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May 3, 2007

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Docket No. 2003N-0573: Draft Animal Cloning Risk Assessment;
Proposed Risk Management Plan; Draft Guidance for Industry**

The Center for Food, Nutrition, and Agriculture Policy (“CFNAP”) at the University of Maryland is an independent, non-profit research and education organization dedicated to advancing rational, science-based food, nutrition, and agriculture policy. CFNAP uniquely operates like an independent “think-tank,” while maintaining its academic affiliation with a major land-grant university. The research, education, outreach, and communications activities of the faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy and regulatory processes on food and nutrition issues, including animal health issues.

Encompassed in the Center’s activities on food and animal health policy are its interests in risk analysis, especially risk assessment and risk communication. As such, we respectfully submit the following comments in response to the Food and Drug Administration’s (FDA) request for comment on its draft Animal Cloning Risk Assessment, docket no. 2003N-0573 as published in the *Federal Register*.¹

Overview of the Comments

We recognize that the FDA Center for Veterinary Medicine (CVM) has a vital role in protecting animal and public health. Moreover, we respect the difficult task that CVM faces in evaluating the science while experiencing the pressures exerted by political, ethical, or moral concerns of some of the public and some issue-oriented, interest groups.

¹ Federal Register: Notices. January 3, 2007, Volume 72, Number 1, pages 136-137.

These comments address several overarching issues:

1. It is the constitutional, legal, and procedural responsibility of the Congress (the public's elected representatives) to address non-science-based public concerns;
2. FDA's risk assessment is thorough and science-based—true to its mandate and within the scope of its legal authority to protect human and animal health;
3. Excellent risk communication is critical to bolster consumer confidence and understanding of potential safety risks of food products derived from somatic cell nuclear transfer (SCNT)-clones and/or their non-cloned offspring. (For many people, somatic cell nuclear transfer cloning [SCNT-cloning] is now synonymous with the term, *animal cloning*.)²

FDA Lacks the Legal Authority to Address Non-Science-Based Concerns

The responsibility for representing the political will and ethical concerns of the public resides in the legislative branch of the government. Congress, as elected representatives of “the people,” is responsible for making laws that address societal problems. The executive branch implements the law(s) through regulations (and specific to FDA) to protect human and animal health. Because FDA legal authority comes from the Federal Food, Drug, and Cosmetic Act of 1938 plus amendments, the agency has neither the mandate nor the legal authority to evaluate (or even consider) the politics and/or ethics of animal cloning.

There is little research to inform the legislative policy process about the political and/or moral concerns of the public relative to animal cloning.^{3, 4, 5} Consumer research indicates that public opinion is for now both unformed and malleable. For example, the Pew Initiative on Food and Biotechnology (PFIB) reported that 12% of Americans have heard a “great deal” about animal cloning; and that about 4 out of 10 consumers have heard “not too much” or “nothing at all.”

Similarly, a quantitative consumer study conducted by the Center for Food, Nutrition, and Agriculture Policy (“CFNAP”) indicates that 40% of Americans have

² Throughout these comments, animal SCNT-cloning will be referred to as “animal cloning.”

³ International Food Information Council, *Food Biotechnology: A Study of U.S. Consumer Attitudinal Trends*, June-July, 2006.

⁴ The Pew Initiative on Food and Biotechnology, *Review of Public Opinion Research*, November, 2006.

⁵ Storey ML. *Final Topline Report: Consumers' Knowledge, Attitudes, Beliefs, and Purchase Intent Regarding Foods from the Offspring of Cloned Animals*, Center for Food, Nutrition, and Agriculture Policy, December 14, 2006.

“little understanding” (18%) or “no understanding at all” (22%) about animal cloning. It is therefore not surprising that the PFIB survey and the CFNAP study both show that many, but not all, Americans are uncomfortable with animal cloning. Historically, a lack of understanding is commonly associated with being uncomfortable across a wide range of issues and/or technologies.

CFNAP also examined consumers’ attitudes about animal cloning relative to several demographic and psychographic factors, including political/social ideology, religious affiliation, and regular attendance at religious services in relation to each consumer’s comfort level with animal cloning.

Religion and Politics. CFNAP hypothesized that consumers’ comfort level with animal cloning might be related to political and/or religious views in addition to demographic variables. Similar to other studies, CFNAP found that one-third of Americans are “mostly comfortable” with animal cloning, but two-thirds of Americans are “mostly uncomfortable” with it. Among those who are uncomfortable, about one-third (or about 20% of the population) consider it morally wrong and 23% (or 15% of the population) are concerned that animal cloning could lead to human cloning. These results suggest that about one-third of the public are uncomfortable with animal cloning for “ethical” reasons.

CFNAP further examined if religious denomination, theological viewpoint, and attendance in religious services had an impact on consumers’ comfort level with animal cloning. Our CFNAP study found that religious denomination has minimal effect on comfort level. Furthermore, once other demographic variables are included in the statistical model, CFNAP finds no differences in comfort level across the denominations – or across theological viewpoints, including fundamentalist, evangelical Pentecostal, mainline, and liberal.

Even so, religion has a role in determining consumers’ comfort level. About one-half (48%) of consumers report they attend religious services several times a month. Those who attend religious services frequently are 33% less likely to be comfortable with animal cloning than are those who do not attend services as often.

Political ideology (including personal conservative, moderate, or liberal views on social issues) has some link to consumers’ comfort level with animal cloning. Our data show that conservatives are more likely to be uncomfortable than are moderates. However, there was no significant difference between conservatives and liberals, moderates and liberals, or any other comparisons.

FDA’s Risk Assessment Is Proper, Thorough, and Science-Based

We commend FDA for its exhaustive and science-based assessment of potential risk of animal cloning to humans and animals. CFNAP has conducted an

evaluation of the science based on more than 400 published papers with more than 95% from the peer-reviewed scientific literature. Like FDA's determination, our separate and independent assessment shows that there is no scientific evidence to demonstrate a safety concern for human health from consuming meat and/or milk from cattle, swine, or goat somatic cell nuclear transfer (SCNT)-clones and/or their non-cloned offspring. In fact, there is strong theoretical and empirical evidence to suggest that there is no difference between the meat and/or milk from SCNT-cloned animals and/or their non-cloned offspring and that from other non-cloned animals. The assisted reproductive technology (ART) technique of SCNT-cloning has been studied by scientists for decades. Through years of research, many species of animals have been SCNT-cloned to improve breeding stock, preserve endangered species, and so forth.

CFNAP's separate scientific evaluation of the publicly available evidence, like FDA's risk assessment, shows that food products derived from SCNT-cloned animals and/or their non-cloned offspring are as safe to eat as animals bred using natural mating and ARTs, such as artificial insemination (AI), *in vitro* fertilization (IVF), and embryo splitting

Composition of meat and/or milk from all food-producing animals varies depending on numerous factors including genetics, husbandry practices, environment, and diet. Variations in (edible) muscle and fat tissue of SCNT-cloned animals and/or their non-cloned offspring are the same as those variations found in non-cloned animal tissues. Sound scientific evidence strongly supports the equivalency of food products from SCNT-clones and non-cloned, animals.

Our CFNAP consumer study shows that 26% of consumers are uncomfortable with animal cloning because of concerns about food safety. FDA's rigorous review should reassure this minority of consumers that foods from SCNT-cloned animals and/or their non-cloned offspring are as safe to eat (and the same as) food products from animals reproduced using all of those ARTs commonly used by farmers and ranchers – plus natural breeding.

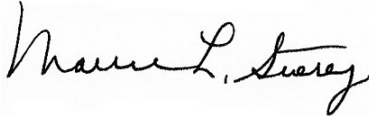
Science-Based Risk Communication Is Critical to Informing Consumers

Among the three elements of risk analysis, risk communication is probably the most difficult, least understood, and most poorly executed. The CFNAP and Pew studies show that consumers have limited awareness, understanding, and knowledge of animal cloning. An important FDA role is to now communicate with consumers and all other stakeholders to help them properly understand the best current scientific estimates of the relative safety of meat and/or milk from SCNT-cloned animals and/or their non-cloned offspring. These FDA communications should be supported by other stakeholders' communication efforts.

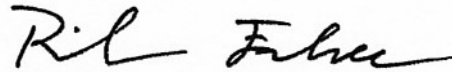
In summary, we urge FDA to:

1. Lift the effective, years-long, voluntary moratorium on the sale of meat and/or milk from SCNT-cloned animals and/or their non-cloned offspring. The best current risk assessments show no additional risk from consuming any of these products.
2. Immediately institute a broad-reaching, risk communication campaign to tell all consumers and stakeholders about the FDA's best current risk assessment about consuming meat and/or milk of SCNT-cloned animals and/or their non-cloned offspring.

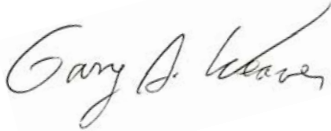
Respectfully submitted,



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