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July 6, 2009

The Honorable Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903-0002

Dear Commissioner Hamburg:

All of us from Keep Antibiotics Working want to thank you for the meeting to discuss the Food and Drug Administration's response to the urgent and growing crisis of antibiotic-resistant microorganisms. We are excited about the new leadership you bring to the agency. We are committed to reducing antimicrobial resistance that stems from the overuse and misuse of antibiotics in food animal production.

As you know, the use of antibiotics in food animals is a significant contributor to the increased levels and severity of antibiotic-resistant human and animal pathogens. This conclusion, reached in a 2003 report from the National Institute of Medicine, *Microbial Threats to Health: Emergence, Detection and Response*, has since been strengthened by a mounting body of scientific evidence. Highlights from this literature can be found on the Keep Antibiotics Working website at http://www.keepantibioticsworking.com/new/indepth_keyevid.cfm#aguse.

As we discussed in our meeting, the amount of antibiotics used in food animal production in the United States is enormous. As detailed by the enclosed report from the Union of Concerned Scientists, an estimated 70 percent of all antimicrobials used in this country are added routinely to animal feeds for purposes other than treating sick animals. Fully half of these uses are from classes of antibiotics also used in human medicine: aminoglycosides, lincosamides, macrolides, penicillins, tetracyclines, streptogramins, and sulfonamides. In swine production, 95 percent of antibiotics used are of medical importance for human treatment.

The most straightforward way to address use-driven increases in resistance traits is to reduce the use of antibiotics wherever possible. Unlike in human medicine, many antibiotics are used in animal medicine for nontherapeutic purposes like feed efficiency, growth promotion, or routine disease prevention. Since these purposes account for the lion's share of antibiotic use in animals and since their goals can largely be achieved in other ways, this sphere of use offers important opportunities to lower the selection pressure for resistant traits.

We are pleased that the Center for Veterinary Medicine is developing an initiative to address the resistance issue, but we are concerned that that initiative, as far as we understand it, will result only in the withdrawal of labeled claims for growth promotion and feed efficiency uses of antibiotics. The elimination of such uses, estimated by industry to be just 10 to 15 percent of the total, would make only a minor dent in the problem. Moreover, given the similarity in the way antibiotics are used for growth promotion and prophylaxis—both involve mixing drugs in feed at relatively low levels—it would be relatively easy for industry to recharacterize growth promotion and feed efficiency uses as prophylaxis or disease control. If this happens, even the hoped-for 10 to 15 percent reduction in use may not be achieved in practice. The only way to achieve substantial reductions of use in production agriculture is to target all uses not aimed at treating sick animals, with very few exceptions.

We are unconvinced by arguments that the withdrawal of approvals for nontherapeutic uses of antibiotics will damage the food animal production industry. On the contrary, every indication from the scientific literature is that withdrawal of routine uses of antibiotics in food animals should be achievable with minimal disruption to agricultural output, farmers' incomes, and consumer prices. These studies demonstrate the industry's great capacity to adapt. Leaders from all production sectors have also shown that it is possible to end the use of medically important antibiotics without undue disruption on production, as they have sought to fill the demand from growing specialty markets.

Piecemeal reductions made on a voluntary basis by individual companies will not achieve broad public health goals. The FDA needs to ensure reductions across the industry. The best way to accomplish such reductions is to remove from the marketplace all medically important antibiotics (those used in both human and animal medicine) approved for nontherapeutic purposes.

Member groups of Keep Antibiotics Working have filed a petition in the past (enclosed) urging this reform, pointing out that this policy would be consistent with the principles already laid out in FDA's Guidance for Industry #152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern*. This guidance represents a science-based approach for addressing the safety of approvals of animal antibiotics from a resistance point of view. To facilitate implementation of the policy, the agency should retrieve from its files all risk assessments already done by the FDA on antibiotics. We ask that those risk assessments be completed and published for public comment, consistent with the agency's commitment to greater transparency. We also encourage you to hold public meetings with all stakeholders, including public health representatives and consumers, to discuss the implications of the risk assessments.

Finally, we believe that the veterinary profession should have in place clinical practice guidelines to guide practitioners' decisions about the appropriate use of antibiotics. If such guidelines were in place, it would be relatively easy to come up with a list of appropriate circumstances for feed use of antibiotics, as discussed in our meeting with Dr. Sharfstein. Unfortunately, no such guidelines are available. Instead, veterinarians and producer organizations have focused on the creation of vague judicious use guidelines that have had no demonstrable effect on antimicrobial use. Because of the absence of agreed-upon practice guidelines, we are developing and will soon

provide you with a description of what we believe are appropriate uses of medically important antibiotics in food animals.

Again, we thank you for meeting with us. We look forward to working with you to ensure that FDA fulfills its public health mandate in keeping antibiotics effective.

Sincerely,



Richard R. Wood
Chair, Keep Antibiotics Working (KAW) Steering Committee

and the following KAW Steering Committee Members present at the meeting:

Mimi Brody, J.D.
The Humane Society of the United States

David Wallinga, M.D.
Institute for Agriculture and Trade Policy

Margaret Mellon, J.D., Ph.D.
Union of Concerned Scientists

Steven Roach
Food Animal Concerns Trust

Brise Tencer
Union of Concerned Scientists

Enclosures: *Hogging It* report
Citizen petition

cc: Dr. Joshua Sharfstein, Deputy Commissioner