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11TH STORY of Level 1 printed in FULL format.

The New York Times

December 9, 1998, Wednesday, Late Edition - Final

SECTION: Section A; Page 8; Column 3; Foreign Desk

LENGTH: 1002 words

HEADLINE: Japanese Scientists Clone a Cow, Making Eight Copies

BYLINE: By GINA KOLATA

BODY:

Scientists in Japan report that they have cloned eight calves from cells they gathered from a slaughterhouse, creating eight identical copies of a single cow. Though half of the calves died, some biologists say the results indicate that the cloning of cows may be at least as efficient as in vitro fertilization.

Cows are the third adult mammal to be cloned. The first was a lamb named Dolly, whose birth was announced in February 1997. She had been cloned from an udder cell. Then came mice, announced last July. And suddenly cloning, which just two years ago had been thought biologically impossible, is looking like it might be entirely feasible, if not easy, according to cloning experts.

It still seems surprising to some scientists. After all, an adult cell, like an udder cell, has reached its final destiny in the body and under normal circumstances, never changes into something else. But with cloning, an adult cell must reverse its development and become an early embryo cell, able to direct the development of an entirely new animal that is the identical twin of the adult that provided the original cell.

But now, "cloning is becoming routine," said Dr. R. Michael Roberts, a professor of animal physiology at the University of Missouri in Columbia and the chief scientist for the Department of Agriculture's competitive grants program in Washington.

A paper by the Japanese scientists, led by Dr. Yukio Tsunoda of Kinki University in Nara, Japan, describing their cloning of a cow, will be published on Friday in the journal Science. Science lifted its usual restrictions on announcing the results before publication of the paper after The Express in London went ahead and wrote about the results.

Dr. Tsunoda and the others say one reason for cloning cattle would be to reproduce exact copies of animals that are superb producers of meat or milk. In fact, Dr. Roberts said that on a recent visit to Japan he saw a calf that another group claimed it had cloned from cells taken from the ear of a prize bull. Those scientists have not yet published their results, he said.

Dr. Roberts said that several other groups, including some in Japan, say they are successfully cloning adult cows and bulls. Dr. Randall Prather, a cloning researcher at the University of Missouri, said that he and others are predicting that more than 50 calves that are clones of adult cows will be born in Japan

by year's end.

But what surprised many cloning experts was not just the fact that a cow was cloned but the ease with which Dr. Tsunoda's group accomplished its task.

"If this is true, it's startling," said Dr. Barry Zirkin, a reproductive biologist at Johns Hopkins University School of Hygiene and Public Health.

To begin the cloning process, the Japanese scientists gathered two types of cells from a Japanese beef cow whose entrails had been discarded in a slaughterhouse: cumulus cells, which cling to eggs and nurse them, and cells from the lining of the cow's Fallopian tube.

Then they used those cells to create embryos, slipping either a cumulus or Fallopian tube cell into another cow's egg from which the genetic material had been removed. The researchers attempted to add cumulus cells to 99 cow's eggs, of which 47 took up the cumulus cells. Eighteen of the resulting embryos survived in the laboratory for eight to nine days until they were ready to be transferred to surrogate mothers. With the Fallopian tube cells, they used 150 eggs, got 94 of them to take up cells, and ended up with 20 embryos. Dr. Tsunoda's group transferred 10 of their 38 embryos to cows that could serve as surrogate mothers. Eight calves were born. Four of the calves died at or soon after birth; the others survived and appear perfectly normal, the scientists say.

In contrast, when Dolly was created, Dr. Ian Wilmut and his colleagues at the Roslin Institute in Scotland began with about 400 eggs that yielded just 29 embryos that they could transfer to surrogate mothers and, from that, had just one live lamb, Dolly.

The Japanese investigators assert that although half of their calves died, their deaths appeared to have had nothing to do with the fact that they were clones. One died of pneumonia stemming from heat stroke, two others from aspirating too much amniotic fluid at birth, the fourth from complications during delivery.

Other scientists say they are not convinced those four calves were entirely normal. Nonetheless, they say, they are impressed with the astonishing efficiency of the cow cloning -- 80 percent of the embryos transferred to surrogate mothers survived until birth. With in vitro fertilization, said Dr. George Seidel, an animal physiologist at Colorado State University in Fort Collins, about 50 percent of transferred embryos survive until birth.

Dr. Mark Westhusin, a reproductive physiologist at Texas A & M University who is working on the cloning of cattle and dogs, said, "They have great results, no doubt about it."

Of course, scientists say, much more must be done to understand how cloning works, and why. But, some say, with cloning in three species, and getting more efficient, it is hard to doubt that humans will be cloned, sooner rather than later. Others urge caution, saying that before that happens, scientists should know more about the technique's safety and long-term consequences. Some raise wider social issues, accusing scientists of "playing God." Federal financing of human cloning technology is banned by executive order, and in 1997, President Clinton proposed a ban on privately financed efforts, but it never passed

Congress.

"Is it possible with humans? Perhaps," Dr. Zirkin said. "But I'm not sure this speaks to that. Different species are just very very different."

But Dr. Lee Silver, a molecular biologist at Princeton University, said he already knows of two qualified fertility specialists who want to clone humans. And so, he says, "anyone who thinks that things will move slowly is being very naive."

LANGUAGE: ENGLISH

LOAD-DATE: December 9, 1998

14TH STORY of Level 1 printed in FULL format.

The Washington Post

December 09, 1998, Wednesday, Final Edition

SECTION: A SECTION; Pg. A01

LENGTH: 1305 words

HEADLINE: Japanese Clone 8 Calves From Cow; New Process Shows Commercial Potential

BYLINE: Rick Weiss, Washington Post Staff Writer

BODY:

Scientists in Japan have cloned several calves from a single adult cow, the third species of mammal to be genetically duplicated after sheep and mice, and the most commercially important animal to be cloned to date.

The new work, the first cloning of a cow to be verified by scientists, represents the most efficient application of cloning technology yet. Eight cows were born from 10 attempts, far more than the single sheep named Dolly born after more than two dozen attempts.

Moreover, several of the cloned calves were made from a kind of cell never before used in cloning experiments. That suggests there may be many ways to copy a cow -- and perhaps easier ways still to be discovered for cloning other mammals, including people.

Most immediately, the cloning of cows promises a simplified method for expanding herds of valuable breeds, such as prize beef cattle or dairy cows that make more or better milk.

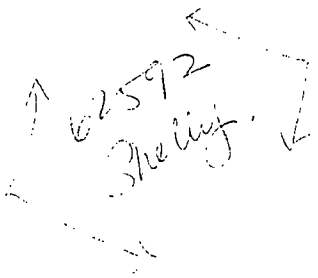
In the longer run, it could help scientists engineer herds of identical cows that make human medicines in their milk -- an avenue of research that is already advancing in cows that are mass-produced by cruder and less efficient techniques.

The results of the work done in Japan will be reported in Friday's issue of the journal Science.

"This says this technology is here, it's repeatable, and we're going to see it moving into the biomedical and agricultural industry," said James M. Robl, a professor of veterinary reproduction and developmental biology at the University of Massachusetts in Amherst. "This is not like when Dolly came out, when all we could say was, 'This was done once.' "

The new research "clearly tells us that . . . the efficiency is high enough to see it being used commercially," Robl said.

The growing parade of cloned animals is testimony to the complete overthrow of a long-standing biological axiom that said adult mammalian cells are incapable of growing into entirely new animals. Adult cells are fully



"differentiated," the theory went -- meaning they had become skin, muscle, bone or other tissues -- and could never revert to the blank-slate state of an embryo cell, which holds the potential to grow into every kind of tissue.

The realization that adult cells can be forced to grow into embryos is now spurring a revolution in agriculture and medicine.

The newly cloned calves, made by scientists at Kinki University in Nara, Japan, are not the first to be grown from from adult cow cells. New Zealand scientists said in August that they had made a calf from a single cell taken from the last remaining cow of a rare breed there.

And five other Japanese groups claim to have made clones of adult cows.

But the Kinki group is the first to describe its results in sufficient detail to get the work published in a scientific journal -- the benchmark of proof demanded by other scientists.

As with all previous adult cloning efforts, the Japanese team started with a single cell from the adult to be cloned. In Dolly's case, that cell was taken from a sheep's udder. The Japanese researchers used so-called cumulus cells taken from a cow's ovaries (the same kind of cell that researchers in Hawaii used to clone mice) or skin cells taken from that cow's fallopian tubes -- a kind of cell never before used for cloning.

The scientists placed those cells in laboratory dishes, each one resting alongside a cow's egg cell whose own genetic material had been removed. An electrical shock forced each pair of cells to fuse into one. Mysterious natural compounds inside the egg cells "erased" the genetic memories of the donor cells, in effect making each donor cell "forget" it was an ovarian cell and begin to divide as though it were part of a newly developing embryo.

Two by two, 10 such embryos were transferred from their dishes into five surrogate mother cows. Eight developed to maturity and were born, seven naturally and one by Cesarean section. Four died soon after birth from infections and other "environmental" causes, but all appeared normal, the team reported.

The researchers said they had another batch of clones developing now, made from liver, kidney and heart cells, with births expected in the spring.

Will Eyestone, a senior research scientist at PPL Therapeutics' research farm in Blacksburg, Va., said cow cloners are driven in large part by the desire to make herds of cows that make human medicines in their milk. PPL, an agricultural biotechnology company based in Scotland, already has made cows whose milk is spiked with alpha-1 antitrypsin, a human enzyme that maintains lung health, and the blood-clotting factor fibrinogen.

Those animals were cloned from embryos and fetuses, however, using older genetic technologies. Those methods are less efficient than the newly emerging techniques, but are more amenable to genetic manipulation and so may remain the best way to mass-produce genetically enhanced cows.

But if the Japanese method can be adapted to allow the cloning of genetically engineered cows as well as normal ones, then farm-fresh pharmaceuticals could

become far more economical to produce than many standard medicines, experts said.

No one has yet cloned an adult mammal with added genes, such as those required to make medicines in milk.

But even without such modifications, the Japanese cattle cloning techniques are probably worth billions of dollars to the meat and dairy industries, Robl said. Indeed, the Japanese government supported the research in part to protect its domestic producers from the increased foreign competition that has resulted from falling trade barriers.

The problem, Robl said, is that beef cattle and dairy cows are notoriously variable in their productivity, even when they are closely related and treated exactly alike. "So there's a lot of pressure on producers to choose a highly productive animal and make a lot of them."

In the $ 30 billion to $ 35 billion U.S. beef industry, for example, in which 40 million head of cattle are slaughtered every year, it has been estimated that ranchers would gain an extra $ 200 per head, or $ 8 billion, if they could produce more uniformly high-quality animals.

In the $ 18 billion to $ 20 billion U.S. dairy industry, Robl said, there are cows that produce the national average of about 16,000 pounds of milk a year and those that yield as much as 25,000 pounds.

"You can see what an increase in value you'd get," he said, with a herd of high-producing clones.

Companies also want to clone herds of dairy cows from the few stars that today produce high levels of protein in their milk. By boosting protein levels from the current 3 percent or 3.5 percent to 4 percent, Robl said, the industry would be worth an extra $ 2 billion.

Cloning Technique

Here's a description of the cloning technique used by Japanese researchers to make eight cloned calves:

1. Scientists take unfertilized eggs from an adult female cow (A) and remove all of the eggs' DNA, leaving behind the gutted cell with the nutrients and cellular machinery needed to foster embryo growth.

2. They remove cells from the adult cow they want to clone (B) and place them in a culture dish. The cells contain a full complement of DNA. These donor cells are raised on a growth medium until they enter a quiescent state that makes them susceptible to being cloned.

3. A donor cell is placed in a dish next to a single gutted egg cell. A spark of electricity makes the two cells fuse. The resulting single cell behaves like a fertilized egg and starts dividing into an embryo.

4. The resulting embryo is kept in a culture dish for eight or nine days, then transplanted into the womb of a surrogate mother (C) to develop normally. The resulting offspring is genetically identical to the animal (B) that donated the cell.

GRAPHIC: IG,,LAURA STANTON

LANGUAGE: ENGLISH

LOAD-DATE: December 09, 1998

Thursday, November 12, 1998

Co. Claims To Create Cow-Human Cell

By ALISON FITZGERALD, Associated Press Writer

"master cells"

BOSTON--Scientists at a Massachusetts company claim that they have made a human cell revert to the primordial state from which all other cells develop by fusing it with a cow egg.

Although the research announced by Advanced Cell Technology of Worcester, Mass., has yet to be published or confirmed, the company said the method eventually could be used to grow replacement body tissues.

Several experts in the field expressed skepticism about the company's claims.

Dr. Michael West, Advanced Cell Technology's chief executive, said the research into creating human "master cells" could eventually solve one of the most difficult problems in human medicine -transplantation of organs.

West said he took the unusual step of announcing the research before it was published to gauge its acceptability, so the privately held company can decide whether to commit money to developing the process.

"Our attempt was to ask for an open and ethical debate about the status of this research. These are issues people have never resolved, he said today.

The company acknowledged there were difficult ethical questions involved in area a cell that is part human and part cow.

The hybrid cell is made by removing the nucleus of a cow egg and inserting a

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the nucleus of a cow egg and inserting a human cell's nucleus. Only a small amount of the cow's genetic material -that found in the mitochondria -would remain.

West said that genetic material influences only the proteins in the mitochondria, which produce energy in cells, but has no effect on the physical traits of the tissue that eventually comes from the cell.

The research, which was conducted three years ago using cells scraped from the cheek of one of the scientists involved in the research, showed that the cow proteins were displaced by human proteins, the company said.

The hybrid cell theoretically could be transferred to a uterus and grown into a clone of the human donor, but the company said that would be unsafe and unethical. Instead, the cell could be guided into becoming human tissue.

"We have absolutely no interest or intent ever of cloning a human being. That's not the point at all," West said. "The point is to address transplantation."

West said his company had not yet managed to direct the cell growth into a particular kind of tissue, such as a muscle, cartilage or nerve.

Despite the announcement, several experts in the field said they needed much more proof before they believed embryonic cells had been created. Some also doubted that the technique would work.

"It's hard to say this is a total sham, but I smell a sham here," Dr. Roger Pedersen of the University of California, San Francisco told The New York Times. He doubted that the cow-derived mitochondria would work well enough in human cells.

Last week, two published studies described how human stem cells, the foundation of cells that form all body parts, can be grown in a laboratory.

Dr. John Gearhart of Johns Hopkins University, who was involved in one of those studies, said of Advanced Cell Technology's claim: "It's not that I don't believe this biologically. I just think they could have given a little bit more assurance as to what was done here."

Biotechnology critics fear misuse of such technology, including the possibility of one day cloning people. The biotech industry strongly opposes cloning humans, said Carl Feldbaum, president of the Biotechnology Industry Organization.

But with today's announcement, he said, it's time for a national consensus on how to use these discoveries.

"You're always going to have people coming out with science-fiction scenarios. Those need to be dealt with" through national debate, he said. "There are significant future medical benefits if the ethical cloning is used wisely and ethically

In January, two Advanced Cell Technology researchers announced they had used the same technique -called embryonic transfer -to create cow "master cells" and eventually clone a cow.

25TH STORY of Focus printed in FULL format.

The Washington Post

July 23, 1998, Thursday, Final Edition

SECTION: A SECTION; Pg. A01

LENGTH: 1470 words

HEADLINE: Scientists Clone Adult Lab Mice; Process May Hurry Human Application

BYLINE: Rick Weiss, Washington Post Staff Writer

BODY:

Using a new and relatively simple cloning technique, scientists in Hawaii have created dozens of cloned mice, marking the first documented cloning of adult mammals since researchers in Scotland announced the birth of Dolly the sheep last year.

Researchers predicted that the newfound ability to study and practice cloning in a laboratory animal as convenient as the mouse would quickly lead to the discovery of even better techniques for cloning various animals -- including, almost certainly, people.

Indeed, one of the key findings of the new work is that a biological roadblock scientists thought might interfere with their ability to clone mice and people is not insurmountable in mice after all, suggesting that human cloning is also achievable with relative ease.

With anticloning legislation stalled in Congress and a growing number of experts touting cloning's potential benefits as a treatment for human infertility or other conditions, several experts said they believe that the birth of a cloned person is inevitable.

"I'm absolutely convinced it will happen," said Lee Silver, a professor of genetics at Princeton University, "and I think it will happen sooner than we thought a year ago."

Silver said he would not be surprised if a person were created by a cloning technique within five years.

Separately, two teams of scientists yesterday reported they had used sophisticated DNA fingerprinting techniques to prove beyond doubt that Dolly is a clone -- a perfect genetic copy of the adult sheep from which she was made. Some scientists had disputed her authenticity after several efforts to repeat the experiment in other species had failed. (A report from Japan earlier this month that researchers had cloned an adult cow has yet to be confirmed in a scientific journal.)

The proof that Dolly is a clone, together with the new work in mice, effectively ends a 17-month age of innocence when people could still believe that Dolly's fatherless birth was a fraud or a fluke, or that cloning might be possible only in sheep.

The new reports, which appear in today's issue of the journal Nature, prove there are at least two different ways to clone mammals. And although the method used by the Hawaii researchers can be used only to clone females for now, scientists said they suspected the approach will be improved upon to work in both sexes and in other kinds of animals.

"These are exciting results," said Ian Wilmut, the scientist who told an astonished world last year that he and his colleagues had cloned Dolly. "They suggest it will be possible to produce adult clones from a range of different cell types and species."

While exciting to scientists, that prospect prompted ethicists and others to call for a renewed debate about the morality of human cloning, which would bypass the mixing of genetic material from two people that occurs during normal procreation.

"These experiments ought to restart our public conversation about whether it's wise to clone humans," said Erik Parens, a research associate at the Hastings Center, a bioethics think tank in Garrison, N.Y., who expressed dismay with what he perceives to be a growing public complacency about the notion of human cloning.

"Increasingly, people who think of themselves as sophisticated feel that worrying about these things is just silly or fruitless or both," Parens said. "But I think that if we look into the future and see where we can go with these technologies, we'd be faster to criticize or at least to reflect."

The mouse cloning work was achieved in the laboratory of Ryuzo Yanagimachi, a pioneer in mouse biology at the University of Hawaii who encourages his students to work three days a week on their "official" laboratory work and two days a week pursuing novel interests in the lab.

"I encourage them to ask crazy questions," Yanagimachi said in an interview. "Nine out of 10 of them will be truly crazy questions, but one will lead to something important."

Teruhiko Wakayama, a 31-year-old postdoctoral researcher, took that philosophy to heart. Without telling his mentor, he began to experiment with cloning techniques. One day last August, Yanagimachi said, Wakayama called him over to his lab bench. "He showed me a mouse fetus with the heart beating and said, 'This is a clone.' "

Over the next few months the team improved the method, which differs in a few key ways from that used by Wilmut to make Dolly. Most notably, the Hawaiian technique used cells called cumulus cells, which nourish eggs in the ovaries of both female mice and humans. Wilmut used a cell from a ewe's udder.

The first resulting cloned mouse to survive to adulthood, named Cumulina, was born Oct. 3.

Most of the hundreds of cloned embryos the team produced did not survive, but more than 50 cloned mice have been born so far. Many of those have mated and given birth, indicating they are healthy and reproductively normal.

Moreover, the Hawaii team has taken cells from some cloned mice and made "second generation" clones, and has even cloned mice from the clones of clones. "We think that's the first report in any vertebrate species of a clone being derived from a clone," said Anthony Perry, a member of the Hawaii team.

The Hawaiian researchers tried the same technique with cells taken from the testicles of male mice, but the efforts failed for reasons that remain unclear. They believe, however, that they should be able to eventually overcome that problem and clone males.

The efficiency rate in females is still modest, Yanagimachi said -- one or two clones are born for every 100 efforts. But considering how easy it is to work with mice, he said, that is good enough to allow a wide array of experiments that could shed light on the molecular mechanisms of reproduction, the process of cell aging and the genetics of cancer -- a disease characterized by embryo-like cell division.

Moreover, the low cost of working with mice and their rapid two-and-a-half month generation time will advance research into mammalian cloning far faster than has been possible in sheep and cattle.

The technology has been licensed to ProBio America Inc., a biotechnology company based in Honolulu.

Some scientists had believed that cloning would only work in some farm animals such as sheep, which do not actually use their cellular DNA until relatively late in embryo development -- a delay that might give the newly transferred genes time to get reprogrammed by the egg. By contrast, human embryo development requires properly programmed DNA fairly early on, and mice need it even sooner. Yanagimachi's proof that mice can be cloned indicates that the reprogramming happens quite quickly, said Robert J. Wall, a physiologist with the Department of Agriculture.

While the Hawaii researchers refused to talk about potential human applications, saying they are only interested in mice, others said the implications of that discovery were clear. "If you can clone from adult mouse cells," said Silver of Princeton, "there's basically no reason you can't do this in humans."

Researchers have cited several reasons why they would like to clone human embryos, and perhaps even full-grown human beings. Cloned embryos grown from a person's own cells could potentially grow into virtually any kind of tissue or organ and would not be subject to rejection. Although the technology to grow specific tissues from embryos is still primitive, said John Gearhart, a Johns Hopkins University researcher looking into the problem, it may be just a few years before it becomes practical.

Others, including Silver, advocate cloning as an option for infertile couples, including homosexual couples.

President Clinton has banned the use of federal funds for human cloning experiments, and the National Bioethics Advisory Commission has recommended that Congress pass a law banning human cloning in the private sector as well. At least four such bills are dormant on Capital Hill. Several states have passed

anticloning bills however, and a number of others are considering similar bills. In the meantime, the Food and Drug Administration has said it would have to approve any human cloning attempt.

A New Technique

Scientists have performed the first documented cloning of adult mammals since Dolly the sheep last year.

* Remove DNA from egg cell.

* Collect cumulus cells from ovaries. (By contrast, Dolly was cloned from an udder cell.)

* Inject DNA from cumulus cell into the gutted egg cell. (By contrast, Dolly was made by fusing an entire udder cell to a gutted egg cell with an electrical jolt.)

* Add chemicals to start cell division. Allow embryo to start developing in laboratory dish. Transfer embryo to womb of surrogate mother mouse.

SOURCES: Nature, Ryuzo Yanagimachi

GRAPHIC: PH,,PROBIO AMERICA INC.; IG,,PATTERSON CLARK, Cast members in cloning: top left, mouse whose hollowed-out egg cell was used; top right, mouse whose DNA was injected into egg cell; center, white mouse that was surrogate mother to embryo; and two cloned offspring.

LANGUAGE: ENGLISH

LOAD-DATE: July 23, 1998

2ND STORY of Level 1 printed in FULL format.

September 6, 1998, Sunday, BC cycle

SECTION: Domestic News

LENGTH: 277 words

HEADLINE: Scientist vows to clone himself

DATELINE: BOSTON, Sept. 6

BODY:

A Chicago physicist who shocked bioethicists and politicians earlier this year has renewed his plans to clone humans, saying he will be the first in line. Richard Seed said Saturday that he wants to bear the responsibility and his wife to bear his clone because cloning of animals carries the risk of stillbirth or birth defects. The Boston Globe reports Seed's wife Gloria has agreed to carry the embryo he will create using a nucleus of one of his cells with a donor egg. Seed said, ''I have decided to clone myself first to defuse the criticism that I'm taking advantage of desperate women with a procedure that's not proven.'' The 69-year-old scientist, who worked in fertility research in the 1980s, said in January that he wanted to replicate humans. Speaking before a meeting of the Association for Politics and the Life Sciences in Boston, Seed said clones would be ''fun,'' and a step toward immortality. Seed operates his Human Clone Clinic near Chicago and once promised to produce a ''happy, bouncing, baby clone'' by 1999. He said parents have expressed an interest in cloning their dying children, and two foreign countries have invited him to move his research facility there. He may have to move abroad since U.S. leaders have decried his plans. Health and Human Services Secretary Donna Shalala immediately dismissed Seed as a ''mad scientist'' in January. President Clinton declared a five-year moratorium on human cloning. California and Michigan have banned human cloning, but Congress hasn't passed legislation banning it. ---

LANGUAGE: ENGLISH

LOAD-DATE: September 7, 1998

5TH STORY of Level 1 printed in FULL format.

September 6, 1998, Sunday, City Edition

SECTION: NATIONAL/FOREIGN; Pg. A6

LENGTH: 728 words

HEADLINE: Would-be cloner plans to start with himself;
Says wife will carry test-tube embryo

BYLINE: By Richard Saltus, Globe Staff

BODY:

Richard Seed, the maverick physicist who provoked widespread opposition earlier this year by announcing plans to clone humans, said yesterday that because of the medical risks involved he has decided that the first person he tries to copy will be himself.

Not only that - the 69-year-old Seed said his wife, Gloria, has agreed to carry the embryo that would be created by combining the nucleus of one of Seed's cells with a donor egg.

Since cloning, even in livestock mammals, carries the risk of stillbirths or abnormal fetuses, there are clearly risks associated with the present technology, Seed said.

"So," he said, "I have decided to clone myself first to defuse the criticism that I'm taking advantage of desperate women with a procedure that's not proven."

Seed, who has been little heard from since his announcement last January, was by turns sober, provocative, and humorous as he spoke at the meeting in Boston of the Association for Politics and the Life Sciences, a group of academic researchers probing the influences of biology and evolution on political behavior.

Saying that clones would be "fun" and would unleash a "torrent of research," Seed declared that learning to reprogram an adult cell's nucleus (as was done in creating the lamb clone Dolly) would be the first step toward discovering immortality.

At a time when the cloning of animals has been advancing rapidly, going from sheep to cows to mice in less than two years, the political and legal status of human cloning remains uncertain. A five-year moratorium declared by President Clinton is apparently being observed by mainstream scientists, but Congress has failed to act on legislation to outlaw human cloning.

Yesterday, Seed continued to insist defiantly that he has support for cloning and the "bioethicists have no constituency." He said he has received several hundred calls, including several from parents of dying children who say they are interested in cloning them, and has been invited by two foreign countries to set up shop there.

The Boston Globe, September 6, 1998

Many scientists have declined to take Seed's plans seriously, saying he has neither the means nor the money. He is not a medical doctor, though he has performed embryo research. He said yesterday he has done "a little bit of work" toward his goal and has raised some money, but needs much more.

Nevertheless, he insisted that his Human Clone Clinic located near Chicago will produce a pregnancy with a human clone within 2 1/2 years. The US Food and Drug Administration warned in January that it would halt any human cloning attempts by Seed or anyone else, but speakers yesterday said they doubted the FDA has jurisdiction.

Seed's presence, representing at least the possibility of serious human cloning attempts, enlivened yesterday's discussions of the pros and cons of cloning and efforts to regulate it. At present, two states - California and Michigan - have banned human cloning and dozens of other states are considering bans.

From an initial reaction following the cloning of Dolly the lamb in 1996 that human cloning would be unthinkable, the debate now seems to have moved toward acceptance that it is probably inevitable.

Only a few applications seem likely to be attempted, speakers said yesterday: to produce a child for an infertile couple unable to conceive in any other way: to replace a dead child if conventional reproduction was impossible, or to produce a child who could donate bone marrow or some other vital tissue to a seriously ill family member.

Dorothy Wertz, a senior scientist and genetics specialist at the Shriver Center in Waltham, said many of the standard arguments against cloning are flawed. The notion that cloning is "an affront to human dignity" and individuality is based on the erroneous notion that clones would in fact be identical because of identical genes. "We are not our genes" but subject to many environmental influences, she said.

Wertz argued that human cloning is not inherently unethical and should not be banned prematurely, and predicted that in time it will become acceptable just like such formerly deprecated practices as test-tube fertilization, donor insemination, and creation of single-parent families.

It is unlikely that headless human clones would be created as a source of spare body parts, since taking the parts would amount to murder, she said.

LANGUAGE: ENGLISH

LOAD-DATE: September 9, 1998

8TH STORY of Level 1 printed in FULL format.

September 6, 1998 Sunday, CHICAGOLAND FINAL EDITION

SECTION: PERSPECTIVE; Pg. 1; ZONE: C

LENGTH: 966 words

HEADLINE: HERE MISSY, MISSY, MISSY, MISSY. . .

BYLINE: By Arlene Judith Klotzko. Arlene Judith Klotzko, J.D. is a visiting scholar at the Center for Bioethics, University of Pennsylvania.

BODY:

Two years after the birth of Dolly the Scottish sheep and eight months after Dr. Richard Seed--the Chicago-based would-be cloner of humans for cash--took his brief turn on the world stage, cloning is back in the news. This time not with a bang or even with a bleat. This time it's a bark.

Scientists at Texas A&M University are poised to clone, for a $2.3 million reward, a pet dog named Missy, an 11-year-old border collie/husky mix.

While at first glance the Missyplicity Project may seem like a natural extension of farm-animal cloning, the goal of recreating Missy is radically different and, indeed, impossible to achieve.

While cloning may replicate our genetic identity, people and their pets are far more than the sum of their genes. Environment and experience play a crucial role in the formation of personality.

Dolly--arguably the most famous farm animal in history--is the product of a series of experiments seeking to produce large transgenic animals (those carrying human genes) that secrete therapeutically useful proteins in their milk.

Because Dolly was cloned from an adult animal, she sets the stage for cloning pigs and cattle from prototypes that have just the desired characteristics. These animals will not be created to be loved--only to be used.

Being able to clone a pig will be particularly important if transgenic pigs turn out to be safe sources of organs for transplantation into humans. In that case, cloning will be a much more accurate technique than current practices, which are hit-and-miss affairs hinging on the injection of human genes into embryos. With cloned pigs, replication--not perpetuation--is the goal.

As with farm animals generally, pigs are basically interchangeable, but people, and their pets, are different. What we prize in our friends and pets is precisely what makes them special and unique. And that is not merely a function of genetic identity: We may be acquainted with identical twins, yet find ourselves drawn to one and not the other.

Chicago Tribune, September 6, 1998

The Texas A&M scientists involved with the Missyplicity Project, led by Dr.Mark Westhusin, have been conducting cattle cloning research since the late 1980s, well before Dolly was a gleam in anyone's eye. Westhusin currently is collaborating with Dr.Jorge Piedrahita.

Westhusin has said that the Missiplicity Project is more than just a way to produce another Missy. He views it as real science, a chance to study basic reproductive physiology in dogs and perhaps catch up with the work already done in other species.

Is the motivating force behind this $2.3 million project the pursuit of science? Five of the six project goals described on

the Missyplicity website (www.missyplicity.com) deal with hard science. But cloning Missy is goal number one. And even more telling are the "Missy Tales," written about Missy by her "human mother."

"How Missy found a home" tells readers how she was selected at the pound: "I didn't want another dog whose bite . . . would bring blood. I wanted to know if she had a high, ear-shattering bark (which I don't like), and if she could howl (which I do like). . . . I offered a howl to her and she raised her nose and howled at the roof. I barked at her and she barked right back, a low rich-toned, businesslike bark. I whined, she whined."

Missy seems to have met all the specifications.

There has been a long history of manipulating dogs to give them traits we like. Since 1884, the American Kennel Club has been registering purebred dogs that represent different ideals of beauty, taste and style. Such predictability is the reason that one might chose a golden retriever over a mutt.

But replacing a beloved dog that has died with another of the same breed will not bring back the lost dog. Neither will cloning.

Environment clearly is a major factor in the development of a dog's personality, said Westhusin, adding that the specific roles of genetics and environment in personality will be clear only after they clone Missy. She will be raised in a different environment from Missy (who came from the pound), and that experience will influence the dog's personality. Certainly, if the clone were to be abused as a puppy, it would affect personality.

A basic problem with the Missyplicity Project is that its announced intentions present the same reasons that have been advanced to justify the cloning of humans--to perpetuate a "unique" life that is drawing to its close by replicating it. For example, dying children could be cloned to produce replacements and thereby assuage their parents' grief. But that sort of thinking reduces people and pets to interchangeable objects. Besides, conferring immortality through cloning by serially perpetuating a unique and beloved human or pet is an impossible dream.

In one sense, cloning a pet is less morally problematic than cloning a human. One of the arguments against the latter rests on the possible psychological damage that being a clone might create. If I learned that I was cloned to be "like" someone else, would I feel pressured to become that person? To excel in the ways that person excelled? To be a violinist, a baseball

player, a physicist? Could I watch my older genetic double sicken and die prematurely without being paralyzed by the fear that this would be my destiny as well? Cloned pets, of course, would be spared such knowledge.

A remarkable paradox lies behind the Missyplicity Project. Its funder has asked that scientists employ a technique that many see as a threat to uniqueness in a futile quest to recreate a unique life. Most of us would abhor the idea of a world in which there are a hundred people just like us. But, contrary to such fears, cloning could never produce such a world. Those who seek reincarnation must look to metaphysics--not genetics.

GRAPHIC: GRAPHIC

LANGUAGE: ENGLISH

LOAD-DATE: September 6, 1998

THE MISSYPLICITY PROJECT

Press Release

San Francisco, August 24, 1998

The Texas Agricultural Experiment Station at Texas A&M University, and Bio Arts and Research Corporation (BARC) of San Francisco, today announced a joint research project into canine reproductive physiology, believed to be the largest such effort ever conducted.

The goals of this project are as follows:

1) improve basic understanding of reproductive biology;
2) enhance reproduction of endangered species, especially endangered canids;
3) develop improved canine contraceptive and sterilization methods; and
4) replicate specific, exceptional dogs of high societal value.

This project will involve research into cloning of adult dogs, and has already recruited senior scientists from several universities and other institutions, working with a privately-funded budget of $2.3 million for the first two years. This effort is titled the Missyplicity Project, in honor of "Missy", the dog whose DNA will be used to produce the first cloned offspring.

The Missyplicity Project will have a significant positive impact regardless of which project goals are attained. Canine reproductive biology is a seriously underfunded area of science, given that it lacks the commercial interests associated with livestock. Despite limited commercial potential, better understanding of canine reproduction could be directly applied to the repopulation of endangered canids, including many species on the brink of extinction.

Conversely, the knowledge gained from this project can also be used to improve existing and develop new pharmacological methods of canine contraception and sterilization, an important issue in the United States where millions of unwanted dogs are euthanized every year.

Finally, the Missyplicity Project will also facilitate the replication of exceptional individual dogs of high societal value, primarily service dogs such as seeing-eye dogs and search & rescue dogs. The best service dogs, while obviously well-trained, also possess specific genetic endowments which can only be propagated precisely via nuclear transfer.

The Missyplicity Project is committed to facilitating the necessary technology and information transfers required to realize the project goals, via both commercial and non-profit partnerships, as well as publishing through traditional academic journals.

More information about this project - including the project Code of Bioethics - is available on the Internet at: www.missyplicity.com, or by contacting Lou Hawthorne of BARC, the Project Coordinator, at 415-646-0417. Anyone interested in speaking with Dr. Mark Westhusin, the Principal Investigator for the scientific team, should contact Texas A&M University Relations at 409-845-4644.

THE MISSYPLICITY PROJECT

Code of Bioethics

Along with the emergence of cloning and transgenic biotechnology, the field of bioethics has emerged as well. Bioethics is the study of the ethical aspects of bioengineering. The overwhelming focus of modern bioethics is the appropriateness and implications of human cloning. On the Missyplicity Project, bioethics will govern the treatment of all animals involved in the development of relevant technology, as well as the treatment of all engineered animals, along with future applications of the resulting technology. The Missyplicity Project Staff - including sub-contracted scientists - has agreed to comply with the following 9-point "Code of Bioethics" - to maximize the benefits and minimize the harm resulting from this project:

1) In accordance with Federal law, no animals will be intentionally harmed at any point during this project, including the research phase. In addition, no animals will be endangered through lack of attention or care, or by being subjected to risky procedures of any type.

2) The psychological welfare, happiness and socialization of all dogs involved with the Missyplicity Project shall be considered at all times. Every dog shall be guaranteed a daily minimum of one hour of outdoor playtime - weather permitting, indoors otherwise - with people hired specifically for this task.

3) Regardless of the source through which dogs are obtained for use as egg donors or surrogate mothers - animal shelters, breeding farms, etc. - at the completion of their role on the Missyplicity Project, all dogs shall be placed in loving homes. No funds shall be expended for dogs raised under inhumane conditions, such as in "puppy mills".

4) The "turnover rate" before an animal involved with the Missyplicity Project is placed in a loving home shall be limited to eight months, with less than six being the goal.

5) Every effort will be taken to minimize the waste of viable embryos, which will only be destroyed if implantation is impossible, or if the embryos are flawed and likely to result in deformities.

6) All dogs born as a result of this project shall be treated as pets, and placed in loving homes, even if they are not actual clones of Missy. In the unlikely event that a dog is born with deformities or other problems, it will only be euthanized if it is suffering, and shall otherwise be placed in a loving home.

7) No transgenic - "gene-changing" - work of any kind shall be performed.

8) Every effort shall be taken to ensure that the technology and procedures developed for the Missyplicity Project will be applied in the future in an ethical and socially positive manner.

9) No data, personnel or other resources shall be knowingly shared with people or programs seeking to clone human beings.

132ND STORY of Focus printed in FULL format.

The Columbus Dispatch

February 23, 1998, Monday

SECTION: EDITORIAL & COMMENT , Pg. 6A

LENGTH: 720 words

HEADLINE: HOLD THE CLONES;
DON'T PROHIBIT LEGITIMATE GENETIC RESEARCH

BODY:

The decision by the U.S. Senate to slow down the rush to legislate a ban on human cloning makes sense, given the evidence that an overly inclusive bill could impede important scientific and medical research.

Few deny the serious moral and ethical implications of cloning human beings, but a bill that would permanently ban a procedure known as ''human somatic cell nuclear transfer,'' similar to the procedure that led to the cloned sheep Dolly, was premature. Lawmakers from both parties on Feb. 11 put a bill sponsored by Sens. Christopher S. Bond, R-Mo., and Bill Frist, R-Tenn., on indefinite hold over concerns that it risks slowing or stopping lifesaving and life-improving biomedical research.

For more than two decades, cloning of individual human cells, tissues and genes has helped develop modern medicines used to treat diabetics, heart-attack and stroke victims and cystic-fibrosis patients. Many scientists also believe that in the future cloned tissue could prove valuable in making other health advances in the treatment of Alzheimer's disease, spinal-cord injuries and severe burns.

It's difficult for the layman to understand cloning research, but one does not have to be an expert to have concerns about the prospects of human cloning.

Unfortunately, some politicians are exploiting that concern to demagogue the issue.

The Republican leadership in the Senate rushed to deny President Clinton the political advantage in being anti-cloning after maverick Chicago physicist Richard Seed said in January he intended to set up a commercial enterprise to clone humans as a way to help infertile couples.

Meanwhile, House Majority Leader Dick Armey, R-Texas, pledged a House floor vote this month on a permanent ban not only on the creation of human clones but also on studies with embryonic cells. This had the unfortunate effect of marrying the cloning debate with the abortion debate.

Anti-abortion advocates are clamoring for a broad ban because they believe that any human-cloning research necessarily involves the creation - and destruction - of genetically engineered human embryos. While these individuals have a right to their beliefs, the Senate is acting responsibly in stepping back for a more comprehensive look at a complicated, technical issue.

Even Frist, a heart surgeon, who claims his bill would not interfere with existing medical research, acknowledged that ''we're banning something before it's fully understood.''

The biomedical-research community is particularly uncomfortable with the Bond-Frist bill, which would permanently ban any attempts to produce a human embryo using somatic cell nuclear transfer technology. It prefers a bill offered by Sens. Dianne Feinstein, D-Calif., and Edward M. Kennedy, D-Mass., that prohibits only the implantation of an embryo made through somatic cell nuclear transfer into a woman for the purpose of creating a human being. The latter bill also has a sunset provision at 10 years to allow lawmakers to reconsider it.

It is possible that neither of these approaches will turn out to be the right one. But the House needs to follow the Senate's lead and look more carefully at cloning.

There are reasons to be both cautious and optimistic about the scientific prospects of cloning technology. It is theoretically possible to clone whole organs, such as livers and kidneys, without duplicating an entire human. Whether this is something science should pursue for transplants will require more study and certainly more debate than the knee-jerk response of ill-informed lawmakers in Congress. More immediately, scientists are close to developing the capability to clone a few cells to repair injured organs or to create fresh cartilage for damaged knees.

One of 277 embryos survived to create Dolly. The New York Times reporter who broke the Dolly story said, ''There were no monsters, no miscarriages, nothing.''

But Frist also has a point that science has been twisted to evil purposes in the past, by Adolf Hitler and others.

Legislative control someday makes sense, even though the Food and Drug Administration, which has jurisdiction over genetically engineered medicines, believes it can regulate efforts to clone human beings. Nevertheless, there is no need to rush a bill through that endangers research.

LOAD-DATE: February 24, 1998

152ND STORY of Focus printed in FULL format.

Newsday (New York, NY)

February 17, 1998, Tuesday, ALL EDITIONS

SECTION: DISCOVERY; Page C07

LENGTH: 1071 words

HEADLINE: IMPASSE OVER ANTI-CLONING BILL

BYLINE: By Earl Lane. WASHINGTON BUREAU

DATELINE: Washington

BODY:

Washington WHEN SCIENCE and politics come together on the frontiers of bioethics, the result sometimes can be an impasse, as backers of a Senate bill to outlaw cloning of humans found last week.

Republicans and Democrats alike oppose any attempt to create the human equivalent of the now-famous sheep in Scotland called Dolly. And major biomedical research groups in the United States have agreed on a voluntary moratorium on any efforts to make genetic carbon copies of a human.

But when Chicago physicist Richard Seed said recently that he was planning to offer cloning services to infertile couples, there was a rush in the Republican-led Senate to craft legislation making such doings a federal crime.

Forget that some scientists say the technical feasibility of human cloning is questionable (it took 277 tries to create Dolly, and some scientists still question her pedigree). Or that Seed has no financing and is unlikely to find researchers willing to endanger their professional reputations by helping him.

The Senate legislation that was drafted - and sent back to the drawing board Wednesday after Democrats and a dozen Republicans voted to block quick floor action - seemed straightforward. But the bill's language brought dire warnings from researchers about its potential impact on medical research.

Called the Human Cloning Prohibition Act, it mandated up to 10 years in prison and stiff monetary penalities for anyone using "human somatic cell nuclear transfer technology."

Somatic cell nuclear transfer is the method used last year in Scotland to create Dolly. The researchers extracted the nucleus from an adult body cell (or somatic cell) from a sheep's mammary tissue. They inserted that donor nucleus into an unfertilized sheep ovum, or egg, whose own nucleus had been removed.

The DNA in the donor nucleus gained the full potential to direct the growth and development of a baby lamb after the egg was implanted into a womb. The resulting lamb, Dolly, was genetically identical to the adult sheep from which the mammary cell had been taken.

There have been some lingering questions about Dolly. Because the mammary cell used to produce her came from a pregnant ewe, Norton Zinder of

Rockefeller University and an Italian colleague say she may have been cloned from a contaminating fetal cell circulating in the ewe rather than from an adult mammary cell. The Scottish research team is confident that did not happen.

The debate will be settled only when other researchers replicate the experiment that produced Dolly. But the implications of the research are enormous.

Scientists have known for years that each cell in the body carries the entire genetic library required to produce a healthy human. During embryonic and fetal growth, however, cells become specialized, with only certain genes in the library activated. One cell becomes part of the liver, another becomes a lung cell, another a muscle cell.

Dolly offered dramatic evidence that the genetic material in an adult body cell can be reprogramed in the egg to restore its potential to produce all possible cell types. Researchers began talking about putting nuclei from body cells into enucleated eggs to produce stem cells for particular types of body tissue. For example, reseachers might be able to replace a person's damaged heart tissue with custom-grown cardiac cells. Since the cloned cells would arise from the person's own body tissue, there would be no rejection problems.

A fundamental understanding of how to reprogram DNA from adult body cells might mean a new era of cell therapies as momentous as previous breakthroughs in the use of drugs, experts say. As Matthew Scott, president of the Society for Developmental Biology, wrote to the Senate: "Instead of diabetes meaning a lifetime of insulin injections accompanied by serious side effects, perhaps we can learn how to cause the reactivation of pancreas development and regeneration of missing cell types. Such exciting ideas are no longer farfetched."

Sen. Christopher Bond (R-Mo.), a co-sponsor of the Senate anti-cloning bill that was set aside last week, said tinkering with cloned human embryos - even for potentially worthy goals - could "lead us down the slippery slope that would allow the creation of masses of human embryos as if they were assembly-line products, not human life."

But Sen. Dianne Feinstein (D-Calif.), co-sponsor of alternative anti-cloning legislation, argues that researchers should be allowed to transfer DNA-containing nuclei from mature body cells into human eggs as long as they aren't intended for implant into a womb.

Such eggs, Feinstein said, are not embryos "in the traditional sense of the word." They are not fertilized by sperm, and they cannot develop into a fetus without being placed into a womb, specialists say.

As a practical matter, there already is a ban on federal funding of human embryo research that likely would make such experiments difficult to pursue except with private funding, specialists said. Animal research is under way.

Roger Pedersen, a reproductive geneticist at the University of California at San Francisco, said cloning of customized human cells for medical use remains a theoretical goal for now. He said use of enucleated human eggs and nuclei from adult donor cells seems a promising approach. Biochemical signals in the egg cytoplasm are crucial to coax production of the desired body cells, Pedersen

said. Eventually, he said, the signal molecules might be isolated, allowing customized cell lines in laboratory cultures without use of egg cells as the initial medium.

For now, Congress faces the task of more carefully examining the language and intent of various anti-cloning bills. Pedersen said it is important that any bill define its terms. For example, a fertilized egg is technically considered a somatic cell, because it has two sets of chromosomes. Pedersen said vagueness in defining somatic cell in the Republican-backed Senate bill could outlaw a possible treatment of a type of infertility that affects women whose eggs have abnormal cell structures called mitochondria. The treatment would use the nuclear transfer technique to remove the fertilized nucleus of the woman's egg It then could be placed in the enucleated egg of a donor woman without mitochondrial disease. That egg would be implanted into the womb of the first woman.

GRAPHIC: AP Photo- Physicist Richard Seed; his plans to clone humans created a rush to make it illegal.

LANGUAGE: English

LOAD-DATE: February 17, 1998

48TH STORY of Focus printed in FULL format.

The Detroit News

May 20, 1998, Wednesday

SECTION: Metro; Pg. Pg. D1

LENGTH: 376 words

HEADLINE: State House passes bills banning cloning of humans

BYLINE: By Gary Heinlein / Detroit News Lansing Bureau

BODY:

LANSING -- It looks like Michiganians will have to continue reproducing the old-fashioned way.

The state House gave final approval Tuesday to legislation making it a felony to clone a human being. The bills are heading to Gov. John Engler, who is expected to sign them into law.

Al Isaacson, 54, a Taylor carpenter, thinks lawmakers did right.

"What do we need it for?" he wondered about cloning. "The Lord giveth and the Lord taketh away. And I'm not a religious individual."

Rep. Kirk Profit, the Ypsilanti Democrat who was the main House sponsor, said: "For a lot of us, it's a statement about the source of life."

Profit said the legislation allows all research short of creating a human through cloning.

Michigan is the first state to pass a permanent human cloning ban. California recently passed a five-year moratorium.

The Michigan Catholic Conference supports the bills. So does University of Michigan pathologist Anthony Killeen. Developing a person through cloning could be "dangerous for the health and longevity of the clone generated," Killeen said. "It's really reckless to go ahead with it at this time."

But others see the legislation as a premature reaction to last year's announcement that scientists had cloned a sheep named Dolly in Scotland, and Chicago researcher Richard Seed's plan to clone humans.

"It looks like it's important because of that guy Richard Seed," said professor Leonard Fleck of Michigan State University's Center for Ethics and Humanities in Life Sciences. "This strikes me as being one of the more distant things the Legislature ought to be concerned about right now."

Toby Citrin, director of Community-Based Public Health at the University of Michigan, said the Legislature would have been smarter to follow President Clinton's National Bioethics Advisory Commission, which suggested a five-year moratorium on cloning.

He said the legislation resulted from discussions between researchers and right-to-life advocates. "That's not necessarily good public policy," he said.

Cloning ban

Violators of Michigan's anti-cloning laws could face:

* Fines of up to $ 10 million.

* Imprisonment for up to 10 years.

* Loss of state-issued professional licenses for up to five years.

LOAD-DATE: May 20, 1998

August 22, 1998, Saturday, Home Edition

SECTION: Metro; Part B; Page 7; Editorial Writers Desk

LENGTH: 605 words

HEADLINE: NEW FUEL FOR CLONING ISSUE

BODY:

Last February, just days after physicist Richard Seed boasted he would soon attempt to clone humans and one year after Dolly the sheep became the first true clone of another living mammal, Sen. Christopher S. Bond (R-Mo.) rushed an emergency measure onto the Senate floor to ban research into human cloning. "This type of research is morally reprehensible," the senator said, "and should be off-limits to science."

The measure seemed a shoo-in, but virtually overnight congressional support for the anti-cloning legislation collapsed, and the bill has lain dormant ever since.

The sudden reversal is attributed to behind-the-scenes lobbying by patient advocacy groups and the biotechnology industry, which argued that a cloning ban would prevent important research to cure disease. The Bond bill would have put a halt, for instance, to Geron Corp.'s efforts to "teach" embryonic mouse cells to produce organs that can be used in transplants.

Henry T. Greeley, a Stanford law and genetics professor, declared after a recent examination of state and federal cloning regulations, "Legislators have lacked the foresight, the technical knowledge, or the candor one would like to see. . . . When legislatures seek to control things they do not understand--and things whose future cannot be confidently foretold--bad results are predictable."

But the reality of human cloning is beginning to loom so large that legislators won't be able to ignore it much longer. When Bond introduced his anti-cloning legislation, the technique for cloning a mammal had worked only once, producing Dolly. In the months since, however, scientists have cloned two other mammalian species with minimal failure rates. And on July 22, University of Hawaii biologists stunned scientists by announcing that they had produced more than 50 cloned mice, including clones of clones, and had set up a prototype process for mass cloning.

Of course many barriers remain--all clones so far have been female, for instance, because scientists have been able to manipulate only females' reproductive system cells. But human cloning, dismissed as science fiction only months ago, is now regarded as feasible, a technology no more involved than other "advanced reproductive technologies" that are now used to help infertile couples bear children.

Given the overwhelming and emotional public sentiment against human cloning, Congress should consider passing a five-year moratorium on the technique, as proposed by the Clinton administration, to give the public and government panels like the National Bioethics Advisory Commission time to weigh the risks and benefits of allowing some people to seek cloning procedures. For couples wherein one partner has genes that could cause serious disease, for instance, cloning one of them may be seen as the safest avenue.

U.S. laws banning human cloning could never fully stop the practice. Americans would probably go abroad for the procedure. And some people would not obey cloning restrictions at home; witness the many couples who in the last decade have ignored state laws against surrogate motherhood contracts. As Lee M. Silver, a Princeton University biologist and geneticist, puts it, "Americans will not be hindered by ethical uncertainty, state-specific injunctions or high costs in their drive to gain access" to new reproductive technologies.

Nothing better exemplifies the limits of politics than legislators' clumsy attempts to grapple with cloning. Elected lawmakers, nevertheless, have no choice but to do just that and seek to help bridge the growing chasm between science and politics.

GRAPHIC: PHOTO: Breakthrough: generations of cloned mice, with the progenitor on the top tier.

LANGUAGE: English

LOAD-DATE: August 22, 1998

9TH STORY of Focus printed in FULL format.

Newsday (New York, NY)

August 4, 1998, Tuesday, ALL EDITIONS

SECTION: HEALTH & DISCOVERY; Page C03

LENGTH: 1109 words

HEADLINE: THE LAW'S LAGGING BEHIND CLONING / RESEARCH IS FULL SPEED AHEAD, BUT BILLS TO CURB IT LANGUISH

BYLINE: By Caroline Daniel. THE WASHINGTON POST

DATELINE: WASHINGTON

BODY:

WASHINGTON DESPITE widespread concerns about the prospect of human cloning, if scientists wanted to try to clone a person today, there arguably would be nothing to stop them.

Several anti-cloning bills have been introduced in Congress, but none has passed. And legal experts question the Food and Drug Administration's assertion that it has the authority to regulate human cloning, noting that the agency has not invoked that authority for other novel fertility treatments.

"There are serious questions about whether the FDA can make its claim to be able to regulate cloning consistent with its lack of regulation of other reproductive techniques," said John Freeman of Fish and Richardson, a Boston law firm that specializes in intellectual property.

The possibility that someone could try to clone a human, and could succeed, became more likely in the past few weeks as scientists in Hawaii announced that they had developed a technique that had enabled them to clone dozens of adult laboratory mice. It was the first confirmed cloning of an adult mammal since Dolly the sheep was born in Scotland last year.

Following the news of Dolly's birth, President Bill Clinton banned the use of federal dollars for human cloning research and asked the National Bioethics Advisory Commission to examine the issue. The commission recommended passing a federal law banning the cloning of human beings, and Clinton last July submitted the Cloning Prohibition Act of 1997. The bill, however, has languished.

Then, in January, a Chicago entrepreneur, Richard Seed, reignited the debate with an announcement that he intended to clone humans. Senate Majority Leader Trent Lott (R-Miss.) called for emergency consideration of a Republican anti-cloning bill.

Seven different proposals emerged. The Human Cloning Prohibition Act, introduced Feb. 3 and sponsored by Sens. Lott, Christopher S. Bond (R-Mo.) and Bill Frist (R-Tenn.), took the lead, with provisions that would outlaw the cloning of both embryos and adults.

With Seed's threat still fresh, and with key support from the Christian Coalition, the bill seemed a shoo-in; it sped to the floor as an emergency

measure without a single committee hearing. But patient groups and scientists waged a successful last-minute lobbying campaign, claiming the bill would obstruct important medical research, and the bill, mustering only 42 votes, 18 short of the 60 required, went down in defeat.

Meanwhile, Democrats offered a rival bill sponsored by Sens. Dianne Feinstein (D-Calif.) and Edward M. Kennedy (D-Mass.). This sought to ban the cloning of people, but not human embryos for research purposes. The bill was referred to the Senate Labor and Human Resources Committee, where it sits in quiet obscurity.

The only other cloning bill that made any progress was one introduced by Rep. Vernon Ehlers (R-Mich.), which would prohibit the use of federal funds for human embryo cloning. It was approved by the House Science Committee in July, 1997, and moved to the Commerce Committee, which has yet to place the bill on its agenda.

The sponsors of the various bills this week largely conceded that it will be tough to address the issue before this fall's elections. "The sense I have is that probably nothing is going to happen on this," said Jim Stacey, spokesman for the American Medical Association. "There are so few days left, and there are other things to do."

Stepping into that legislative void, the FDA announced in February that anyone wanting to clone a person would have to apply for permission from that agency. But critics have questioned the legal basis of that claim.

One concern is whether cloned cells are "medical products," which would place them under the agency's purview, or whether cloning is simply a new variant of fertility treatment. "The FDA is not supposed to regulate the practice of medicine," said Richard Merrill, a professor at the University of Virginia School of Law.

A second concern is that the FDA has no basis for considering ethical factors - such as the psychological impact of being born a clone - in its decisions.

A third concern is a technical one, but one that is central to the FDA's case that it has the right to regulate would-be human cloners. It has to do with the amount of cellular manipulation involved in cloning.

The FDA does not always demand prior approval for research on cells that will only be "minimally manipulated." However, if those cells are deemed to be "more than minimally manipulated," the work is subject to FDA regulation.

Cloning involves removing the genetic core, or nucleus, of an egg cell and injecting into that gutted cell the nucleus of another cell from the animal or person to be cloned. "What you're left with is a highly manipulated cell," asserted an FDA official, who spoke on the condition of anonymity.

Some question, however, how the FDA came to that conclusion. They note that in vitro fertilization, or IVF, also involves manipulation of cells, and other fertility techniques are even more aggressive than IVF, but the FDA has not tried to regulate them.

Cloning "may give us the creeps," Freeman said. "But is it 'more than minimal manipulation'? I frankly have a lot of trouble seeing it."

Lori Andrews, a professor of law and bioethics at the Chicago-Kent College of Law, agrees. "The question here is, Why haven't they been regulating analogous procedures such as ICSI an invasive variant of IVF in which sperm are injected directly into eggs , which also has a high-risk profile?"

Both experts also make the point that some forms of cloning - for example if a woman wanted to clone herself - may be safer than traditional IVF, because it involves little risk of passing on a communicable disease, such as AIDS. Under new FDA guidelines, the transfer of cells or tissues back into the individual from whom the cells came requires less oversight by the FDA.

As it turns out, the FDA is not comfortable with its position and has set up a working group to look into such questions. "One could look at it and say ICSI is nothing more than bringing two gametes together and allowing them to fertilize naturally," the FDA spokesman said. "Or you could say that inserting a needle into an egg and injecting a sperm is altering it. It is a pretty close call."

The FDA working group may have to work fast if it wants to settle such issues before the first human clone arrives. Scientists said last week that the first human clones could be born in the next five years or so. And Seed, in a telephone conversation last week, said he was "vigorously" pursuing his goal.

LANGUAGE: English

LOAD-DATE: August 4, 1998

Tuesday, April 29, 1997

Reproductive Research Far Outpaces Public Policy

Political controversy has put lid on tax-funded work, but private-sector lab technology is unregulated.

By SHERYL STOLBERG, Times Staff Writer

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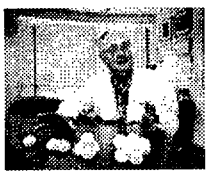

Dr. Gary Hodgen

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OVERVIEW

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NORFOLK, Va.--Dr. Gary Hodgen stands at the place where science and politics collide. As America's lawmakers grapple with the cloning of a sheep named Dolly, he would like to contribute a little history to the debate.

Hodgen is a fertility pioneer. In 1980, while at the National Institutes of Health in Bethesda, Md., he proposed an experiment that, he believed, held the promise of someday eradicating Tay-Sachs disease, a genetic affliction that kills children by the time they become toddlers.

Hodgen wanted to screen embryos--while in the test tube--for Tay-Sachs. The experiment would be performed soon after the union of egg and sperm, when the embryo was a microscopic bundle of just eight cells. Embryos that carried the deadly gene would be discarded. Those that did not would be implanted in the mother's uterus.

The goal was to help Tay-Sachs carriers have healthy babies. But Hodgen's plan ran smack into a ban on government funding for human embryo research, and his bosses vetoed it. So he packed his bags and headed south, to this sunny port city, home to a renowned private fertility clinic with its own research labs.

Here, at the Jones Institute for Reproductive Medicine, Hodgen's experiment has come to fruition. In 1994--the same year that President Clinton declared that human embryo research "raises profound ethical and moral questions"--Hodgen engineered the birth of a healthy girl to a Louisiana couple whose first child had died of Tay-Sachs at age 3.

Hodgen's experience illustrates the paradox of America's approach to the brave new world of reproductive biology. While the United States has shut on the tightest restrictions any industrial nations on what can be done with government funds, it has no limits on what private money can buy and little appetite to interfere with the private practice of medicine.

In the 19 years since the birth of the world's first test-tube baby, at least a dozen nations have engaged in far-reaching ethical discussion about and regulation of the new biology

ethical discussion about--and regulation of--the new biology of life, including cloning, reproductive medicine's outermost frontier. Six countries have banned human cloning outright.

The United States government, by contrast, has been strangely silent, choosing instead to address reproductive medicine's thorny ethical questions by simply eliminating taxpayer-financed research. The nation most adventuresome in the pursuit of science may be politically the most afraid of it.

"We don't have a clear way of figuring out what our collective social values are," said Lori Andrews, who teaches law and genetics at Chicago-Kent College of Law. "In the United States, our dominant cultural value is 'Show me the money.' "

A Congress Awash in Hearings

Now, America is taking on the issue of human cloning.

It has been two months since Scottish scientists shocked the world with the disclosure that they had, for the first time, cloned an adult mammal, with techniques that could someday be refined for use in humans.

In Washington, lawmakers are struggling with whether--or how--to prevent this from occurring. Congress is awash in public hearings. Ian Wilmut, Dolly's creator, has been paraded around Capitol Hill as though he were Exhibit A. Clinton has weighed in with a 90-day moratorium on federal funding for human cloning research--a largely symbolic act, given that there are no such studies going on or planned. He has asked that the private sector voluntarily hold off as well.

At Clinton's request, a new National Bioethics Advisory Commission is examining cloning's moral and legal implications. Measures to ban or severely limit cloning-related research are pending in both the House and Senate and in several state legislatures from Sacramento to Albany.

To Hodgen, this is a sorely misguided approach.

"You cannot have government simply say you can't go and learn that, don't be curious about that. . . ," said the 53-year-old scientist, now president of the Jones Institute. "It has always failed."

Certainly, it failed in Hodgen's case.

The embryo research ban was intended by abortion foes to keep their tax dollars from funding what they viewed as immoral science. Instead, in the spirit of the American free market, the fertility industry simply grew up around the research ban--albeit at a slower pace than it would have otherwise. And with federal authorities out of the picture, there are no government-funded studies to determine what procedures are safe and little guidance from policymakers about what society considers ethical.

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'Energy, Ambition' and 'the Will to Succeed'

There is a sign hanging over the door to Hodgen's office. It says "Spizzerinctum." It is not a word one can find in the dictionary; Hodgen invented it. He defines it as "energy, ambition, the will to succeed."

Spizzerinctum, it might be said, took a young Gary Hodgen, fresh out of medical school, to the National Institutes of Health in 1969. He arrived with an ambitious, if politically delicate, agenda. He wanted to study the origin of human life.

How, he wanted to know, are eggs fertilized? How do embryos grow? Can science intervene in the creation of new life, not only to benefit the infertile but to treat and prevent illnesses at the beginning of life, rather than the end?

Hodgen expected a free hand in pursuing these interests. America has a long tradition of protecting academic freedom; nowhere is this tradition more ingrained than at the NIH, one of the country's premier scientific institutions.

"We believe very strongly as a nation that if you free science to do its job, that it will rebound to human good," said Lawrence Gostin, professor of law and public health at Georgetown University. "It is part of the pioneering spirit of the United States. We are much more likely to take risks, to be adventurous."

But as Hodgen quickly discovered, that pioneering spirit tends to wither in the face of the politics of abortion.

In the mid-1970s, shortly after the U.S. Supreme Court handed down its landmark Roe vs. Wade decision, abortion foes began pressing the government to put an end to research involving fetal tissue and early embryos.

"We believe that life begins at the beginning, not in the middle, and that even a single-cell child has the dignity of all the children of God," said John Cavanaugh-O'Keefe, director of the bioethics arm of the Virginia-based American Life League.

In 1975, the Department of Health, Education and Welfare, sensing the sensitivity of such research, ruled that it would not fund in vitro fertilization research until its ethics advisory board had reviewed the proposal.

But there was a catch: There was no ethics advisory board.

It took two years for HEW to create one. In 1979--one year after the birth of Louise Brown, the world's first test-tube baby--the board issued an extensive report that recommended the government fund studies to determine the safety of in vitro fertilization.

But the recommendations were never adopted, and the board's report "has gathered dust for 18 years," lamented Georgetown University ethics expert LeRoy Walters, who helped write it.

From time to time, government has tried to revisit these issues i li le su ess T e ly ressi al pa el a

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might have dipped into the new biology of life dissolved in 1989, the victim of a fight between abortion rights advocates and opponents over who would fill its last seat.

Then, in 1994, the NIH convened an ethics panel specifically to reopen the question of human embryo research. The group recommended that, in certain limited instances, government scientists be permitted to create human embryos for research or use "spare embryos" obtained from fertility clinics.

The furor was instantaneous.

Within 24 hours, Clinton had stepped in to declare that the government would not fund scientists who created embryos for research. Congress later used its appropriations authority to effectively ban all embryo studies.

Now, Clinton has turned to the bioethics community yet again for advice on another hot-button issue: cloning. And the question raging in ethics circles is whether the president will listen to them or whether politics will once again intervene.

The debate over whether to ban the cloning of humans will be the easy part; public sentiment is lined up fairly solidly against it. Much trickier will be the discussion over whether to permit studies involving the cloning of adult human cells for purposes other than creating babies.

At a recent Senate hearing, Dr. Harold Varmus, the director of the National Institutes of Health, told lawmakers that the cloning technique pioneered by Wilmut--"nuclear transfer technology"--could be used to cure disease. For instance, it might be helpful in generating bone marrow for transplantation.

"My own view," Varmus said, "is that legislation and science frequently don't mix very well. . . . The matters are complex. If there were to be legislation--which I hope will not be necessary--it will be very important to be specific about what would be excluded."

Burdens, Frustrations Come With Progress

The issues in embryo research are complex as well. It was the government's inability to sort them out that drove Gary Hodgen to the private sector.

By the late 1970s, Hodgen had climbed the ladder to become the chief of the pregnancy research lab at the National Institute on Child Health and Human Development. But he had become increasingly frustrated.

Four times, Hodgen submitted his Tay-Sachs proposal. Four times, it was rejected. "The government's heavy hand was getting in the way of following the natural course of medical inquiry," he complains. "It became clear that I had to leave."

The ensuing decade was a remarkable time for reproductive medicine--a time when laboratory advances were quickly translated into medical practice. America's first test-tube baby,
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fertility treatment; in 1994 alone, 6,000 test-tube babies were born in North America.

In a pretty brick courtyard at the Jones Institute, one can see the fruits of these successes. Brick after brick is engraved with the names of happy parents and their babies--often twins and triplets. "Our Dream Come True," one brick reads. "A Double Joy!" reads another. It is hard to stand there and not be moved.

But there are burdens to scientific progress--pressing ethical questions from surrogate motherhood to the ownership of frozen embryos. Around the globe, in the late 1980s and early 1990s, nations began to confront these concerns, and much of the industrialized world now has regulatory policies on the issue.

A notable exception is the United States.

In part, this difference comes about because our health care system does not require a policy. Unlike the European model, American health care is private, and thus lawmakers do not have to determine what the government will and will not pay for. The result is that private doctors and their patients are constantly pushing the edge of what society considers acceptable.

Conflicts often wind up in the courts, where decisions are not always consistent. In 1993, a Tennessee judge was asked to award custody of frozen embryos belonging to a divorcing couple; he sided with the man. In 1995, a New York judge heard a similar case and sided with the woman.

"In the United States, our policies develop from the individual cases up," says Charo, the Wisconsin ethicist. "The European system tries to design the dog and let it wag its tail. We have 50 or 100 or 150 wagging tails from which we then try to reconstruct the dog. It's no wonder that our dog looks a little bit like a Picasso."

'A Simple Set of Rules'

Hodgen has developed his own ethical standards--"a simple set of rules" that he calls his "double-based litmus test."

The test consists of two questions that Hodgen asks himself before every experiment: Will it meet an unmet need of patients or their families? And will it help--or harm--society?

The test came in handy four years ago, when Hodgen and his colleagues at the Jones Institute learned how to determine the sex of test-tube embryos. The procedure was developed to identify so-called X-linked genetic diseases--such as hemophilia--that affect only boys.

Hodgen's dilemma was whether to allow doctors at the Jones Institute clinic to employ the test for patients who wanted to pick the sex of their children.

He decided not to.

"It fails the second question," he explains. "If I value being a [illegible]

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He is aware that others might reach a different conclusion--and indeed, others already have.

Great Britain, for instance, has a ban on test-tube sex selection. But a British doctor named Paul Rainsbury recently set up a clinic in Saudi Arabia to avoid that ban--announcing that his British patients could evade their country's laws and choose the sex of their child for the extra price of an airplane ticket. Rainsbury said he expected 80% of his clients would seek boys.

To Hodgen, this is simply a casualty of doing business in a free world. Scientists, he says, must be free to let their consciences guide them; if society objects to their ethical choices, he says, let society mete out the punishment. "Each person," he says, "must search their own soul for what they spend their time doing."

At its heart, this is what the cloning debate in Washington is about. How much is society willing to let scientists search their own souls in the pursuit of knowledge? Will lawmakers simply cut off federal funding, allowing the private sector to press forward unhindered? Will they permit the cloning of human cells but ban the creation of babies by cloning? Will they make human cloning a crime, like bank robbery or murder?

And regardless of what they decide, can lawmakers make their rulings stick, or will ambitious scientists and wealthy clients simply cross national boundaries to find permissive jurisdictions?

Some say the notion of human replicas separated by time is so abhorrent that politicians the world over must join hands to ban it outright. Wilmut, Dolly's creator, subscribes to this view; he recently asked a panel of U.S. senators to launch an international drive to ban cloning in humans. Gostin, the Georgetown ethicist, senses that Americans would favor such a move.

"Cloning," Gostin says, "was a defining moment in our perception of science. . . . I think that this might be a spur, where we would draw the line."

Others say that society will eventually get used to the idea of human cloning, just as it has gotten used to artificial insemination and in vitro fertilization.

Already, some commentators are wondering if Americans might support cloning in certain instances, such as the case of a family that loses a child. And human cloning has its defenders, among them U.S. Sen. Tom Harkin (D-Iowa), who recently offered an impassioned defense of science's right to pursue cloning research, wherever it may lead.

"Some would make us believe Dolly is a wolf in sheep's clothing," Harkin said, "but I don't think so. . . . I don't think it's legitimate for us to try to stop this."

If humans were to be cloned, the logical place for it would be i pri a e er ili y li i s li e e es s i u e d e says

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that is not about to happen on his watch; cloning fails both criteria of his litmus test. Still, he speaks vociferously against a government ban.

"I join with the massive plurality of Americans and other people around the world who say, 'Let's not have human cloning.' " Hodgen says. "We don't have a reason to do it and we have many reasons not to do it. But let's come to that decision as free individuals, not by the heavy hand of government."

12/94 President banned use of federal funds for human embryo research where the embryo would be "destroyed, discarded, or knowingly subjected" to painful procedures

2/97 "Dolly," researchers in Schotland created genetic copy of sheep through **somatic cell nuclear transfer**.
Sen. Christopher S. Bond (R. Mo.) introduced emergency ban on human cloning

3/4/97 President announces ban on federal funds for cloning of human beings; calls for **private sector voluntary 5-year moratorium** on human cloning; asked National Bioethics Advisory Committee (NBAC) to examine the issue

3/10-11 Dr. Varmus delivers the "HHS Oversight Testimony on Cloning: Challenges for Public Policy"

6/9/97 Draft Bill on SCNT Moratorium submitted
"Cloning Human Beings" issued by NBAC

7/97 President submitted **"Cloning Prohibition Act of 1997"** -- no action

1/98 R. Seed announces plans to clone for infertile couples in his clinic

2/3/98

- Bond/Lott/Frist's **"Human Cloning Prohibition Act"** (outlawed cloning of both embryos and human children) defeated 2/11/97 by Senate
- Feinstein/Kennedy's **Alternative Human Cloning Prohibition Act** (banned cloning of people, but not human embryos for research purposes) - sitting in *Senate Labor and Human Resources Committee* **[call them]
- Ehler's **Prohibition of Federal Funds for Human Embryo Cloning** - approved by *House Science Committee* in July 1997; presently sitting in *Commerce Committee*

2/98 FDA jurisdiction

6/22/98 University of Hawaii scientists announced successful cloning of over 50 mice, including clones of clones; Ryuzo Yanagimachi's laboratory, Teruhiko Wakayama's research

9/5/98 Seed announces renewed plans to fertilize his wife with his own clone

9/6/98 *Chicago Tribune* reports on **Missyplicity Project** at Texas A&M (www.missyplicity.com) to clone dogs