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COMMITTEE

United States Senate

WASHINGTON, DC 20510-0606

January 22, 1998

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Dr. Jane Henney
Commissioner, Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney;

I am writing to express my concern about the proposed framework recently used by the Food and Drug Administration to regulate antibiotic use in food producing animals. As both a veterinarian and an elected official, I have serious reservations about the scientific basis of your agency's proposal.

In the agency's document entitled, "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food Producing Animals," it states that, "... FDA's primary public health goal must be to protect the public health by preserving the long-term effectiveness of antimicrobial drugs for treating diseases of humans." I applaud you for taking a special interest in the issue of antimicrobial resistance. I am concerned, however, that the efforts outlined in the proposed framework suggest the establishment of what appear to be insurmountable obstacles to the approval of new animal antimicrobials, without having demonstrated a significant negative impact on human health.

In July, 1998, the National Research Council issued a report entitled, "The Use of Drugs in Food Animals: Benefits and Risks." The NRC initiated this project to provide a comprehensive review of relevant information concerning the use of drugs in food animals and establish recommendations pertaining to the availability and effective and safe use of drugs in food animals. The NRC report, "acknowledges that there is a link between the use of antibiotics in food animals, the development of bacterial resistance to these drugs and human disease, although the incidence of such disease is very low." The report goes on to conclude that, "information gaps hinder the decision-making and policy process for regulatory approval and antibiotic use in food animals. A data-driven scientific consensus on the human health risk posed by antibiotic use in food animals is lacking."

There is no question that resistance in food borne pathogens can occur with antibiotic treatment of animals in experimental conditions, but the likelihood and extent to which this may occur in a farm setting has been neither adequately assessed nor clearly established. Nor has the extent of the human health impact been established. Because of this fact, I support first doing a risk assessment which includes a farm-to-table approach to quantify public health impacts. With

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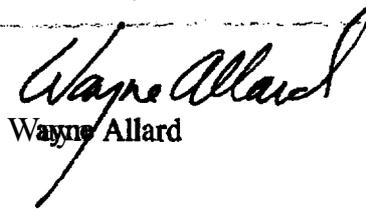
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before making substantial policy changes that could have a tremendous negative impact on U.S. **agriculture and animal health** and welfare, and an unknown impact on human health. I understand that a panel of experts is being convened to review this issue. I would appreciate it if you would include my comments in the record of the Veterinary Medicine Advisory Committee Meeting scheduled for next **week**. I look forward to working with you and the industry to adequately and appropriately address the issue of antibiotic resistance.

Sincerely,


Wayne Allard

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the results of the risk assessment, FDA will then have better data to determine an appropriate course of action. I am also troubled by the fact that, at a time of great economic distress in animal agriculture, the federal government is proposing a complex and very expensive solution to a problem we have not yet measured. In addition, it would likely have the effect of reducing availability of existing and new animal drugs which could result in less healthy farm animals, negatively impact animal welfare, and possibly have unexpected negative human health impacts because of increased transmission of zoonotic pathogens through the food supply.

The document fails to recognize the interventions being implemented to reduce the potential transfer of resistant zoonotic pathogens from animals to humans. Veterinary organizations have created judicious therapeutic antimicrobial use principles. They are in the midst of customizing the principles to reflect the needs of diverse animal species and have committed to emphasizing the message of judicious use through continuing education programs. Additionally, advances in food processing technology serve as additional control points. The major zoonotic pathogens of concern for the development of antimicrobial resistance are *Salmonella* spp. and *Campylobacter jejuni*. As of 1997, the incidence of disease caused by these pathogens has decreased to levels below the year 2000 targets established by the Department of Health and Human Services. For *Salmonella* spp., the 1987 baseline was 18 cases per 100,000 and the year 2000 target was 16. Preliminary 1997 data demonstrate 13.8 cases per 100,000. For *Campylobacter jejuni*, the 1987 baseline was 50 cases per 100,000, the year 2000 target was 25. The 1997 preliminary data demonstrate 23.0 cases per 100,000. Also, initial 1998 reports from USDA's Food Safety Inspection Service (FSIS) regarding *Salmonella* prevalence testing of animal carcasses demonstrated significant reductions for poultry and swine carcasses. Reportedly, the initial sampling period did not result in any *Salmonella* positives for beef. The point is that as the number of cases of salmonellosis and campylobacteriosis decrease, so does the number of cases that possibly require antimicrobial therapy and the number of infections with decreased susceptibility to antimicrobials.

Furthermore, I am concerned that the framework proposed by your agency ignores the efforts of the livestock and poultry industries to assure the safety of food. These groups have worked closely with veterinarians to develop guidelines for the judicious use of antibiotics. These efforts, although encouraged by FDA, are rendered meaningless by the purely regulatory structure contained in the framework. It would seem more appropriate for the agency to focus their efforts to ensure the safety of the food supply on encouraging continued adoption of HACCP and the dissemination of educational information like that contained in the Fight Bac program.

I am concerned about the issue of antibiotic resistance and what implications that has for public health. However, I would encourage you to focus agency efforts on developing better data