American Anti-Vivisection Society • Center for Food Safety • Consumer Federation of America • Consumers Union • Farm Sanctuary • Food & Water Watch • Friends of the Earth • The Humane Society of the United States • Union of Concerned Scientists

December 18, 2007

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner:

The undersigned groups, representing more than 70 million consumers nationwide, are concerned that the FDA intends to finalize its risk assessment by the end of this year and allow milk and meat from cloned animals and their progeny to be sold to the public. This action flies in the face of serious gaps in the agency's analysis and the fact that 150,000 public comments received by the FDA overwhelmingly opposed the approval of meat and milk from cloned animals out of concern for human health, animal welfare, and economic impacts.

In the past week, Congress has clearly indicated that it shares our concerns through two separate legislative acts. These provisions would delay the Food and Drug Administration's decision regarding meat and milk from cloned animals and their progeny.

1. The Consolidated Appropriations Act contains bipartisan language agreed to by both the House and Senate Appropriations Committees that strongly encourages the FDA to continue the voluntary moratorium on introducing food products from cloned animals into commerce. The report language directs the FDA to enter into an agreement with the Economic Research Service at USDA to study the domestic agricultural and international trade economic implications of permitting cloned animals and their progeny into the food supply. The House has already passed the appropriations bill with these provisions and the Senate is expected to pass it later this week.

2. The Senate-passed version of the Farm Bill (H.R. 2419) contains a bipartisan provision that requires the FDA to delay issuance of its final risk assessment on food from cloned animals until further studies by the National Academy of Sciences and the USDA are completed.

Our organizations believe that the FDA should respect the will of Congress and the public that cloned foods not enter the food supply until more is known about their potential impacts on human health and the economy. We urge you to delay any action related to issuing a final risk assessment or lifting the voluntary moratorium on the use of cloned animals or their progeny for food until the concerns raised by the pending legislation are addressed.

Sincerely,

Tracie Letterman, Esq.
Executive Director, American Anti-Vivisection Society

Joe Mendelson
Legal Director, Center for Food Safety

Chris Waldrop
Director, Food Policy Institute, Consumer Federation of America

Michael Hansen, PhD
Senior Scientist, Consumers Union

Julie Janovsky
Director of Campaigns, Farm Sanctuary

Wenonah Hauter
Executive Director, Food & Water Watch

Gillian K. Madill
Genetic Technologies Campaigner, Friends of the Earth

Michael Greger, M.D.
Director of Public Health and Animal Agriculture
The Human Society of the United States

Margaret Mellon
Director of Food and the Environment, Union of Concerned Scientists
Attachments:

1. Consolidated Appropriations Act Language
2. Senate Farm Bill Language—Managers' Amendment

CC: President George W. Bush
Secretary Michael O. Leavitt, Department of Health and Human Services

Attachment 1: Consolidated Appropriations Act

House Amendments to Senate Amendment to H.R. 2764 – State, Foreign Operations, and Related Programs Appropriations Act, 2008 (Consolidated Appropriations Act, 2008)

Joint Explanatory Statement to Accompany Consolidated Appropriations Amendment

DIVISION A-AGRICULTURE, RURALDEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2008

Pages 81 - 82

Congress passed, and the President signed, the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA placed a cap on the number of waivers that can be issued annually and reduced them by 25 percent over the life of the Act. The Committees note that the waiver limits passed in FDAAA were less stringent than those proposed by FDA in March 2007. The Committees remind FDA that the FDAAA limitations are a ceiling and strongly encourage FDA to continue its efforts to limit the use of financial conflicts of interest waivers to greatest extent possible.

The Committees note that on December 28, 2007, the Center for Veterinary Medicine issued a draft risk assessment on animal cloning which concluded that food products from cloned animals are safe to enter the food supply. During the public comment period, thousands of submissions were received by FDA. Many of these asked the FDA to obtain more information not assessed in the initial risk assessment, including further evaluation of the potential health, economic, and trade impacts, before acting further. In addition, many comments expressed concern that several of the studies on which the risk assessment was based did not undergo a scientific peer review process. The Committees strongly encourage FDA to continue the voluntary moratorium on introducing food products from cloned animals into commerce until FDA completes a review and analysis of

comments and evaluates the need for additional studies recommended during the public comment period.

The Committees direct the Food and Drug Administration to enter into an agreement with the Economic Research Service at USDA to study the domestic agricultural and international trade economic implications of permitting commercialization of milk and meat from cloned animals and their progeny into the food supply.

Insert

Attachment 2: Farm Bill Language

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AMENDMENT NO._____ Calendar No._____

Purpose: To require studies by the Secretary of Agriculture on the effects of food products from cloned animals entering the food supply.

IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.

H. R. 2419

To provide for the continuation of agricultural programs through fiscal year 2012, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. MIKULSKI (for herself and Mr. SPECTER)

Viz:

On page 1045, after line 2, insert the following:

SEC. 7505. STUDIES AND REPORTS BY THE DEPARTMENT OF AGRICULTURE AND THE NATIONAL ACADEMY OF SCIENCES ON FOOD PRODUCTS FROM CLONED ANIMALS.

(a) STUDY BY THE DEPARTMENT OF AGRICULTURE.—

(1) IN GENERAL.—The Secretary of Agriculture, in coordination with the Economic Research

Service, and after consultation with the Secretary of Health and Human Services, shall conduct a study and report to Congress on the state of domestic and international markets for products from cloned animals, including consumer acceptance. Such report shall be submitted to Congress no later than 180 days after the date of enactment of this Act.

(2) CONTENT.—The study and report under paragraph (1) shall include a description of how countries regulate the importation of food and agricultural products (including dairy products), the basis for such regulations, and potential obstacles to trade.

(b) STUDY WITH THE NATIONAL ACADEMY OF SCIENCES.—

(1) IN GENERAL.—The Secretary of Agriculture shall contract with the National Academy of Sciences to conduct a study and report to Congress regarding the safety of food products derived from cloned animals and the health effects and costs attributable to milk from cloned animals in the food supply. Such report shall be submitted to Congress no later than 1 year after the date of enactment of this Act.

(2) CONTENT.—The study and report under paragraph (1) shall include—

(A) a review and an assessment of whether the studies (including peer review studies), data, and analysis used in the draft risk assessment issued by the Food and Drug Administration entitled *Animal Cloning: A Draft Risk Assessment* (issued on December 28, 2006) supported the conclusions drawn by such draft risk assessment and—

(i) whether there were a sufficient number of studies to support such conclusions; and

(ii) whether additional pertinent studies and data exist which were not considered in the draft risk assessment and how this additional information affects the conclusions drawn in such draft risk assessment; and

(B) an evaluation and measurement of the potential public health effects and associated health care costs, including any consumer behavior changes and negative impacts on nutrition, health, and chronic diseases that may result from any decrease in dairy consumption,

attributable to the commercialization of milk from cloned animals and their progeny.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to impede ongoing scientific research in artificial reproductive health technologies.

(d) TIMEFRAME OF FINAL RISK ASSESSMENT.—Notwithstanding any other provision of law, the Secretary of Health and Human Services (acting through the Commissioner of Food and Drugs) shall not issue the final risk assessment on the safety of cloned animals and food products derived from cloned animals until the date that the Secretary of Agriculture completes the studies required under this section.

(e) CONTINUANCE OF MORATORIUM.—Any voluntary moratorium on introducing food from cloned animals or their progeny into the food supply shall remain in effect at least until the date that the Secretary of Health and Human Services (acting through the Commissioner of Food and Drugs) issues the final risk assessment described in subsection (d).