

United States Senate
WASHINGTON, DC 20510

December 11, 2006

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt,

We are writing in response to an October 17, 2006, the *Washington Post* report that indicated the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) is planning to take actions that will allow the inclusion of meat and milk from cloned animals in commercial markets. Because milk is a unique wholesome and natural nutritional product that is so important in the diets of America's children and adults, we are concerned about this report.

As you know, in 2003, FDA released the Draft Executive Summary of "Animal Cloning: A Risk Assessment." However, FDA did not release the full draft risk assessment at that time due to the scarcity of scientific data available on cloned animals. According the recent Washington Post article, FDA has reviewed numerous new scientific reports on cloned meat and milk since that time, though FDA has yet to submit those scientific reports to the appropriate advisory committee for review. In 2003, FDA officials assured the public that the evaluation process going forward would be "thorough and deliberate," and that the public would be informed and invited to participate before the ban on cloned milk and meat was lifted. We strongly believe a thorough and thoughtful review of the science and public participation in this process is critical.

Currently, an overwhelming majority of American consumers reject the idea of milk and meat produced from cloned animals. Years of surveying by the Gallup organization and the Pew Initiative on Food and Biotechnology, indicate that consumers oppose animal cloning and would not buy cloned meat and milk even if the government declared them safe. Research also indicates that lifting the voluntary moratorium on selling milk from cloned cows will result in a 15% drop in purchases of U.S. dairy products. This could lead to catastrophic income loss for U.S. dairy farmers and cause devastating ripple effects throughout our nation's schools and communities, as well as across U.S. nutrition and farm programs. Clearly, consumers are not clamoring for this new food technology.

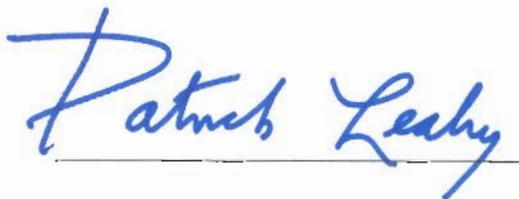
Consumers deserve to feel confident in the Department's procedures, if it plans to determine the safety of this new food technology. Most importantly stringent peer

reviewed science is critical to ensure the public has all the facts. We therefore ask that you require FDA to take the following steps:

1. Re-submit FDA's new draft risk assessment to scientific peer review by the Veterinary Medicine Advisory Committee. The availability of new scientific data demands that FDA pursue comprehensive scientific scrutiny on this issue.
2. Publish the risk management plan after the risk assessment is finalized. Sound risk management depends on accurate, unbiased, and transparent risk assessments. In the 2003 Executive Summary of "Animal Cloning: A Risk Assessment," FDA promised that risk management options would follow the risk assessment. Recent reports seem to indicate FDA now plans to issue them simultaneously. This departs from normal procedure and does not allow adequate time for the public to respond to the risk assessment.
3. Communicate all draft and final decisions to the public through the Federal Register. The Department seems to have chosen to release important updates and information on its review of this food technology through scientific journals with very limited public access. Apparently, the journal *Theriogenology* is set to publish an abstract of FDA's draft risk assessment, risk management, and risk communication plan. If FDA is going through a scientific journal, rather than the Federal Register to inform the public, we would like to know how this meets FDA's commitment to share information and have an open and deliberate process.
4. Utilize the advisory committee and inter-agency review process for animal cloning to invite maximum public and stakeholder input. According to the press, the Administration is participating in an inter-agency review process. This review should include an analysis by USDA and USTR of the economic impact of the commercial release of milk from cloned cows on the dairy industry; consider the impact on global trade, and the implications for domestic nutrition and dairy support programs. FDA must not pursue lifting the current ban without a complete consideration of the impact this would have on global trade and the implications for the economic impact on the U.S. dairy industry as a whole.

We look forward to your response before FDA publishes the draft risk assessment or takes any other steps to lift the present ban on milk from cloned cows entering the marketplace.

Sincerely,



Patrick Leahy



Norm Coleman

John

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Hub Kohl

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