FDA DRAFT GUIDANCE FOR INDUSTRY:
EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN

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The Problem

I am Director of *Keep Antibiotics Working (KAW): The Campaign to End Antibiotic Overuse*. KAW is a broad coalition of health, consumer, agriculture, trade, environmental, humane, and other advocacy groups with a combined membership of over nine million members. While the coalition encompasses a broad range of interests, the organizations within the coalition have come together to address a very specific problem: the overuse of antibiotics in animal agriculture that is contributing to the growing public health problem of increasing resistance of bacteria to many antibiotics, making it harder to treat serious and life-threatening diseases. I will lay out the policy context in which KAW views the FDA's Draft Guidance for Industry. Experts from KAW member organizations will address more specific technical issues related to the Draft Guidance.

A federal task force convened by the Department of Health and Human Services last year said that antibiotic resistance is a "growing menace to all people." The Union of Concerned Scientists (UCS) estimates that seventy percent of antibiotics used in the United States are fed to animals that are not sick, and that half of those drugs are in eight classes of drugs that are identical or closely related to antibiotics used to treat humans. An estimated 24 million pounds of antibiotics are fed nontherapeutically to cattle, swine, and poultry annually. [*Hogging It, p. 60 (1991)]* In June 2002, the respected medical journal *Clinical Infectious Diseases* published the report of a Scientific Advisory Panel composed of physicians, veterinarians, microbiologists, and other experts. After a two-year study of more than 500 published papers, the Panel concluded that antibiotic use in farm animals "contributes to the growing problem of [antibiotic] resistance in animal and human infections," and that "antimicrobial resistance in pathogenic bacteria limits treatment options; raises health care costs; and increases the number, severity, and duration of infections."

The Proposed FDA Response

KAW and its member organizations commend the FDA for acknowledging that use of antibiotics in animal agriculture contributes to the growing problem of antibiotic resistance. This acknowledgement is a major step forward in the public dialogue on how to address this problem. We recognize and applaud the fact that FDA is setting out a thoughtful process for carefully reviewing applications for approving additional agricultural antibiotics. While we have some concerns about certain aspects of the proposed guidance as my colleagues will discuss, it's certainly a step in the right direction, and obviously important that future applications be carefully scrutinized so that we don't make the current problem worse.

From our perspective the key question is whether the FDA is going to reevaluate the safety of antibiotics already approved for use in animal agriculture, because it is here that the greatest current danger to public health lies. The answer in the Draft Guidance is a definite "maybe." Only two pages in Appendix C of the Draft Guidance – out of a total document of 48 pages - address FDA's intentions with respect to already approved antibiotics. To us, this is a case of the tail wagging the dog. Discontinuance of the use of millions of pounds of drugs that have already been approved is of far greater importance to public health than approval of new drugs for use in agriculture. Only one novel antibiotic has been developed and approved for human use in the last 25 years. Furthermore, in Appendix C, FDA makes no commitment to do anything at all. Every operative phrase is preceded by the words "intends to" or "may." Most importantly, there is no commitment or timetable for the FDA to take any action or even begin to take action on any specific drug. A definite, binding timetable is the *sine qua non* of meaningful FDA action.

The historical record also raises concerns about the FDA's ability to take action on a timely basis. In March, 1999 the Center for Science in the Public Interest and other organizations filed a "Petition to Rescind Approvals of the Subtherapeutic Uses in Livestock of Antibiotics Used in (or Related to Those Used in) Human Medicine." The FDA responded that, "For legal, scientific and resource reasons, *withdrawal actions for the petitioned drugs need to be considered on a drug by drug basis.*" (Emphasis added) The FDA response also pointed out that, "The Agency's experience with contested, formal withdrawal proceedings is that the process can consume extensive periods of time and Agency resources." Indeed, the Agency noted that withdrawal of nitrofuran approvals took 20 years, and that withdrawal of DES approvals took six years. Because there are eight classifications of

drugs used in animal agriculture that are important in human medicine, FDA procedures, by the Agency's own admission, could take over a hundred years!

For all of these reasons, and until FDA demonstrates that it can and will take effective action to restrict current uses of antibiotics in animal agriculture, KAW and its member organizations believe that Congressional action is necessary. S. 2508 / H.R. 3804, "The Preservation of Antibiotics for Human Treatment Act of 2002" would withdraw approvals for nontherapeutic agricultural use of eight specific named classes of antibiotics that are important in human medicine. This legislation is supported by the American Medical Association, the American Public Health Association, the American College of Preventive Medicine, the Ambulatory Pediatrics Association, and about 145 health, consumer, environmental, vulnerable population, and other organizations. In addition, the legislation would ban the use of Cipro-like drugs in poultry, proposed by FDA in 2000 but now tied up in FDA's endless administrative procedures.

Conclusion

In sum, we are greatly encouraged, but not fully satisfied, by the FDA draft guidance.