

AAAP Committee on Drugs and Biologics

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The proposed FDA ban on adding low levels of tetracycline and penicillin to animal and poultry feeds and required veterinary prescriptions for therapeutic use has been suspended for the moment. The public hearings on this subject have clearly raised valid objections to the proposed regulations. Major arguments were the lack of data regarding the actual dangers of antibiotic resistance and the unenforcibility of the prescription requirement.

First the safety issues will be thoroughly studied by the National Academy of Sciences. If sufficient data can be accumulated to warrant reintroduction of the proposed regulation, then the issue of the required veterinary prescription will be brought up again subsequently.

In order to avoid unduly restrictive policies of FDA for the poultry industry in the future, a suggestion has been made to the AAAP Committee on Drugs and Biologics to institute a form of permanent veterinary surveillance in the poultry industry, which would make harsh FDA regulations superfluous and unnecessary.

A permanent surveillance program would require that each poultry production unit or integration would have a prescribed poultry health program which would be reviewed and updated regularly by a veterinarian/poultry pathologist. Such a surveillance program would allow for obtaining a permanent blanket permit for the use of antibiotics in poultry feeds for preventive or therapeutic use. The members of the AAAP Drugs and Biologics Committee have generally reacted positively to the described proposal.

It was felt strongly that a case by case prescription rule would be unworkable and insane. To institute a health surveillance program, the veterinarian/poultry pathologist would have to be chosen as an individual who is uniquely qualified in the field of avian medicine, which would rule out most local practicing veterinarians, who are usually not qualified and not interested in this field.

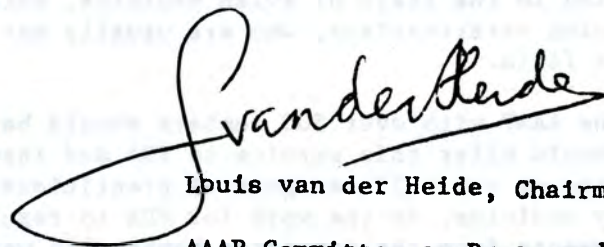
The AAAP with over 500 members should be able to handle such a problem. AAAP should offer this service to FDA and insure our involvement in the program. Otherwise we may well see general practitioners and others less experienced in poultry medicine, do the work for FDA to regulate our industry. Other questions and comments from the Committee Membership were:

1. Does the veterinarian have to be licensed in the state where company headquarters or where the birds are?
(Answer: Most likely where the birds are, should be dealt with by AAAP and AVMA so that issue of covering several states can be solved).
2. Is there a potential conflict with State Veterinary Practice Act and Pharmacy Laws.
(Answer: In case the licensing issue is solved, should not be a problem).

3. Which drugs are to be included in the prescribed health program?
(Answer: At the moment the issue at hand is only penicillin and tetracycline. However, FDA will undoubtedly expand the regulations into other antibiotics and chemotherapeutics).
4. What benefit is there for the consumer, if abuses continue under the blanket permit?
(Answer: A surveillance program would offer at least a corrective force in the production area. An unenforcible prescription law would have very little advantage over a surveillance program, from the standpoint of abuse prevention).
5. The most negative critique heard was that the concept of a professional surveillance program is doomed to failure because it creates regulation, red tape and cost without providing real control).
(Answer: Considering the alternative of a prescription law, which would be disastrous, unenforcible and impractical, the surveillance program appears far more attractive and probably more productive.

In conclusion: The AAAP Committee on Drugs and Biologics would propose to the AAAP membership to consider one or more of the following steps:

- (1) Proposal to FDA that AAAP set up a program of prescribed health surveillance for the poultry industry with subsequent blanket permits for use of antibiotics and chemotherapeutics in poultry feeds.
- (2) Proposal to AVMA to solve the issue of multiple state veterinary licensing for veterinary poultry pathologists.
- (3) Consider possible involvement of qualified non - veterinary poultry pathologists in a surveillance program.
- (4) No action at this time, but wait until the safety issue will be studied by FDA, which will take some time.



Louis van der Heide, Chairman

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