



Consumer Federation of America

May 3, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket Number 2003N-0573

The following comments on the Food and Drug Administration's Draft Animal Cloning Risk Assessment (Docket # 2003N-0573) are filed on behalf of the members of Consumer Federation of America (CFA). We realize that these comments are being filed a few hours after the May 3 deadline for public comments. We request that FDA still consider these comments as part of the public docket despite their late submittal and appreciate the agency's indulgence.

CFA is a non-profit association of over 300 organizations, with a combined membership of over 50 million Americans. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Since its founding in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

The organization's policy positions are determined by vote of member representatives at board meetings and an annual meeting. At the March 2007 annual meeting, CFA members adopted a resolution vigorously opposing the FDA's intention to permit milk and meat from cloned animals and their offspring to be put into the food supply.

CFA's members believe that the FDA's stated intention to permit the sale of meat and milk from cloned animals and their offspring is not justified by the science the agency has presented; that the agency's process has been biased in favor of action favorable to the cloning industry; that FDA has ignored the wishes of the American people in order to advance the interests of a narrow group of businesses; and that the egregious nature of these actions are compounded by the decision to forego labeling.

FDA’S RISK ASSESSMENT DOES NOT SUPPORT THE CONTENTION THAT MEAT AND MILK FROM CLONED ANIMALS IS SAFE FOR HUMANS

The risk assessment asserts that there is “no difference” between milk and meat from clones and their offspring and milk and meat from animals produced using other assisted reproductive technologies. However, FDA cannot cite any peer-reviewed studies on milk and meat from cloned cattle or their offspring, milk or meat from cloned goats or their offspring, or meat from cloned pigs or their offspring. Many of the studies FDA relied on involved only small populations. The agency relied on whatever it could find in the available literature rather than research that meets FDA’s own specifications for comparative safety studies. The agency has asserted that it can move forward without these studies because it does not have authority to require them to be done. The agency does however have an obligation to notify the public of the weaknesses that arise from a lack of comparative safety data.

Since there is no public benefit to be gained by rushing ahead to permit the use of this technology, there is no justification for proceeding based on inadequate data.

FDA’S RISK ASSESSMENT DOES NOT SUPPORT A FINDING THAT MEAT AND MILK FROM CLONED ANIMALS IS SAFE FOR ANIMALS

FDA acknowledges the scientific data demonstrate that there are substantially higher rates of health problems, birth defects, miscarriages and premature deaths among cloned animals than in animals produced through other forms of assisted reproduction.

In an amazing display of scientific sophistry the agency contends that these defects, health problems and premature deaths must not be considered because they are not of a different type than those that occur through use of other technologies. Numbers do count. Cloning inflicts unnecessary pain and suffering on animals. Numerous published studies show that there is a 95 to 99 percent likelihood that a cloned animal will die in utero or shortly after birth. A large percentage of clones suffer from impaired immune systems, physiological abnormalities, large heads and organ dysfunction. Other assisted reproductive technologies have far lower rates.

FDA insists that cloning technology is improving and this will result in lower rates of animal suffering in the future. However, a 2005 report by Tevit and Sandoe shows cloning success rates remain less than 5% no matter what technology is used¹.

Members of the FDA’s Advisory Committee on Veterinary Medicine did not agree that there is adequate data to demonstrate that cloning involves no greater pain suffering, abnormalities and premature deaths than other reproductive technologies.

¹ Geir, T., Sandoe, P. (eds), (2005) “The Science and Technology of Farm Animal Cloning: A Review of the State of the Art of the Science, the Technology, the Problems and the Possibilities.” Danish Center for Bioethics and risk Assessment, p. 25, at: www.sl.kvl.dk/cloninginpublic/index-filer/CloninginPublicTechnicalReport.pdf.

Since there is no public benefit to be gained by rushing ahead to permit the use of this technology, there is no justification for approving a technology that inflicts more pain and premature death than other available technologies.

FDA'S ARGUMENT THAT ITS DECISIONS ARE VALUE FREE AND BASED SOLELY ON SCIENTIFIC DATA PRESENTED IN THE RISK ASSESSMENT IS INVALID

Only FDA scientists delude themselves and mislead the public by insisting that their risk assessments are free of bias. Scientists and regulators and the National Academy of Sciences acknowledge that scientific risk assessments are not value free. The initial decision to explore some questions and not others shapes the outcome of the risk determination.

The NAS 2002 report noted that there might be some increased danger of pathogen contamination in cattle as a result of the increased stress associated with pregnancy and birth in clones. Stressed animals frequently carry increased loads of pathogens in their gut and may increase the risk of pathogen contamination of meat. The NAS report suggested the FDA explore this as part of its risk assessment. However, the FDA's risk assessment does not address this issue. Until it does so it is inappropriate to suggest that meat from cloned animals is as safe as other meat.

An appropriate regulatory process requires that an agency construct a risk assessment that is as free of value judgment as possible, acknowledging that it is not possible to remove all human bias from that process, and maintain strict neutrality while it collects the best science available. Whether and how the agency acts should then be determined by considering the predominant societal values and the public's willingness to accept or tolerate risk. These factors are legitimate elements of the decision making process regardless of whether or not they are consistent with the scientific assessment of the risk.

FDA HAS PROCEEDED ON THE ASSUMPTION AND ASSERTS THAT ANIMAL CLONING AND THE INTRODUCTION OF MEAT AND MILK FROM CLONED ANIMALS INTO THE FOOD SUPPLY HAS AN INHERENT PUBLIC VALUE

Advocates for putting cloned meat and milk into our food supply, including FDA officials, insist that the public will benefit from the introduction of these products into the food supply. There is not one whit of evidence to support this contention. Cloning advocates argue that healthier animals produce healthier food. They provide no data to support that. Cloning advocates argue that using the technology will increase the supply of milk and meat and lower prices. They have no data to support the claim. A quart of milk costs less today than a quart of water. Dairy farmers produce more milk than Americans drink and the surplus costs the taxpayers billions of dollars a year. Supporters

argue that cloning will make it possible to create a fatter, juicier steak. This is a matter of questionable value in a nation plagued with overweight and obesity. There are no public benefits to allowing the use of milk and meat from cloned animals and their offspring into the food supply. FDA's intention advances the interests of a small number of businesses over the concerns of the American people.

A STRONG MAJORITY OF AMERICANS BELIEVE CLONING ANIMALS IS IMMORAL AND OPPOSE HAVING MEAT AND MILK FROM CLONED ANIMALS IN THE FOOD SUPPLY AMERICANS

Gallup Polls report that over 65 percent of Americans think it is immoral to clone animals. Both the Pew Initiative on Food and Biotechnology and the industry-funded International Food Information Council found that a similar percentage say that, even if approved by FDA, they won't buy cloned milk and meat.

The FDA is committing the nation to an activity that millions find morally repugnant. In 2002, the National Academy of Sciences recommended that the government explore the moral and ethical concerns raised by creating cloned and transgenic animals. In 2003 then-Commissioner Lester Crawford said FDA would address ethical concerns. Now the FDA argues that such considerations are outside its purview. However, decisions about whether and for what purposes our country will encourage the manufacture of transgenic and cloned animals are far too important to be determined solely on whether these activities meet the narrow definitions of animal and human safety set forth in the Federal Food Drug and Cosmetic Act. The agency had the option of asking the Department of Health and Human Services to help them carry out the NAS recommendation by appointing a committee to examine these issues. FDA chose not to do so.

FDA'S REFUSAL TO REQUIRE LABELING OF CONTROVERSIAL PRODUCTS WILL FORCE AMERICANS TO CONSUME PRODUCTS THEY FIND MORALLY REPUGNANT

Ordinarily when products offend consumers, they exercise their right not to purchase them. That won't be possible with milk from cloned cows. FDA argues these products are chemically identical to conventional products, and therefore do not require labeling. Again the agency is not serving the public interest.

FDA's insistence that Americans consume milk and meat from cloned animals and their offspring distorts the intentions of the FDCA and does not serve the American people. It is the agency's responsibility to assure that the foods it regulates are safe. The agency is taking the position that because it has determined that meat and milk from cloned animals and their offspring are safe, the American people are obliged to purchase and eat them. This suggests that Americans are required to eat anything a scientist can cook up in the laboratory and FDA can declare safe. American consumers should not be compelled to

eat food they don't want and don't like or that is produced through methods the individual finds offensive.

RECOMMENDATIONS

Consumer Federation of America urges the FDA to withdraw the risk assessment because it is fatally flawed. Further the agency should not withdraw the voluntary moratorium on use of these products in the food supply but should seek peer-reviewed studies on the basic safety of meat and milk from cloned animals, consider the number of negative outcomes of pregnancy and premature deaths in cloned animals, request that the Department of HHS undertake a review of the ethics of cloning and of depriving Americans of the information they need to operate effectively in the marketplace, and provide essential information to the public so they can use their food dollars in a manner consistent with their moral, ethical and religious views.