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Dolly: Clone or Commodity?

RAFI Follows the Money

Taking Care of Business

Dolly, the first cloned mammal, and now the world's most famous lamb, is living proof that viable offspring can be developed from a single adult cell. Dolly was born to a surrogate ewe in July, 1996 at the Roslin Institute in Scotland. The rest of the world learned about the startling feat over seven months later in February, 1997. Why the delay? Because there's a great deal of money to be made from the cloning of mammals. Before disclosing the breakthrough, patent applications were filed and research papers prepared for publication. "Business before science," observes Ruth Hubbard, professor emerita of biology at Harvard University.[1]

Dr. Ian Wilmut is the Scottish embryologist who led the sheep cloning experiment at the non-profit Roslin Institute. Dr. Wilmut's team is funded in part by PPL Therapeutics, a small biotechnology company that was formed by the Roslin Institute in 1987 to commercialize the Institute's research. Dr. Wilmut will undoubtedly be one of the primary "inventors" of the mammal-cloning technology, but PPL Therapeutics will likely be assigned the patent. After the cloning achievement was announced, shares of PPL Therapeutics jumped 16% in one day on the London Stock Exchange.[2] (This is noteworthy because the small biotech company isn't expected to see profits for at least 4 years.)

PPL Therapeutics has several human protein products in development, and holds at least one patent (US Patent No. 5,476995) on a method to produce therapeutic proteins in the milk of transgenic sheep. Since 1992, the company entered research agreements with at least four major pharmaceutical corporations, including Novo Nordisk (Denmark), American Home Products (USA), Bayer (Germany) and Boehringer Ingleheim (Germany).[3]

According to one industry observer, the cloning breakthrough "will lead to the creation of a multibillion-dollar segment within the health care sector."[4] This could be an understatement. Cloned sheep, goats or cows offer a cheaper way to produce valuable human therapeutic proteins in animal milk, such as blood clotting proteins for hemophiliacs, or insulin for diabetics. Scientists believe that cloned animals with genetically engineered traits will become highly efficient, living drug factories because a female mammal can yield far greater quantities of protein in her milk than genetically manipulated cells grown in the laboratory. PPL Therapeutics' Chief Executive Officer Ron James told the *Wall St. Journal* that his company hopes to have cloned animals

producing useful medicines within a year or two.[5] Once genetically engineered animals can be cloned routinely, it will mean faster and more uniform production of profitable proteins. According to industry analysts, the market for therapeutic proteins is currently about $7.6 billion per annum, and is expected to grow to $18.5 billion by 2000.[6]

Another potential and highly profitable use of cloned livestock is the assembly line production of "spare-part" animal organs for human transplant. Pig clones, for example, could be genetically engineered to be a source of replacement organs for humans. Pig cells grown in the laboratory could be altered genetically so that they would "look" like human cells to the human body, thus diminishing the likelihood that the human body would reject the cloned animal's transplanted organ.

There is a huge potential market in replacement organs from transgenic animals. In 1995, 35,000 patients worldwide received human organ transplants. But because of a chronic shortage of human organs, approximately 100,000 more were in demand.[7] The immediate need for organs is estimated to be a $6 billion market[8], and will likely be many times greater in the years to come.

From Sheep to Shepherd? Few Technological Barriers

One of the most remarkable aspects of Dr. Wilmut's work is that the technology he used to clone an adult sheep is relatively simple and inexpensive. Consider, for example, that Dr. Wilmut's sheep cloning team worked on a budget of approximately (US) $300,000 last year. In short, there may be few technological barriers to overcome in the cloning of cows or human beings. Dr. Ronald Munson, an ethicist at the University of Missouri told *The New York Times*, "It doesn't require the sort of vast machines that you need for atom smashing. These are relatively standard labs. That's the amazing thing about all this biotechnology. It's fundamentally quite simple."[9]

Just one week after the sheep cloning experiment was disclosed, an Oregon (USA) primate centre announced it had successfully produced two monkeys from cloned embryos. Don Wolf, the scientist heading the research team, pointed out that some 300 clinics in the US are already handling human embryos, "and they're doing it almost totally without regulation."[10] While US law prohibits government funding for human embryo research, there are no barriers to private sector research.

Hello Dolly...or Goodbye Dolly?

Public discussion and debate on the uses of cloned livestock have become virtually passé in the popular press. Today, the livestock issues are overshadowed by the more troubling prospect of cloning humans. Nevertheless, the cloning breakthrough raises important concerns related to the loss of livestock genetic diversity.

Livestock cloning is likely to become one more tool in a host of reproductive technologies (artificial insemination, embryo transfer, *in vitro* fertilization, etc.) that allow corporate breeders to produce elite, genetically uniform livestock breeds that are

selected solely for maximizing production of meat, milk and eggs. Worldwide, the greatest threat to domestic animal diversity is the highly specialized nature of intensive livestock production. As fewer and fewer animals are used for breeding, a breed's genetic base is narrowed with every generation. Genetically uniform animals are especially vulnerable to outbreaks of disease and changes in environmental conditions. Industrial livestock breeds alone are an inadequate gene pool for the future.

With the spread of industrial agriculture worldwide, the rate of extinction of livestock breeds has accelerated dramatically over the past 100 years. The United Nations' Food and Agriculture Organization concludes that domestic livestock breeds are disappearing worldwide at an annual rate of 5%, or six breeds per month.[11]

Why worry? Because livestock diversity--like plant diversity--is the key to sustaining and enhancing the productivity of agriculture. Traditional livestock breeds often possess valuable traits such as disease resistance, high fertility, good maternal qualities, longevity and adaptability to harsh conditions. The gradual disappearance of local breeds that are able to survive in extreme environments undermines food and livelihood security, especially for the poor. An estimated one-third of the world's population depend on livestock for some portion of their livelihoods.

Proponents are quick to point out that animal cloning may give us the tools we need to rescue endangered breeds. In theory, yes. But these are proprietary technologies that will be applied primarily to industrial livestock breeds. Rather than becoming tools for conserving and using greater diversity, it is more likely that cloning will exacerbate the problem of genetic uniformity.

The cloning of mammals becomes a death knell for livestock diversity if we allow human arrogance and corporate greed to persuade us that technology can save diversity. No matter how skilled we become in cloning cells, transferring embryos or designing transgenic livestock, we still can't "create" diversity once it's gone. Extinction is still forever.

WHO's on First

On 11 March 1997 the World Health Organization (WHO issued a statement condemning human cloning and announced that it would take the lead on debating the issue of cloning by initiating a series of national and regional consultations to define codes of good practice, guidelines and possible legislation.[12]

WHO is to be commended for responding quickly to the need for intergovernmental debate relating to ethical aspects of health-related research and technology.

RAFI urges that the "Dolly debate" not be limited to human cloning. There are many closely linked issues that must be addressed urgently. The January-February, 1997 issue of *RAFI Communique*, "The Human Tissue Trade," documents profoundly disturbing trends relating to the global trade in human tissue--especially that of rural populations

and indigenous peoples. Dolly underscores intense ethical concerns regarding ownership of human biomaterials and a large and growing movement of international tissue exchange routes that are developing in an almost total policy and regulatory vacuum.

These gaps in international policy must be addressed by WHO and other multilateral bodies. Failure to put the appropriate policies and regulations in place will result in damage to human rights and medical research.

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[1] Ruth Hubbard, "Irreplaceable Ewe," The Nation, Selected Editorial, on the internet at: www.thenation.com:80/issue/970324/0324hubb.htm

[2] Daniel Kadlec, Time, March 10, 1997. On the internet at: http://pathfinder.com/@@g@UcbwYAeJNrknjm/time/magazine/1997/dom/970310/

[3] Bioscan, Vol. 10, February, 1997 and Vicki Brower, "PPL floats IPO as companies consider transgenic switch," Nature Biotechnology, Vol. 14, June, 1996, p. 692.

[4] Larry Tye, "Small firms flock to profit off path opened by cloned sheep," The Boston Globe," February 26, 1997. Tye quoted Viren Mehta, of the New York health investment firm, Mehta and Isaly.

[5] Robert Langreth, "Cloning has Fascinating, Disturbing Potential," Wall St. Journal, February 24, 1997, p. B2.

[6] Lawrence M. Fisher, "Cloned Animals Offer Companies a Faster Path to New Drugs, New York Times, February 24, 1997, p. C17.

[7] Biotech Reporter, February, 1997, p. 2.

[8] Larry Tye, "Small firms flock to profit off path opened by cloned sheep," The Boston Globe, February 26, 1997.

[9] Gina Kolata, "With Cloning of a Sheep, the Ethical Ground Shifts," New York Times, Feb. 24, 1997, p. C17.

[10] MS-NBC

[11] FAO Press Release. "New FAO World Watch List for Domestic Animal Diversity Warns: Up to 1,500 Breeds Are at Risk of Extinction," 5 December 1995.

[12] Chakravarthi Raghavan, "Health: WHO Chief Condemns Human Cloning," Geneva, 11 March 1997.