KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

www.KeepAntibioticsWorking.com

August 5, 2009

Ms. Melody Barnes
Assistant to the President for Domestic Policy
The White House
Washington, D.C. 20500

Dear Ms. Barnes:

On behalf of the more than eleven million Americans who belong to our member organizations and have long been concerned about protecting public health, animal welfare, and food safety, the Keep Antibiotics Working coalition (KAW) urges President Obama to support the Food and Drug Administration in its newly announced goal of restricting the non-judicious uses of antibiotics in animal agriculture. H. R. 1549 and S. 619, The Preservation of Antibiotics for Medical Treatment Act of 2009 ("PAMTA"), could play a constructive role in accomplishing that goal, and we urge President Obama to support this important legislation.

We note that during the presidential campaign, then-Senator Obama was asked in a questionnaire, "Will you support legislation such as the Preservation of Antibiotics for Medical Treatment Act, S. 549 and H.R. 962 [the bill numbers in the last Congress], to phase out routine non-therapeutic use of antibiotics in farm animals?" He responded "Yes," adding, "I support stronger protocols, standards, and appropriate prohibitions for animal medicines to prevent disease resistant strains or adverse health effects in humans."[1]

The continuing decline in effectiveness of antibiotics against common bacterial infections due to non-judicious use is recognized as a crisis by the federal government and world authorities. Treatments for infections are becoming increasingly limited and expensive and, in some cases, nonexistent. An estimated 70 percent of all antibiotics used in this country are routinely fed to farm animals for non-therapeutic purposes, principally to keep them from getting sick in overcrowded and unsanitary industrial-scale farms. With improvements to animal husbandry practices, this profligate use of antibiotics at low doses for virtually the entirety of animals' lives would not be necessary.

Restricting non-judicious uses of antibiotics in agriculture can most directly be achieved by the FDA revoking its approvals for non-therapeutic uses of antibiotics. Many of these approvals were granted by the agency decades ago, before it began giving

[1] http://www.fund.org/pdfs/senator-obama-response.pdf (pp. 6)

in-depth consideration to resistance during the drug approval process. Under current law, the FDA has full authority to cancel approvals for specific uses of drugs no longer considered to be safe from a resistance point of view. But the law also affords drug sponsors numerous opportunities to appeal such decisions, first within FDA and then in federal courts. As a result, contested cancellations of antibiotics can take many years and consume valuable agency resources, all the while leaving the drugs on the market where they continue to generate resistant microorganisms and drive up health costs. A prime example is the revocation of the approval of fluoroquinolones in poultry. Though the evidence of increased resistance resulting from this approval was clear and compelling, the cancellation was contested by Bayer and it took FDA almost five years – from October 2000 to September 2005—to get the drug off the market for poultry use after the FDA had determined its continued use was unsafe.

As acknowledged by FDA Principal Deputy Commissioner Joshua M. Sharfstein in his July 13 testimony to the Committee on Rules of the U.S. House of Representatives, this statutory framework "is very burdensome on the agency." With hundreds of approvals of antibiotics for different species and different non-therapeutic uses, it could take the agency into the next century to work through the cancellations and appeals process for each – time we really cannot afford to take if we are to effectively address this serious problem.

PAMTA would help expedite this process by limiting appeals and clearly requiring drug sponsors to bear the burden of proving their drugs safe. The bill amends the Federal Food, Drug, and Cosmetic Act to provide that the current non-therapeutic uses in food animals of seven classes of medically-important antibiotics – penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides – will be banned in two years unless during that period the FDA determines "that there is a reasonable certainty of no harm to human health" from such use. That is the current legal standard for both approvals and cancellations of drugs. In essence, the legislation restores the original burden of proof that faced manufacturers when they first sought approval of an antibiotic for use in food animals, but before the agency was giving real consideration to resistance concerns. By limiting the appeals to a two-year time frame and formally placing the burden of proof on the drug sponsors, PAMTA would remove dangerous drugs from the market more quickly and protect FDA's scientific resources from being wasted on years of needless litigation.

The FDA's new mission to restrict the non-therapeutic use of medically-important antibiotics reflects a broad consensus among experts and other governments. In 2002, the World Health Organization called upon all nations to shift away from the use of antibiotics in non-human medicine. In 2003, the Institute of Medicine of the National Academies of Science reported that a decrease in antimicrobial use in human medicine alone would have little effect on the growing problem of resistance, and substantial efforts must be made to decrease inappropriate overuse in animals and agriculture; the National Academies then called on the FDA to ban the use of antibiotics for growth promotion in food animals if those drugs are also used in human medicine. In 2006, the European Union banned antibiotic growth promoter use in food animals because of food

safety concerns (note that several individual European countries have also restricted disease prevention uses in food animals).

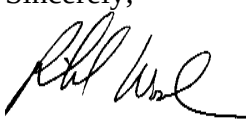
To meet the challenge effectively, FDA must address the full range of non-therapeutic uses. Addressing only the growth promotion and feed efficiency uses of antibiotics, estimated by industry to be just 10 to 15 percent of the total, would make only a minor dent in the problem. Moreover, given the similarity in the way that antibiotics are used for growth promotion, feed efficiency, and disease prevention – all involve mixing drugs in feed at relatively low levels – it would be relatively easy for industry to recharacterize its growth promotion and feed efficiency uses as "disease prevention" to avoid any reductions at all.

We urge President Obama to support the FDA in its long overdue initiative to address the overuse of antibiotics in animal agriculture – including for routine disease prevention, as well as for growth promotion and feed efficiency – and to support the enactment of PAMTA, which would enable the agency to accomplish this crucial goal in a timely fashion with more efficient use of its overstretched scientific personnel.

For your convenience, we enclose our July 13 congressional testimony and some recent editorials endorsing the passage of PAMTA.

On behalf of the member organizations of Keep Antibiotics Working, we thank you for considering our request.

Sincerely,



Richard Wood
Chair, Keep Antibiotics Working Steering Committee
Executive Director, Food Animal Concerns Trust

Mimi Brody, J.D.
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

Enclosures (5): July 13, 2009 testimony of Margaret Mellon, Ph.D.

"Save Antibiotics for People, Not Poultry," *St. Louis Post-Dispatch* editorial (July 21, 2009)

"Farms and Antibiotics," *New York Times* editorial (July 23, 2009)

"Limit antibiotics in livestock," *Fort Wayne Journal Gazette* editorial (July 24, 2009)

"Antibiotics in animals have effect on humans," *Times Herald-Record* (NY) editorial (July 25, 2009)

cc: Dr. Margaret Hamburg, Commissioner of Food and Drugs, FDA
Dr. Joshua Sharfstein, Principal Deputy Commissioner, FDA
Michael Taylor, J.D., Senior Advisor, FDA