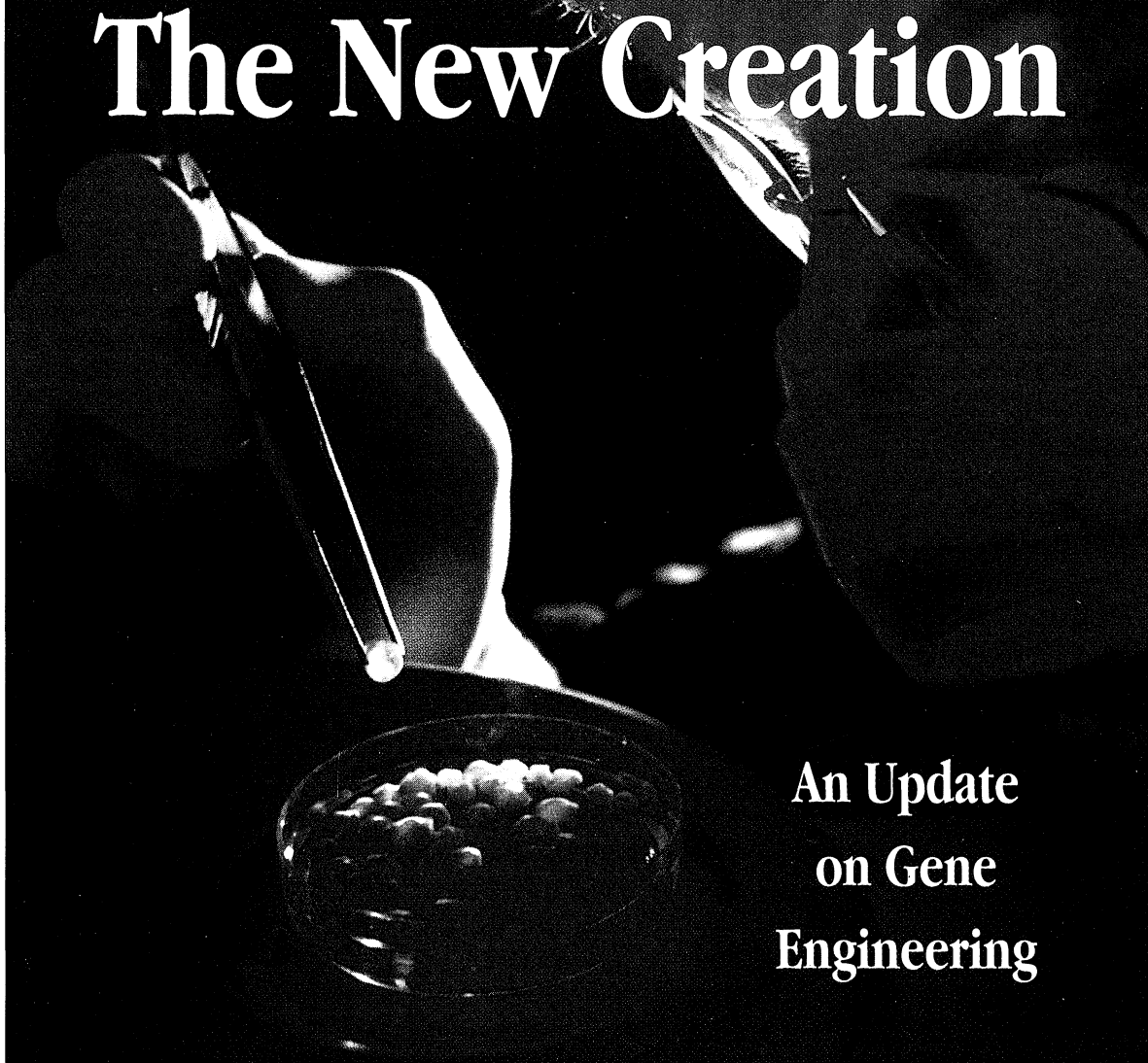


# The New Creation



## An Update on Gene Engineering

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By Michael W. Fox, D.Sc., Ph.D., B. Vet. Med., MRCVS

Several recent developments in genetic engineering show how the new industry applies biotechnology to agriculture and medicine. The value of these new developments in terms of real progress in improving agricultural practices and human health remains to be seen. The following examples clearly reveal that a “New Creation,” a new world order of the biotechnology industry, is far from any utopian dream of a world made perfect for humankind.

One can read between the lines of new patent applications, news releases, and scientific reports concerning the latest feats of genetic engineering and glimpse the near future. The wonder-world of New Creation is not quite here today, but it may be upon us sooner than we expect. A whole new generation of genetically engineered, or transgenic, animals is on the way, animals carrying genes transplanted from humans and other species. In the world of commerce, transgenic animals will be regarded as “new” species, the patentable commodities of a new world order.

### Transgenic Animals

Scientists in the United States, Canada, Japan, Europe, and Australia have created a number of transgenic animals: pigs, lambs, calves, and fish who contain the growth-hormone genes of other species, including those of humans. To date, an estimated ten thousand varieties of transgenic mice have been created. However, gene-splicing success rates are extremely low, and the entire process is time-consuming and costly. Much of the funding for this research comes from the public via tax revenues.

*Michael W. Fox, D.Sc., Ph.D., B. Vet. Med., MRCVS, is HSUS vice president, Farm Animals and Bioethics. His new book dealing with genetic engineering, Superpigs and Wondercorn, will be published this fall by Lyons and Burford.*

Researchers at the University of California at Davis opted to splice extra growth-regulating genes from sheep into lambs to avoid the use of human gene tissue because, according to scientist James Murray, "... transgenes composed entirely of sheep-gene sequences would be more acceptable to laypersons, in particular, to consumers." Dr. Murray hoped to develop a strain of sheep whose lambs would efficiently convert their feed and rapidly grow to marketable size. But the transgenic lambs developed diabetes and other severe health problems that killed them before they ever reached puberty. Dr. Murray concluded, "The cause of death varied, but there is clear data that the overexpression of GH [growth hormone] adversely affects liver, kidney, and cardiac function."<sup>1</sup>

Merck and Company, an international pharmaceutical firm, applied for a patent in Europe on a "superchicken" it called Macro-Chicken. In the hopes of cornering the worldwide poultry market with highly feed-efficient, fast-growing birds, Merck developed the Macro-Chickens, a line of broiler chickens that carry the growth gene from cattle.<sup>2</sup> Merck's Macro-Chickens may well have a variety of health problems, but if the birds eat well and grow quickly, they may be ready for slaughter before severe health problems ever develop. What will happen to the reserve stock of transgenic chickens, the ones not raised for slaughter? Will they suffer?

Because such information is proprietary, corporations are not likely to reveal the problems and risks of their new patentable creations. Trade secrets notwithstanding, creating transgenic farm animals has social and economic consequences for farmers, agribusiness distributors, and consumers—consequences that have been given scant attention.

Critics of the genetic engineering of farm animals have questioned the use of public funds to make these animals produce more meat (even if it is leaner) when the short- and long-term costs of such research are not considered (see the Spring 1990 *HSUS News*). A major problem of modern intensive animal agriculture is overproduction. In many nations, meat and milk overproduction is a chronic problem. It is unlikely that the creation of transgenic farm animals will help feed the hungry of the world, since meat-production efficiency has built-in limitations and inevitable environmental costs.<sup>3</sup>

Genetic engineers are now attempting to alter milk from sheep and cows to be suitable for people who are lactose intolerant.<sup>4</sup> Researchers are inserting into calf embryos the human genes responsible for the production of proteins in mother's milk. They hope to create a new generation of cows able to produce "humanized," or more digestible, milk.<sup>5</sup> Such research may be more helpful in feeding the hungry since milk production is far more efficient, ecologically sound, and cost-effective than meat production.

Australian government scientists have used genetic engineering to make sheep produce more wool. The body chemistry of the sheep is altered so the animal can convert sulfur-bearing compounds into methionine,

an amino acid that increases wool growth.<sup>6</sup> The Australians have also genetically engineered a hormone that can be injected into sheep to make them shed their fleece; it eliminates shearing costs. However, the hormone has caused pregnant sheep to abort. These scientists plan to genetically engineer sheep who secrete insect repellent from their hair follicles to ward off blowflies, which cost the sheep industry \$85 million a year in losses. As a spinoff they hope that the sheep will also produce the world's first moth-proof wool.<sup>7</sup>

Most genetic-engineering research on farm animals has focused on increasing productivity; genetic engineering to increase resistance to disease is still very much in its infancy.<sup>8</sup> This disease-resistance research is questionable since improvements in farm-animal husbandry are surely more cost-effective ways of improving animal health and well-being.

#### Transgenic "Molecular Pharming"

**G**enetic engineers have inserted human genes into farm animals to produce salable pharmaceutical products such as blood with blood-clotting factors and other substances. Harvey Bialy, editor of *Bio/Technology* magazine, has praised what he terms "molecular pharming technologies," as exemplified by research teams from the United Kingdom, the United States, and the Netherlands that have produced transgenic sheep whose milk contains human alpha-1-antitrypsin; transgenic goats who secrete a human tissue-type plasminogen activator, called t-PA, into their milk; and the first transgenic dairy cattle. "Taken together," he writes, "their results provide a convincing demonstration of the feasibility of using animals as commercial bioreactors."<sup>9</sup>

Recently DNX, a biotechnology company in Princeton, New Jersey, reported that it has developed a line of transgenic pigs able to produce human hemoglobin.<sup>10</sup> Companies in the United States and the United Kingdom are developing transgenic pigs with human immune systems to serve as organ donors for people needing new hearts and other organ parts. It may be many years before these new animals provide any medical products for humans, but venture capitalists are investing now in this speculative line of research and development.

#### Other Innovations

**O**ther developments in farm technology that do not entail gene transfer but which can have profound social and economic ramifications include the development of cow clones<sup>11</sup> and a technique to preselect the sex of offspring.<sup>12</sup> Scientists are baffled by the fact that some 25 percent of calves produced by cloning are almost twice normal size at the time of birth and must therefore be delivered by cesarean section.

To date no plant genes have been inserted into animals, but animal genes have been successfully incorporated into the genetic structure of various plants. Re-

searchers have successfully implanted human genes into tobacco plants to produce functioning human antibodies that may be used to diagnose and treat human diseases. The "antifreeze" gene of the flounder, which produces a protein to stop the fish from freezing, has been cloned and inserted into tomatoes and tobacco. In the future, fish genes may protect such crops from frost.<sup>13</sup>

Fish farming is growing, so biotechnologists have been busy developing "superfish" by inserting growth-hormone genes from humans, cattle, chickens, mice, or other species of fish into a variety of commercially raised fish, such as carp, rainbow trout, catfish, Atlantic salmon, walleye, and northern pike. The antifreeze gene of the flounder is also being inserted into other fish species to expand commercial fish production in cold regions.<sup>14</sup>

At the Army Research Laboratory in Natick, Massachusetts, biotechnologists cloned the silk-producing gene of the Golden Orb weaver spider and spliced it into bacteria that in turn produce large quantities of spider-silk protein. Stronger than silkworm silk and perhaps even stronger than steel, this product may have wide commercial applications, including new fabrics for bullet-proof vests, helmets, parachute cords, and other types of strong, light equipment.<sup>15</sup>

Working on the frontier of medicine, scientists have created a variety of transgenic mice and rats. One family of transgenic mice carries human genes that result in deformed red blood cells. Research using the mice has provided a new model for sickle-cell anemia.<sup>16</sup> Researchers also developed a line of rats that carries the human gene HLA-B27, which causes a painfully crippling form of arthritis.<sup>17</sup> Not only has the clinical effectiveness of many of these new research efforts not yet been demonstrated, but there is also no foreseeable benefit to the animals made transgenic.

Researchers continue trying to identify the genes responsible for various inherited diseases (especially those found in purebred dogs and livestock) and the genes that play a role in development, growth, milk or egg production, disease resistance, and other physiological processes in animals. U.S. Department of Agriculture (USDA) scientists have recently been given \$2 million to start mapping the genes of cattle and pigs. The result of such costly research may eventually benefit animals in terms of their health and overall well-being, but the benefits will be limited if the focus of the research is too narrow. Unless the DNA-mapping research is integrated with a more holistic approach to improving animal health and well-being, it may only exploit animals.

Most research on DNA structures has focused on identifying genetic defects and strengths in humans. All to what end? The discoveries will certainly lead to new medical and veterinary products and services, but genetic determinism may ultimately lead to eugenics, the science of improving the hereditary qualities of a race or breed. In my view eugenics means genetic imperialism. Do we really want or need such a thing—Creation made over into the human image of perfect utility?

#### New Animal Drugs

**T**he development of genetically engineered vaccines, hormones, immune-system enhancers, birth-control regulators, and diagnostic tests may benefit animals. However, this new generation of veterinary products and services may also be a mixed blessing. It is not without potentially adverse animal-health, socioeconomic, and ecological consequences. Such products are no substitute for sound breeding, good nutrition, and humane animal husbandry.

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#### Public Attitudes

**W**hile private-industry and government-funded research centers strive to create genetically engineered animals who may prove profitable to agribusiness and to the medical-industrial complex, the public views such research with some apprehension. In a recent poll of Europeans: *fewer than half thought biotechnological research on farm animals "to make them resistant to disease, or grow faster" should be encouraged. A third thought applying biotechnology to animals "to develop life-saving drugs or study human diseases" was morally acceptable, "provided the animals' welfare is safeguarded," but 20 percent said it was morally wrong, and 27 percent said government should decide each case. Only 13 percent thought such work justified "some animal suffering."*<sup>18</sup>

A national survey in Japan revealed that 67 percent of respondents were opposed to research that could lead to new forms of plant or animal life.<sup>19</sup>

In 1985 opinion polls in the United States showed that 34 percent of the attentive (informed) public wished to prohibit the creation of new forms of animal and plant life.<sup>20</sup>

This transgenic "geep," the result of mixing goat and sheep genes, was born in Cambridge, England, in 1982.

Most genetic-engineering research on farm animals has focused on increasing animal productivity.

## Animal Patenting

The controversy over patenting genetically engineered animals began on April 7, 1987, when the U.S. Patent and Trademark Office ruled that such animals, provided that they were nonnaturally occurring "manufactures" and "compositions of matter," could be included under Section 101 of the Patent Act as patentable subject matter. The patenting of animals was vigorously opposed by The HSUS and a coalition of other organizations.

In 1987 Rep. Charlie Rose introduced legislation to impose a moratorium on the patenting of animals so that the potential adverse implications of such patenting could be carefully studied. In 1988 Sen. Mark Hatfield introduced a similar moratorium bill in the Senate. (Neither bill became law.) On April 13, 1988, the U.S. Patent and Trademark Office issued patent number 4,736,866 to Harvard University and Du Pont Chemical Company for the "Onco Mouse," a genetically engineered, cancer-prone mouse. Since then no other animal patents have been awarded in the United States. But the U.S. Patent and Trademark Office has

mal patents is that, to date, there is no clear regulatory structure for the commercial marketing of transgenic animals.<sup>22</sup>

The Senate is currently considering a bill (S. 1291) sponsored by Senator Hatfield to impose a five-year moratorium on the granting of patents on invertebrate and vertebrate animals, including those having been genetically engineered. A similar bill (H.R. 4989) was introduced in the House by Rep. Benjamin Cardin in April 1992. The HSUS supports both bills.

On the day Senator Hatfield's bill was introduced, this statement from The HSUS appeared in the *Congressional Record*:

*In order for society to reap the full benefits of advances in genetic engineering biotechnology, the social, economic, environmental, and ethical ramifications and consequences of such advances need to be fully assessed. Considering the rapid pace of developments in this field, which will be spurred on by the granting of patents on genetically altered animals, a five-year moratorium on the granting of such patents is a wise and necessary decision. A moratorium will enable Congress to fully assess, consider, and respond to the economic, environmental, and ethical issues raised by the patenting of such animals and in the process, establish the United States as the world leader in the safe, appropriate, and ethical applications of genetic engineering biotechnology for the benefit of society and for generations to come.*<sup>23</sup>

It is very likely that the White House Council on Competitiveness, chaired by Vice President Dan Quayle, will try to block this bill. The council is actively working to deregulate the entire biotechnology industry and has proposed administrative and regulatory guidelines for the Environmental Protection Agency and the USDA.<sup>24</sup> If these guidelines are adopted, animal welfare, environmental needs, and all of the possible adverse consequences of such new developments in biotechnology will be virtually ignored.

Although the genetic engineering of animals is not likely to end, greater public awareness of and debate over the critical issues of biotechnology are clearly essential. A five-year moratorium on the patenting of "new" animal creations would be prudent and timely, especially since the United States is moving toward a new world order of free trade. Free-trade agreements should require all nations to adopt regulations and stringent controls over biotechnology. Otherwise the privatization of the world's resources and of the genetic material of life itself, coupled with the misapplication of genetic engineering in agriculture and medicine, will oppose the public interest and the public good of generations to come.

## Conclusion

To understand and evaluate the costs and consequences and the risks and benefits of all new developments in science, technology, and industry, one must consider several interrelated dimensions. Genetic-engineering biotechnology and the patenting of its processes and

products must be viewed from these perspectives: ethical and spiritual, moral and religious, legal and political, social and economic, environmental and cultural. Because these areas of concern, constraint, and direction have been virtually ignored by policymakers or seen as obstacles to economic growth and industrial expansion, the gap between private (corporate) and public interest has widened.

Today we witness the rise of a global industrial biotechnocracy, which needs to be rigorously evaluated. To question this development should not be misjudged as antisience or antiprogress. With greater involvement, an informed public can direct the policy-making process. Advances in science and technology, in biotechnology in particular, may then serve the public good and help enhance the quality of life and the environment alike.

Today the U.S. government is attempting to deregulate the biotechnology industry, and the European Community's Commission on Biotechnology is trying

to eliminate socioeconomic considerations in the licensing of new animal drugs. Clearly the biotechnocracy of the industrialized world is proceeding neither prudently nor appropriately.<sup>25</sup>

Despite the many documented health problems of transgenic mice carrying human, bovine, rat, and sheep growth genes,<sup>26</sup> research continues along the same lines with farm animals. One must wonder how such suffering can ever be justified, when transgenic pigs, designed to be lean and to grow quickly, develop pericarditis; enlarged hearts, livers, and other internal organs; enlarged and heavier bones; arthritis; diabetes; loss of appetite; sterility; respiratory distress; and increased stress and disease susceptibility.<sup>27-29</sup> Even if future improvements in gene-insertion techniques reduce health problems suffered by farm animals genetically engineered for human consumption, the legacy of the suffering that animals endured in the early stages of the technology's development should keep anyone from consuming such animals in good conscience. ■

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Five sheep cloned from a single embryo in England: in a recent poll, fewer than half of the Europeans questioned thought biotechnical research on farm animals for disease resistance or increased growth should be encouraged.

notified GenPharm International of Mountain View, California, that patents will soon be issued on two of the company's mice, the TIM (transgenic immunodeficient) and cancer-prone PIM lines.

Officials of the U.S. government and multinational corporations have been pushing for changes in European patent laws that currently prohibit the patenting of animals.<sup>21</sup> The U.S. State Department effectively squashed the Rose and Hatfield bills on the grounds that they would weaken U.S. economic competitiveness in the world marketplace.

Some 145 patent applications for genetically engineered animals are now awaiting approval at the U.S. Patent and Trademark Office. Approximately 80 percent of such patent applications have medical utility, while the remainder involve agricultural animals. One possible explanation for the delay in awarding new ani-