Stephen Sundlof, Director
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, HFV-12
Rockville, Maryland 20855

October 9, 2002

Dear Dr. Sundlof,

On behalf of the Humane Society of the United States, the nation's largest animal protection organization with more than seven million constituents, we respectfully request that the Food and Drug Administration should urgently find means to prevent the entry of cloned animals, their byproducts, and their offspring into the food chain. The use of this technology for the production of food animals has too high a cost in terms of real and potential animal suffering and little benefit for humans and animals alike.

Current welfare problems

The National Academy of Sciences (NAS) review of this issue found that the cloning of animals has adverse effects on their welfare. NAS pointed out that intrusive and potentially painful reproductive manipulations are done to produce transgenic and cloned animals and that the value of the breeding stock means these animals can be subjected to these procedures repeatedly. Furthermore, cloning is highly inefficient at this point and incurs high rates of fetal deaths. For those animals born alive it is evident that they suffer from a large number of abnormalities such as brain lesions, skeletal malformations, and incomplete development of the vascular tract. As well, it is common for cloned calves and sheep produced by *in vitro* culture methods to have higher birth weights, often necessitating cesarean sections which may be done repeatedly on the same breeder animal.

While some of these welfare problems are not exclusive to cloned animals their high rate of occurrence and potential for suffering means use of the technology should be called into question. The FDA stated that if they found "human subjects are or would be exposed to an unreasonable and significant risk of illness or injury," this would be sufficient reason to put a study on clinical hold. We believe this stance should be extended to the animals concerned too. Given the high failure rate the production of cloned animals poses an unreasonable risk of harm to animals and therefore presents circumstances in which the CVM would need to exert its authority to prevent unnecessary suffering.

Extension of current practices

The cloning of high-producing animals is inappropriate when current practices of artificial selection have resulted in a number of production related diseases in farm animals. These diseases include mastitis and laminitis in dairy cows, skeletal problems in broilers and turkeys, osteoporosis in laying hens, excitability and stress susceptibility in pigs. Because they are potentially painful and crippling disorders that affect a large number of animals, these represent a significant welfare problem. It is ethically unjustifiable to use a technology that would exacerbate these problems by copying the very animals –those with maximum production- in which effects will be worst.

Potential welfare concerns

This technology is in its infancy and could have unforeseen consequences in terms of animal welfare. Dolly, the first mammal to be cloned, has arthritis and there is concern that this may have been caused by the cloning procedure. There is also concern that creating animals that are so similar genetically could allow a single pathogen to infect many individuals, putting animal safety and our food supply at risk. This is a significant concern in light of the recent problems with disease encountered by Britain and the potential for bioterrorism. There is insufficient information to address the risks of cloning animals, which the FDA cited as a reason for preventing human cloning, and it would be extraordinarily premature for such technology to be approved for animals.

Unnecessary

In light of the detrimental impacts of this technology on animal welfare, the broader question of the necessity of its use and its impact on society must be considered. Increasing production through cloning is questionable at a time when the animal protein market is glutted and federal money is being used to subsidize the production of pork by buying meat from producers for the school lunch program. Furthermore, it ignores the fact that there are farmers in the United States who practice humane and sustainable animal production. These farmers work with nature rather than against it, without degrading the environment and without the use of cloned animals which is costly and fraught with ethical issues.

Cloning could have a substantial impact on the economic structure of our society. This expensive technology will benefit only biotech companies and large agribusiness. This could exacerbate the ongoing trend in agriculture today of the loss of small family farms which are often more humane and ecologically sustainable.

We commend the FDA for its actions thus far in commissioning the NAS report and requesting that food from cloned animals should not enter the market place. These measures show an appropriate, precautionary approach, and we trust the FDA will further this by putting more weight on the animal safety issues outlined in the NAS report. We urge the FDA to find mechanisms to continue to prevent the entry of food from cloned animals into the market place. Thank you for your time and consideration.

Yours sincerely,

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