloning, testing, and research are controversial and growing more complicated with every announcement from genetic science and biotechnology, and they can be expected to be present on the political agenda, in scientific research, and in public debate for some time.

See also Abortion; Crime and Corrections; Privacy.

## FOR ADDITIONAL INFORMATION

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American Medical Association  
 515 North State Street  
 Chicago, IL 60610  
 (312) 464-5000  
 (312) 464-4184 FAX  
[www.ama-assn.org](http://www.ama-assn.org)

Human Genome Project Information  
 Oak Ridge National Laboratory  
 1060 Commerce Park, MS 6480  
 Oak Ridge, TN 37830  
 (865) 576-6669  
 (865) 574-9888 FAX  
[www.ornl.gov/hgmis](http://www.ornl.gov/hgmis)

Michigan Economic Development Corporation  
 300 North Washington Square  
 Lansing, MI 48913  
 (517) 373-9808  
 (517) 335-0198 FAX  
<http://medc.michigan.org/lifescience>

National Academy of Sciences  
 2001 Wisconsin Avenue, N.W.  
 Washington, DC 20007  
 (202) 334-2000  
[www.nationalacademies.org](http://www.nationalacademies.org)