Medicine may be key to cloning's future

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The cloning of animals may have come from agriculture, but its real promise may be in the lucrative field of medicine rather than as food.

Genetically modified cows and goats can produce proteins in their milk that can be extracted as a drug component. Cloning animals to create living drug factories could lower the costs of medicines used to save lives.

Examples include cows that pump pharmaceutical proteins and antibodies in their milk and blood; chickens that lay drug-producing eggs; and pigs that grow human-ready organs. Making perfect copies of these animals, through cloning, could speed up the drug-making process, according to scientists.

"Once you create a genetically engineered animal, you want to make copies," said David Andrews, director of animal biotechnology at the Biotechnology Industry Organization, a trade association that represents 1,200 companies.

In Dane County, Wis., a now-closed biotech firm created cloned pigs that had human-friendly, transplantable organs.

The same firm, Infigen, created a herd of cloned cows with drug-making capabilities.

Infigen wanted to produce proteins for the treatment of hemophilia, an affliction that causes uncontrolled bleeding, and Pompe's disease, a rare

genetic disorder that can lead to muscle degeneration.

The science was proven, but the firm ran out of money and closed in 2004.

"Because we were breaking new ground, where the FDA approval process was not fully developed, investors were hesitant. That became the stumbling block," said Michael Bishop, Infigen's former president.

"We knocked the science out and achieved some very amazing things," he said. "And the interesting thing is I don't think the technology has advanced very much since then. As a matter of fact, I think Infigen enjoyed better success than anybody else in the business."

Currently, a Massachusetts biotech firm is using genetically engineered dairy goats to make a human protein that prevents dangerous blood clots from forming. GTC Biotherapeutics extracts the protein from the goats' milk for a drug that helps prevent strokes, pulmonary embolisms and other life-threatening conditions.

The FDA-approved drug, called ATryn, could be followed by other medicines made from the milk of genetically engineered animals. Cloning would be an efficient way to create them, said Yann Echelard, GTC vice president of corporate and technology development.

There are ways to do this without cloning, but it's a more predictable process, he said.

Now that the FDA has said it's safe to consume the milk and meat from cloned animals, it could help pave the way for creating drugs.

"As scientists, we can do this stuff," said Mark Cook, an animal sciences professor at the University of Wisconsin-Madison.

"The big issues that came up were more regulatory than science based. Just to get a drug through FDA clearance can take 10 to 15 years and cost a billion dollars."

A herd of 150 dairy goats could produce enough of a life-saving drug to meet the needs of thousands of people.

The mammary gland in cows and goats was designed by nature to make proteins, Echelard said.

But some people are wary of the use of genetically engineered animals, saying a mating between one escaped animal and a natural one could trigger a chain of events that could contaminate a species.

"What we have learned from the genetic engineering of crops is that nature finds a way" to reproduce, said George Kimbrell, an attorney with the Center for Food Safety, a nonprofit group focused on food issues.

"I am dubious, at best, of claims that if we produce these transgenic animals there are not going to be some accidental escapes that will impact the environment and, potentially public health, through the food chain," Kimbrell said.

Genetic engineering raises animal cruelty questions, said Pete Shanks with the Center for Genetics and Society, a nonprofit group that encourages responsible use of genetic technologies.

Last year in New Zealand, a government-owned company created four genetically engineered calves intended to produce a hormone for treating infertility. Three of the calves developed huge ovaries, the size of tennis balls rather than the usual thumbnail size, and two of them died unexpectedly at the age of 6 months, according to Shanks.

"There are many possible responses to this debacle," said Shanks, author of "Human Genetic Engineering: A guide for activists."

"But we should start by noting the callous response of the scientists involved, who did not see the deaths as a big deal and called it part of the learning process."

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