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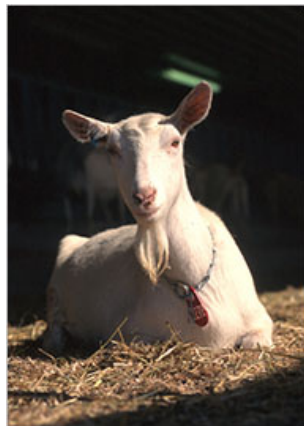
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F.D.A. Approves Drug From Gene-Altered Goats

By ANDREW POLLACK
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Opening the barn door to a new era in farming and [pharmaceuticals](#), the [Food and Drug Administration](#) on Friday approved the first drug produced by livestock that have been given a human gene.

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GTC Biotherapeutics

A goat at GTC Biotherapeutics' farm.

The drug, meant to prevent fatal blood clots in people with a rare condition, is a human protein extracted from the milk of genetically engineered goats.

At the same time, the F.D.A. also approved the goats used to make the drug, the first such animals cleared under guidelines the agency adopted only last month to regulate the use of transgenic animals in the nation's drug and food supply.

Made by a company called [GTC Biotherapeutics](#), the human anticlotting protein is produced by a herd of 200 bioengineered goats living under carefully controlled conditions on a farm in central Massachusetts.

Proponents say such "pharm animals" could become a means of producing biotechnology drugs at lower cost or in greater quantities than the existing methods — which include extracting proteins from donated human blood or growing them in large steel vats of genetically engineered cells.

The protein in the goat milk, antithrombin, is sometimes in short supply or unavailable for pharmaceutical use because of a shortage of human plasma donations. GTC Biotherapeutics said one of its goats can produce as much antithrombin in a year as can be derived from 90,000

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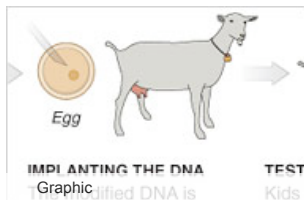
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blood donations. And if more drug is needed, the herd can be expanded.

“If you need more, you breed more,” said Thomas Newberry, a spokesman for GTC, which is based in Framingham, Mass.

Drugs have been derived from animals before, of course. Most insulin used by people with [diabetes](#) formerly came from pigs or cows. Genetically engineered mice are now used to develop some drug ingredients. But this is the first drug from a herd of genetically engineered animals created specifically to serve as living pharmaceutical factories.

Turning animals into walking drug producers does not sit well with some environmental advocates and animal rights activists.

“It is a mechanistic use of animals that seems to perpetuate the notion of their being merely tools for human use rather than sentient creatures,” the [Humane Society of the United States](#) says in its position paper on the practice.

There are other concerns: that the animals could be harmed, that animal germs might contaminate the drug, that the milk or meat from genetically engineered drug-producing animals might enter the food supply or that the animals might escape and breed with others, spreading the gene, with unpredictable consequences.

But the F.D.A. approval could now encourage drug makers to consider this type of production.

The F.D.A.’s move “really takes away one of the biggest issues that have always been on the table, which is how do regulatory agencies view this kind of technology,” said Samir Singh, president of the American operations of Pharming, another company using such technology.

Pharming, which is based in the Netherlands, plans to apply this year for approval of a drug, produced in the milk of transgenic rabbits, to treat [hereditary angioedema](#), a protein deficiency that can lead to dangerous [swelling](#) of tissues.

Another company, PharmAthene, is developing a treatment for nerve gas poisoning in the milk of transgenic goats.

Still, it could be difficult to persuade established manufacturers to depart from their existing methods, which have improved markedly since GTC first began its work.

“I think we have very good ways of making therapeutic proteins today,” said Norbert Riedel, chief scientific officer at [Baxter International](#), which makes proteins both from human plasma and in cell cultures grown in huge steel tanks.

Sales of the GTC drug, called ATryn, are expected to be modest, judging from the small sales so far in Europe, where the drug was approved in 2006.

ATryn will be sold in the United States by Ovation Pharmaceuticals, which said it had not yet set the price.

GTC’s stock, which was below 11 cents in mid-December, had risen recently on expectation of the F.D.A. approval. It traded above 90 cents a share earlier this week. On Friday, as investors evidently sold on the news, it fell more than 14 percent, closing at 70 cents.

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The drug was approved to prevent blood clots in people born with a rare hereditary deficiency of antithrombin while they undergo surgery or childbirth. At other times such people can reduce their clotting risks by taking blood thinners like warfarin, but during surgery or childbirth blood thinners are typically avoided because of the risk of excessive [bleeding](#).

To make its protein, GTC took the human gene for antithrombin and linked it to goat DNA that normally controls production of a protein found in milk. That ensured that the antithrombin would be produced only in the milk.

The gene was injected into a one-celled goat embryo, which was then implanted into the womb of a surrogate mother. After a goat was born that produced the protein in its milk, the herd was expanded by conventional breeding.

Many of the newer protein-based drugs, like the [cancer](#) drug [Avastin](#) and the [arthritis](#) drug Enbrel, are produced in genetically engineered Chinese hamster ovary cells that are grown in big stainless steel vats. But a cell culture factory can cost hundreds of millions of dollars to build. Using livestock shrinks the investment to tens of millions of dollars, said Geoffrey Cox, GTC's chief executive.

GTC executives say the animal technology might be best suited to making proteins that cannot be produced well in cell cultures. Antithrombin, the protein in ATryn, is one such drug. Some other drugs require huge volumes that are impractical to achieve with cells.

Production in animal milk might also appeal to new companies hoping to make lower-priced copycat versions of biotechnology drugs, if the regulatory procedures are eventually adopted for approving generic versions of such drugs.

GTC itself is planning to make a copycat version of Rituxan, a cancer and arthritis drug sold by [Biogen Idec](#) and [Genentech](#). It is also planning to make clotting factors for [hemophilia](#) treatment.

One risk of using animals is that drug production can be lost if a disease wipes out the herd. Mr. Newberry, the GTC spokesman, said the goats were fully vaccinated. Access to them by people is controlled and there is a double fence around the farm to keep out wildlife.

Mr. Newberry said that none of the goats in the herd, including nontransgenic ones used as surrogate mothers, would be allowed in the food supply. Nor will any of the milk.

The F.D.A. said it was confident that products from the goats would not enter the food supply or harm the environment. "There were no novel or controversial issues" with the goats, Bernadette Dunham, director of the agency's Center for Veterinary Medicine, said Friday.

But Gregory Jaffe of the [Center for Science in the Public Interest](#), a Washington consumer group, called for assurances that the milk or meat would be safe if it did inadvertently enter the food supply.

"Humans are fallible; accidents happen," he said.

A version of this article appeared in print on February 7, 2009, on page B1 of the New York edition.

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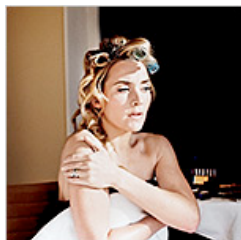
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