What About the Animals?
The truth about cloning animals for food

Cloning is the term commonly used to refer to a procedure known as somatic cell nuclear transfer (SCNT), the procedure which was first used to create Dolly the sheep in 1996.[1] Since then, researchers have cloned a number of different animals, including cows, pigs, goats, horses, mice, cats, and dogs.[2] The process is far from perfected, however, with only 1-4% of cloning attempts, if any, generally succeeding.[3]

Despite such an abysmal record, the biotech industry is moving to commercialize animal cloning by asking the FDA to allow milk and meat from cloned animals to be sold to the public. The FDA intends to release a draft risk assessment announcing the safety of consuming food products from cloned animals by the end of 2006 or early in 2007.[4] If the draft is upheld by the end of the comment period that follows, cloned food products will be allowed on the market, and the FDA will likely not require that these products be labeled.

Food safety, however, is only one of the many issues that need to be examined before such a decision can be made. With 96-99% of cloning attempts regularly causing death or severe health problems, for example, there is widespread recognition in the scientific and medical communities that cloning presents serious risks to the animals involved.[5,6,7,8] But questions about the impact of cloning on animal welfare have yet to be adequately addressed, much less resolved.

The American Anti-Vivisection Society (AAVS) is working to ensure that the federal government engages in a public discussion about the threats that cloning poses to animal welfare, as well as other pressing moral and ethical questions related to cloning, before food from cloned animals are allowed on the market. Cloning is a remarkably inefficient and unpredictable technology, and it should not be allowed to proceed in a regulatory vacuum.

An Overview of Cloning: The technology and its applications

When an animal is cloned using SCNT, the nucleus, which contains most of the genetic material of a cell, is removed from an unfertilized egg and replaced with the nucleus of an adult (somatic) cell from the donor animal to be cloned. In this way, the egg is "reprogrammed," ultimately resulting in an animal that is an almost exact genetic copy of the donor. However, because there is mitochondrial DNA that lies outside the nucleus and remains from the original egg, a clone will exhibit some differences. These differences, and the extent to which the egg can or cannot be reprogrammed, are largely responsible for the high degree of inefficiency and unpredictability that characterize cloning.[9]

Agriculture researchers are interested in cloning livestock primarily for breeding purposes, in an attempt to create copies of 'valuable' animals. Currently, farmers use the animals that have the best genetics for some desired quality such as fast growth, leaner meat, or high milk production as breeding animals to produce offspring that will have similar qualities. By cloning these 'top'

breeders, farmers are trying to extend their reproductive potential and create whole herds or flocks with these uniform characteristics.[10]

Cloning is also used to produce copies of transgenic animals, animals who have been engineered with genes from another species in order to have better traits for production (such as faster growth, disease resistance, altered milk or meat products with 'health benefits' for humans, etc); to produce pharmaceuticals in their milk, blood, urine, or semen (pharming); or to produce tissues and organs for transplantation into humans (xenotransplantation).[11,12,13] If animal cloning is approved, generation and proliferation of transgenic animals is likely to become a major application of cloning technology.

Threats to Animal Health and Welfare: The clones, the surrogate mothers, and the egg donors

The remarkable inefficiency of cloning poses serious threats to animal welfare. Often, less than one percent of cloning attempts will result in a successful birth, and of those that are born, only a relatively small percentage are healthy enough to live for more than a few days or weeks.[14,15] According to one recent study,[16] 18% of cloned calves died at birth, and 32% of cloned calves who survived birth in another study[17] died within the first month. With such low success rates, not only must the cloned animals endure suffering, but so must hundreds of additional animals as their eggs are harvested, or as they are surgically implanted with embryos, often repeatedly, in an attempt to produce just one cloned animal.

To clone Dolly, for example, 277 cloned embryos were implanted, only 13 pregnancies resulted, and only 1 animal was born successfully, Dolly.[18] In a Texas A&M study using cows, 17% of 322 SCNTs developed into embryos (roughly 54), of which 26 were successfully implanted. After 40 days of pregnancy, six fetuses survived. After 290 days, only one survived. This calf had significant metabolic and cardiopulmonary abnormalities similar to those seen in previous studies, diabetes mellitus, and was susceptible to severe immune-system deficiencies.[19]

Problems afflicting cloned animals early in life

The Texas A&M study highlights the severe health problems that plague cloned animals. While very little information about cloned animals is publicly available (due to research confidentiality), it is clear that abnormalities are the norm, not the exception. Cloned animals suffer from respiratory distress, hypoglycemia, weakened immune systems, developmental problems, deformities, and a variety of ailments that claim the lives of most neonates.[20]

According to a recent study conducted by Cyagra, one of the biotech companies leading the push for cloned foods, 37% of cloned calves that survived birth had enlarged umbilical cords, a condition that often requires surgery; 19% had respiratory problems; 20% exhibited signs of depression; 17% were hyper- or hypothermic; and 75% required antibiotics.[21] Despite access to complete veterinary care, including extensive testing and monitoring, and despite the fact that any of more than 10 different interventions were performed, 42% of cloned calves who survived birth died within the first 150 days.

'Large Offspring Syndrome' (LOS) is another commonly observed problem with cloned animals in which the animal develops to be significantly bigger at birth than a conventional animal. It is not uncommon for the animal to be twice the normal size, and one lamb was reported as being five times larger than normal.[22] LOS is often accompanied by a variety of other symptoms as well. Gross abnormalities of organ growth are typical, for example, as well as breathing difficulties, reluctance to suckle, and sudden perinatal death.[23,24]

Problems afflicting surrogate mothers and their fetuses
Because cloned fetuses are often abnormally large, labor and delivery are likely to be painful and stressful, and the mother is less likely to survive the pregnancy. In one published study describing a cattle cloning project, three of 12 surrogate mothers died during pregnancy.[25]

In general, intervention for delivery is far more likely in a clone pregnancy than a more conventional pregnancy. Fifty-four percent of surrogate mothers in the Cyagra study[26] required a cesarean section for delivery, with an additional 30% requiring non-surgical intervention, whereas less than 1% of artificially inseminated females from another study[27] required such surgery.

Abnormal fetal development also translates into abnormal pregnancies, with a host of complications that threaten the lives of the unborn clones and their surrogate mothers.[28] Conditions known as hydrallantois (in which the mother swells with fluid to point of looking like she is about to burst), hydrops fetalis, or placental edema occur frequently (in over 50% of clone pregnancies in the Cyagra study[29]) and often result in death for the fetus or the mother.

Clone pregnancies are also associated with a greater risk of late term loss, with roughly 45% of pregnancies reported lost in the second or third trimester in studies at a research farm in France.[30] Such losses are normally uncommon and "expose the recipients [surrogates] to conditions that threaten their welfare."[31]

Problems afflicting cloned animals later in life
Even the small proportion of cloned animals who live for longer than 6 months and appear otherwise healthy have been known to suffer unexpected health consequences later in life. Studies in mice have shown serious genetic abnormalities even in those animals who survive the critical neonatal period and appear normal. Studies in cows have documented cases of sudden, unexplained deaths and subclinical pathologies that had gone undetected. In fact, in an article recently published in *The New England Journal of Medicine*, Rudolf Jaenisch, a prominent cloning researcher at the Whitehead Institute for Biomedical Research in Cambridge, Mass., stated that "given the available evidence, it may be exceedingly difficult, if not impossible, to generate healthy cloned animals…."[32]

The FDA's Assessment of Animal Health Risks: Comparisons to assisted reproductive technologies

It is clear that cloned animals are at an extraordinarily high risk of suffering from any of a variety of severe health problems, abnormalities, and deformities, typically resulting in death. In fact,

one group of cloning researchers even coined the phrase "Cloning Syndrome" to describe the suite of problems that tend to afflict cloned animals and their surrogate mothers.[33]

The FDA, however, has repeatedly attempted to gloss over the animal welfare problems raised by animal cloning. In reports of its draft risk assessment on cloned foods,[34] the FDA essentially dismisses any concerns by asserting that cloning poses no "*unique*" risks to animal health that are not seen with the assisted reproductive technologies (ARTs) already practiced by many large-scale livestock operations.

ARTs include artificial insemination (AI), embryo transfer, and *in vitro* fertilization, all of which involve progressively greater human involvement and interference to maximize the reproductive potential of 'valuable' animals.[35] Using ARTs as a benchmark for animal health is questionable given that there are recognized problems with ARTs. 35% of artificial inseminations,[36] for example, and 50% of *in vitro* fertilizations[37] have been reported to result in miscarriage.

Of even greater concern, however, is that, in its comparison of cloning to natural mating and ARTs, the FDA is grossly mischaracterizing the animal health risks caused by cloning by obscuring the tremendous *increase in frequency* with which these risks occur.

For example, 85-90% of natural pregnancies are carried to term, but only about 12-23% of clone pregnancies result in a birth,[38,39] 18% of which died during the birth according to one study.[40]

Hydrallantois, the typically fatal condition in which the pregnant animal swells with fluid to the point of looking like she is about to burst was found to occur in 14% of clone pregnancies in one reported study[41] (in 24% in another study[42]), but never or rarely in pregnancies produced through AI or natural breeding.[43]

24-36% of the cloned animals who survive birth have been reported to die within 6 months,[44,45,46] compared to approximately 5% of AI or naturally-bred animals,[47] despite access to extensive veterinary care and numerous different medical interventions, including surgery. The cloned animals suffer from any of a number of serious health problems and physiological deformities, including abnormally large bodies and malformed hearts, livers, or thymuses, which are generally uncommon normally.

When the FDA convened a panel from its own Veterinary Medicine Advisory Committee in 2003 to evaluate the agency's preliminary risk assessment on cloned animals, several members of the panel expressed concern that the FDA had not sufficiently characterized the risks that cloning presents for animals.[48,49] At that time, the FDA had stated, "No reports of risks qualitatively different from those encountered by animals involved in modern agricultural practices were detected, although the frequency of the risks appears to be increased in some species during the early portions of the life cycle of animal clones."[50]

The FDA's position in 2006, however, is essentially the same, despite the availability of additional studies that all document serious health problems arising from cloning. The FDA states in a recent article summarizing its risk assessment that, "…Cloning poses no new risks to

the health of the animals involved in the cloning process, but…none of these risks is unique to cloning, and all have been observed in animals derived via other ARTs or natural mating."[51]

The FDA can attempt to mask the issue by saying no new problems arise from cloning, but no risk assessment is complete without considering how often these problems are likely to occur. In addition, the FDA's proposed risk management plan, as described in the recently published report, is entirely too vague to sufficiently address the serious risks that cloning poses to animal health and welfare.

An Ethical Mandate: Establishment of an ethics advisory committee

According to one group of cloning researchers in Canada, the animal health problems associated with cloning "are of concern to the general public and government institutions, with consequences for the *acceptability, use, and regulation* of animal clones and their progeny [emphasis added]."[52]

It is no surprise, then, that a recent survey found that 64% of Americans think cloning is "morally wrong,"[53] and another 63% would not buy cloned food even it were labeled as "safe."[54] Just because a food *can* be produced does not mean it *should*. The FDA, by proposing that no significant management or regulation of cloning is necessary, has clearly not taken such concerns into adequate consideration.

63% of Americans, however, want the government to factor in ethical considerations when making a decision on animal cloning.[55] It is therefore essential that the federal government establish an ethics committee to publicly discuss and advise the FDA and Health and Human Services (FDA's parent agency) on such matters *before* animals are allowed to be commercially cloned for food.

Given the severity of the animal health problems associated with cloning, and the magnitude of ethical qualms Americans have with using the technology, there is both a pressing need and an overwhelming demand for the government to establish a proper regulatory framework to oversee animal cloning, one that takes into consideration both ethics and science. An advisory committee, mirroring the Health and Human Services' Secretary's Advisory Committee on Genetics, Health, and Society, which serves as a public forum for deliberations on the broad societal issues raised by the development and use of genetic technologies in humans, must be established to deliberate both publicly and officially the ethical challenges presented by animal cloning.

End Notes

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