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STATE OF MAINE
DEPARTMENT OF
AGRICULTURE, FOOD & RURAL RESOURCES
28 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0028

EDWIN R. PORTER
ACTING COMMISSIONER

January 31, 2006

Senator John Nutting
Representative John Piotti
Members of the Joint Standing Committee on Agriculture, Conservation and Forestry
2 State House Station
Augusta, Maine 04333-0002

Re: Resolve, To Examine the Nontherapeutic Use of Antibiotics

Dear Senator Nutting, Representative Piotti and Members,

The Resolve, To Examine the Nontherapeutic Use of Antibiotics directed the Commissioner of the Department of Agriculture, Food and Rural Resources and the Director of the Bureau of Health to examine ways to reduce the use of antibiotics in the animal industry with the goal of maintaining the therapeutic efficacy of antibiotics. The Resolve also directed the Commissioner and Director to convene a study group to review the use of antibiotics in animal agriculture, with particular attention to those antibiotics also used in human medicine. The following identifies the members of the study group and outlines their recommendations.

Each working group and departmental representative added value to the process and each gained a greater appreciation of the facts surrounding this complex issue. The recommendations were derived through consensus with the recognition that the challenges really reside with agricultural production outside the State of Maine. It needs to be noted that most agricultural practices within the State of Maine conform to the principles of judicious use of antibiotics. Maine farmers should be proud of their record. Unfortunately, most of our foodstuff purchases come from out of state.

Members

- Matt Townsend, DVM, Maine Veterinary Medical Association
- Steve Sears, M.D, Infectious Diseases
- Syd Sewall, M.D., Pediatrician
- Dee Potter, Maine Beef Producers Association, representing AGCOM, a diverse statewide agricultural organization
- Betty Lamoreau, Director, Bureau of Purchases
- Scott Haskell, DVM, University of Maine Cooperative Extension
- Bill MacDonald, Keep Antibiotics Working
- No participation, Medical Pharmacologist
- Shelley Doak, Department of Agriculture
- Don Hoenig, VMD, Department of Agriculture
- Kathleen F. Gensheimer, MD, MPH, Department of Health and Human Services

Background:

According to the Infectious Disease Society of America, the development of antimicrobial agents (antibacterials, antivirals, antifungals and antiparasitics) to treat infections has been one of the most notable medical achievements of the past century. These advances in medical care are now threatened by increasing resistance among all microorganism classes, but particularly resistance among bacteria to antibiotic agents. The seriousness of antimicrobial resistance is reflected in the:

- steadily increasing frequency of resistance over time among individual pathogens
- increased presence of resistance among critical bacterial species causing common infections
- global extent of the resistance problem

The rate of resistance has become so high that there are no longer effective agents to treat some disease causing organisms. The manageable causes of antimicrobial resistance are diverse and include:

- overuse and misuse of antimicrobial agents in humans, food animals, agriculture and consumer products
- increased pressure to prescribe antimicrobial agents as a result of advances made in the use of invasive medical technology and indwelling prosthetic devices
- transmission of antimicrobial-resistant organisms because of inadequate infection control practices
- insufficient development and application of immunization as a preventive strategy
- government policies that permit direct over-the-counter purchase of antimicrobial agents by consumers

The relative contribution of each of these factors to the overall problem of antimicrobial resistance is not known. Some antimicrobial resistance is expected to develop over time as a consequence of any antimicrobial use (even appropriate use) as microorganisms mutate and adapt in response to exposure to the drug. It is not realistic to expect that antimicrobial agents can be used indefinitely without eliciting any resistance. However, appropriate use will slow the development of resistance. As a result, it is imperative that antimicrobial agents be used responsibly in the treatment of individual patients to preserve their utility and value as agents for treating others in the future, recognizing that use of antimicrobial agents incurs societal as well as individual effects.

The study group delineated two major principles to limit the impact of antimicrobial resistance:

Good Antimicrobial Stewardship: Good antimicrobial stewardship is the optimal selection of antimicrobial agents for the appropriate indication, dosage and duration of therapy that results in the maximum benefit and minimum of adverse events for the patient and minimizes the development of antimicrobial resistance.

Control and Prevention: This includes the consistent development and application of infection control and immunization policies and practices to prevent transmission and infection caused by resistant organisms.

The study group also gave high priority to the following strategies in the belief that support for these efforts will most rapidly achieve control of the problem of antibiotic resistance and/or provide the scientific basis to manage it in a rational manner:

- Rigorous measurement and mandatory industry reporting of antimicrobial agent usage in human, animal, plant and inanimate applications.
- Routine surveillance for antimicrobial resistance rates in key microorganisms found in humans, animals, plants, food products, and the environment
- Continued availability of high quality diagnostic microbiology laboratories in human and animal health care facilities
- Improved diagnostic testing in humans and in animals to aid practitioners in better identifying those subjects with infections who will and who will not benefit from antimicrobial treatment
- Steadfast and unfailing support for infection control programs in all health care settings
- Education of the public and of professionals to change expectations and to increase awareness of the risks of antimicrobial resistance when these agents are used
- Responsible marketing and promotion of antimicrobial agents that incorporate concern about the potential for development of antimicrobial resistance

Recommendations

1. Direct the Governor and Maine's Congressional delegation write to the Food and Drug Administration urging them to provide adequate funding to expedite risk assessments on approved drugs, with particular emphasis on those drugs classified as "critically important" or "highly important" for human therapeutic use.

The Food and Drug Administration oversees the approval of new and emerging drugs. Many of the nontherapeutic drugs used in animal agriculture were approved for use over 30 years ago. It is nearly impossible to ascertain what approval process was used at that time. Many of the antimicrobial drugs approved for nontherapeutic use at that time received an "over-the-counter" designation by the FDA. Currently there is an effort underway within FDA, Center for Veterinary Medicine to reexamine these drugs and perform a risk assessment on their effects on human health and the potential for antimicrobial resistance. The committee is in favor of this process and believes that more resources and personnel should be applied to expedite testing.

2. Direct the Governor and Maine's Congressional Delegation to support efforts to reduce nontherapeutic use of antibiotics at the Federal level.

3. *Encourage the Governor and Maine's Congressional Delegation to support funding of the Food Animal Residue Avoidance Databank and the National Antimicrobial Resistance Monitoring System.*

Antimicrobial compounds play an essential role in ensuring the health and well being of livestock. Protecting the health of livestock is also an important contributor to providing consumers an abundant supply of safe, wholesome and affordable food. In order to maintain the human safety, animal safety and continued efficacy of these important products, animal health professional needs prompt access to data relating to prudent use, including complex pharmacokinetic data. This data is an important contributor to prudent-use decisions as well as to aid in preventing violative residues in animal products. Since its inception in 1982, the Food Animal Residue Avoidance Databank has developed and maintained a unique and valuable pharmacokinetic food safety database for veterinarians, livestock producers, state and federal regulatory agencies and extension specialists. In addition, the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) has established the Guidance for Industry #152 framework for evaluating the safety of antibiotics relative to their potential to contribute to the development of antimicrobial resistance. It is important that such resistance patterns, if present, are addressed so as not to jeopardize public health as a potential indirect consequence of antibiotic use in livestock. The US Department of Agriculture (USDA), FDA-CVM and Centers for Disease Control and Prevention (CD) have jointly funded the National Antimicrobial Resistance Monitoring System (NARMS) for many years. The NARMS program is the post-approved monitoring system for new and existing antibiotics and the data are a central element in the decision-making process employed by the FDA Veterinary Medical Advisory Committee as they implement the Guidance for Industry #152 evaluation process.

4. *Direct the Division of Purchases to implement a purchasing preference policy.*

It is the policy of the State to protect the public health by encouraging the prudent use of antibiotics. In soliciting bids for meat products, the Division of Purchases in the Department of Administrative and Financial Services shall inform meat suppliers that, assuming similarity in quality, quantity, availability and price, the State prefers to purchase products that have not been produced using medically important antibiotics for non-therapeutic purposes. Furthermore, the Division of Purchases shall continue to encourage school districts to take advantage of contracts awarded to suppliers whose products meet this preference.

The Division of Purchases will provide information through the Department website on the State purchasing preference, participating producers and suppliers, and additional information consistent with the State policy. The Division of Purchases will work with the Department of Education to provide a one-stop information service so that State agencies and school districts can access information through the State websites and not incur any additional expenses to the individual districts and agencies.

The State policy, and the supporting educational efforts, will stress the importance of maintaining the effectiveness of antibiotics used in human medicine by encouraging judicious use of antibiotics in meat production.

5. *Enhance the Maine Cattle Health Assurance Program, Maine Beef, Dairy and Pork Quality Assurance Programs and parallel poultry and small ruminant programs to incorporate protocols for the prudent use of antibiotics.*

These programs involve the producer, practitioner and state agency coordinators in conducting on farm risk assessments and education that promote animal health, food safety and quality and environmental stewardship. These programs reach numerous producers across a variety of animal species. Program criteria will be modified to apply greater emphasis on the judicious use of antibiotics.

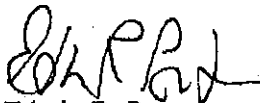
6. *Provide a continuing education course for licensed veterinarians on best management practices for the use of antibiotics.*

There are approximately 30 large animal practitioners who regularly attend Department of Agriculture sponsored continued education courses. These courses are approved through the Maine Veterinary Medical Association and the Veterinary Licensing Board. While producers often obtain nontherapeutic antibiotics directly from the manufacturer, veterinarians can provide credible advice based on sound science.

Sincerely,



Dora Ann Mills, M.D.
Maine Center for Disease Control
Department of Health & Human Services



Edwin R. Porter
Acting Commissioner
Department of Agriculture, Food and Rural Resources