



PEW COMMISSION ON
INDUSTRIAL FARM
ANIMAL PRODUCTION

May 20, 2008

Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2008-N0225]

Dear Sirs:

The Pew Commission on Industrial Farm Animal Production is a two year study funded by a grant from The Pew Charitable Trusts to Johns Hopkins Bloomberg School of Public Health to study the public health, environmental, rural communities, and animal welfare problems created by concentrated animal feeding operations. The commission was comprised of 15 members from diverse professional backgrounds and experience, including animal agriculture, public health, medicine, veterinary medicine, ethics, and state and federal policy.

The final report of the Commission was released on April 29, 2008, including all of the Commission's recommendations. The first five recommendations by the Commission concern antimicrobial resistance since the Commission believes the indiscriminate use of antibiotics and other antimicrobials in animal agriculture is a serious threat to public health.

The recommendations state:

Recommendation #1: Restrict the use of antimicrobials in food animal production to reduce the risk of antimicrobial resistance to medically important antibiotics.

a. Phase out and ban use of antimicrobials for non-therapeutic (i.e. growth promoting) use in food animals¹ (see PPCIFAP definition of "non-therapeutic").

b. Immediately ban any new approvals of antimicrobials for non-therapeutic uses in food animals² and retroactively investigate antimicrobials previously approved.

¹ The PCIFAP defines nontherapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e. any use of the drug as a food or water additive for **growth promotion**, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

c. Strengthen recommendations in FDA Guidance #152 which requires the FDA determine that the drug is safe and effective for its intended use in the animal prior to approving an antimicrobial for a new animal drug application.

d. To facilitate reduction in IFAP use of antibiotics and educate producers on how to raise food animals without using nontherapeutic antibiotics, the USDA's extension service should be tasked to create and expand programs that teach producers the husbandry methods and best practices necessary to maintain the high level of efficiency and productivity they enjoy today.

Recommendation #2. Clarify antimicrobial definitions to provide clear estimates of use and facilitate clear policies on antimicrobial use.

- a. The Commission defines as *nontherapeutic*³ any use of antimicrobials in food animals in the absence of microbial disease or known (documented) microbial disease exposure; thus, any use of the drug as an additive for growth promotion, feed efficiency, weight gain, routine disease prevention in the absence of documented exposure, or other routine purpose is considered nontherapeutic.⁴
- b. The Commission defines as *therapeutic* the use of antimicrobials in food animals with diagnosed microbial disease.
- c. The Commission defines as *prophylactic* the use of antimicrobials in healthy animals in advance of an expected exposure to an infectious agent or after such an exposure but before onset of laboratory-confirmed clinical disease as determined by a licensed professional.

Recommendation #3. Improve monitoring and reporting of antimicrobial use in food animal production in order to accurately assess the quantity and methods of antimicrobial use in animal agriculture.

² The PCIFAP defines nontherapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e. any use of the drug as a food or water additive for **growth promotion**, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

³ For the Commission's recommendations, the members considered many definitions; a complete list of sources is in Appendix 1.

⁴ This definition is adapted from PAMTA.

- a. Require pharmaceutical companies that sell antimicrobials for use in food animals to provide a calendar-year annual report of the quantity sold. Companies currently report antibiotic sales data on an annual basis from the date of the drug's approval, which makes data integration difficult. The FDA is responsible for oversight of the use of antimicrobials in food animals and needs consistent data on which to report use.
- b. Require reporting of antimicrobial use in food animal production, including antimicrobials added to food and water, and incorporate the reported data in the USDA's National Animal Identification System (NAIS).⁵ The FDA CVM regulates feed additives but does not have the budget or personnel to oversee their disposition after purchase. In addition, CVM and USDA are responsible for monitoring the use of prescribed antimicrobials in livestock production, but rely on producers and veterinarians to keep records of the antibiotics used and for what purpose.
- c. Institute better integration, monitoring, and oversight by government agencies by developing a comprehensive plan to monitor antimicrobial use in food animals, as called for in a 1999 National Research Council (NRC) report (NAS, 1999). An integrated national database of antimicrobial resistance data and research would greatly improve the organization, amount, and types of data collected and would facilitate necessary policy changes by increasing data cohesion and accuracy. Further, priority should be given to linking data on both antimicrobial use and resistance in the National Antimicrobial Resistance Monitoring System (NARMS). This could be accomplished by full implementation of Priority Action 5 of *A Public Health Action Plan to Combat Antimicrobial Resistance*, which calls for the establishment of a monitoring system and the assessment of ways to collect and protect the confidentiality of usage data ((CDC/FDA/NIH, 1999). Since the USDA already provides antimicrobial use data in fruit and vegetable production it seems logical that usage information can be obtained from either agriculture producers and/or the pharmaceutical industry without undue burden.

Recommendation #4. Improve monitoring and surveillance of antimicrobial resistance in the food supply, the environment, and animal and human populations in order to refine knowledge of antimicrobial resistance and its impacts on human health.

⁵ The USDA APHIS has begun implementing an animal tracking system, the National Animal Identification System (NAIS; <http://animalid.aphis.usda.gov/nais/index.shtml>). Announced in May 2005, the NAIS tracks both premises and 27 species of food animals (including cattle, goats, sheep, swine, poultry, deer, and elk). The data are linked to several databases run by private technology companies, while the USDA shops for a technology company with data warehousing expertise to run the full national database. The United Kingdom uses a similar database system for its Cattle Tracing System (CTS; <http://www.bcms.gov.uk/>), which facilitates tracking and is accessible online to users and administrators. See PCIFAP Recommendation #6 in this section for more information.

- a. Integrate, expand, and increase the funding for current monitoring programs.
- b. Establish a permanent interdisciplinary oversight group with protection from political pressure, as recommended in the 1999 NRC report *The Use of Drugs in Food Animals: Risks and Benefits*. The group members should represent agencies involved in food animal drug regulation (e.g., the FDA, CDC, USDA), similar to the Interagency Task Force (CDC/FDA/NIH, 1999). In order to gather useful national data on antimicrobial resistance in the United States, the group should review progress on data collection and reporting, and should coordinate both the organisms tested and the regions where testing is concentrated, in order to better integrate the data. Agency members should coordinate with each other and with the NAIS to produce an annual report that includes integrated data on human and animal antimicrobial use and resistance by region. Finally, the group should receive appropriate funding from Congress to ensure transparency in funding as well as scientific independence.
- c. Revise existing programs and develop a comprehensive plan to incorporate monitoring of the farm environment (soils and plants) and nearby water supplies with the monitoring of organisms in farm animals.
- d. Improve testing and tracking of antimicrobial-resistant infections in health care settings. Better tracking of AMR infections will give health professionals and policymakers a clearer picture of the role of antimicrobial-resistant organisms in animal and human health and will support more effective decisions about the use of antimicrobials.

Recommendation #5. Increase veterinary oversight of all antimicrobial use in food animal production, to prevent overuse and misuse of antimicrobials.

- a. Restrict public access to agricultural sources of antimicrobials.
- b. Enforce restricted access to prescription drugs. By law, only a veterinarian may order the extralabel use of a prescribed drug in animals, but in fact prescription drugs are widely available for purchase online, directly from the distributors or pharmaceutical companies, or in feed supply stores without a prescription. Without stricter requirements on the purchase of antimicrobials, extralabel (i.e., nontherapeutic) use of these drugs is possible and even probable. For that reason, *no* antibiotics should be available for over-the-counter purchase.
- c. Enforce veterinary oversight and authorization of all decisions to use antimicrobials in food animal production. The extralabel drug use (ELDU) rule under the Animal Medicinal Drug Use Clarification Act (AMDUCA) permits veterinarians to go beyond label directions in using animal drugs and to use legally obtained human drugs in animals. However, the rule does not permit ELDU in animal feed or to enhance production. ELDU is limited to cases in which the health of the animal is threatened or in which suffering or death may result from

lack of treatment. Veterinarians should consider ELDU in food-producing animals only when no approved drug is available that has the same active ingredient in the required dosage form and concentration or that is clinically effective for the intended use (1994). North Carolina State University, the University of California-Davis, and the University of Florida run the Food Animal Residue Avoidance Databank (FARAD) (<http://www.farad.org/>), which includes useful information for food animal veterinarians, including vetGRAM, which lists label information for all food animal drugs. To be effective, AMDUCA and ELDU must be enforced. In addition, the FDA CVM should compel veterinarians to submit prescription and treatment information on farm animals to a national database to allow better tracking of antibiotic use as well as better oversight by veterinarians, as technology allows. Veterinary education for food animal production should teach prescription laws and reporting requirements.

- d. Encourage veterinary consultation in these decisions.
- e. AMDUCA requires the veterinarian to properly label drugs used in a manner inconsistent with the labeling (i.e., extralabel) and to give the livestock owner complete instructions about proper use of the drug. Further, ELDU must take place in the context of a valid, current veterinarian-client-patient relationship—the veterinarian must have sufficient knowledge of the animal to make a preliminary diagnosis that will determine the intended use of the drugs. The producer should be encouraged to work with the veterinarian both to ensure the health of the animal(s) and to conform to antibiotic requirements. For example, the National Pork Board Pork Quality Assurance program encourages consultation with veterinarians to maintain a comprehensive herd health program (NPB, 2005).

We would appreciate the inclusion of these recommendations in the hearing record.

Sincerely,

Robert P. Martin
Executive Director