

February 10, 2000

9 7 8 3 '00 FEB 16 A9 :59

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

RE: DOCKET NUMBER 98D-0969

Thank you for sponsoring the December 9-10 Workshop on Risk Assessment and the Establishment of Thresholds. The general presentations on risk analysis and public health as well as the presentations that specifically addressed the draft "Risk Assessment on the Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken" were very interesting and informative.

We believe that the risk assessment model is appropriate for addressing the issue of antimicrobial resistance in human pathogens due to antimicrobial use in animals. We also thank you for beginning the risk analysis process and support your continued efforts. The assessment process will allow decisions to be made based on information available now and in the future. Temporal relationships and associations that have generated important hypotheses about the role of antimicrobial use in food animals and the development of resistance to human pathogens may be proven to be the cause of such resistance or to have a minor role in the development of such resistance.

We have heard many comments that we believe are important to the risk analysis that will follow the initial assessment and especially support efforts to determine if there are sources other than poultry for fluoroquinolone resistant campylobacter that would cause the usual sporadic human infections. We realize the risk assessment addressed the incremental effect on human infection due to consumption of chicken with fluoroquinolone resistance campylobacter, but believe that further determination of causation will be necessary before risk management decisions are made.

We believe the entire population of our country is the appropriate population for your public health efforts and risk assessments. We also believe that the standard for acceptable risk should be based on relative safety and costs versus benefits at different levels of risk. As such, all analyses should first establish the level of additional harm or improvement in health that will come to the general population. Once those levels are established, specific subsets may be evaluated for the change in their health.

As an example, consider a situation in which a stated number of cases of fluoroquinolone resistant campylobacter infections were due to fluoroquinolone use in poultry. Before steps are taken to reduce the number of such resistant infections, a risk assessment should determine the possible additional infections that would result from the use of alternative therapeutic choices, due to either resistant organisms or to increased foodborne infections. In addition, the costs of such steps should be balanced against the benefits of their implementation.

98D-0969

e/b

As policies for risk management, based on the presented risk assessment, are considered, the costs for effectively changing antimicrobial use patterns, if indicated, should be included. Responsible parties will work towards implementing rational change and represent the vast majority of those using antimicrobials in livestock, but a small minority may exist that will not be as willing to change. Even now, there may be instances where a valid veterinarian-client-patient relationship for legend or extra-label drug use does not exist. Regulatory discovery and action is infrequent and difficult to achieve given the very unique North American livestock production systems.

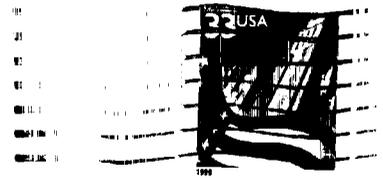
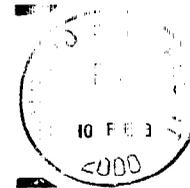
We suggest that the risk assessment model and the subsequent risk management should also account for the expected impact of any changes. If it is going to take ten years before an existing bacterial population has a change in susceptibility, perhaps our resources would best be applied to areas other than a change in the use of existing antimicrobials.

Bovine veterinarians and the producers for whom they work are sincerely committed to food safety, including responsible use of antimicrobials to reduce the development of resistance in human pathogens and the number of pathogens present in products derived from cattle. They will be most supportive of any changes in their use of antimicrobials when the benefit of those changes, for either resistance or pathogen load, are demonstrated to have a greater effect on causation than other possible choices. The risk assessment, with the modifications we and others have suggested, should be an appropriate and valuable tool in addressing concerns over antimicrobial use in food animals.

Sincerely,

Lloyd L. Knight
Chairman
Committee on Pharmaceutical and Biologic Issues
American Assoc. of Bovine Practitioners

Lloyd L. Knight, D.V.M.
PO Box 819
Glenns Ferry, ID 83623



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

20857+0001 