

Association of Veterinarians in Broiler Production APR -7 11:10
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March 12, 1999

Dr. Margaret Miller
HFV-1, Room 482
FDA, Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dear Dr. Miller:

I am writing on behalf of my association which consists of veterinarians working for poultry companies. The companies produce, process and sell over 90% of the chickens produced in this country. My purpose for writing is to comment on the "Propose Framework for Evaluation and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food Producing Animals." I had the pleasure to attend the VMAC Meeting in January when this plan was introduced.

My opinion of this proposal is not favorable as I think it will virtually eliminate new drug development for food animal medicine without correcting the specified problem-increased bacterial resistance in human medicine. I say this because the proposal in no way modifies drug usage either in human medicine or in nonfood-animal medicine. It is very difficult to believe that all "the problem" comes from antibacterial drug usage in food animal medicine.

I understand the category classification, based on usage of the drug in human medicine, but there are no means in this system to allow for a drug to move from a category I to II or III as new drugs are introduced to the market. Also on what basis (arbitrary?) is a drug assigned to a particular class?

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No importance is placed on the drug to food animal medicine which is particularly distressing. While no one would place more importance on animal life than human life, animal health does play a role in human health and quality of human life. As an industry we try to grow chickens through emphasis on management and vaccination with antibacterial drugs used as a necessary complement. Also who will pay for the higher cost associated with less ability to treat disease? We too are concerned about bacterial resistance.

Many scientists place great significance on the pending risk assessment study at Georgetown University and yet you initiate this new frame work without waiting for the results of that study. Additionally AVMA is developing its "judicious use guidelines" which can probably accomplish some of the intentions of the frame work. Again, why the rush when the science is still unclear?

The frame work calls for on farm post-approval monitoring programs which raises even more concern. What are the resistance thresholds for each drug that would prompt concern? If these are not known-who will define them? Currently manufactures of certain pharmaceuticals are being required to develop PAMP's for their products. Would these data be used to calculate resistance thresholds or would more studies be required? On farm work means more people coming on the farm. We and other animal groups have disease biosecurity issues.

While I recognize the concern about antimicrobial drug resistance I really wonder if this framework document doesn't represent a hasty action which may not even reach the target. I also wonder if anyone has given serious consideration to the potential impact of less availability of antimicrobial drugs in food producing animals on the microbial load carried by those animals.

I would be happy to discuss this matter with you if you would like to do so.

Sincerely,

A handwritten signature in cursive script, appearing to read "Spangler Klopp".

Spangler Klopp

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