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October 9, 2008

Mr. Michael O. Leavitt, Secretary
United States Department of Health & Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Leavitt,

We are writing on the behalf of The Alliance for the Prudent Use of Antibiotics (APUA) an independent organization with affiliated chapters in over 60 countries. Since 1981, APUA has been working to improve antibiotic use in order to preserve the power of these life-saving drugs.

We write now to express our strong opposition to EPA's recent decision to approve the use of gentamicin, a critically important medicine for humans, for spray treatment for the plant disease of fireblight in apples. Antibiotics are different from other drugs in that each individual use can have an effect on the build-up of resistance genes in the environment and the community of plants and animals. For this reason there are strict requirements for antibiotic use in humans and the same should apply to antibiotic uses in food and plant agriculture. Gentamicin use in growing apples will create an additional selective pressure directly or through transfer to related bacteria carried by humans, and lead to drug resistant bacteria on apples and plant foliage in apple orchards.

According to an APUA expert panel on the need to improve antimicrobial use in agriculture (Clinical Infectious Diseases, June 1, 2002, Volume 34 Supplement 3); "Resistant pathogens in the environment may infect people through direct or indirect means as through the food supply." Dr. Sherwood L. Gorbach, professor at the Tufts University School of Medicine and chairman of that panel warns, "These resistant bacteria can then be transferred to applicators and consumers and can make them more vulnerable to serious infections, it is outrageous that they are planning to release gentamicin into the environment in this irresponsible manner."

This expert panel recommended that regulatory agencies must carefully consider processes by which antibiotic resistance spreads and should invoke the precautionary principal in considering the approval of antibiotic uses in agriculture. Children are of special concern since they eat many apples and are more vulnerable to infections. The report also suggests that alternatives to antimicrobial use in plants should be further pursued including: biocontrol agents, transgenic plants, and novel chemicals.

The concern here is about transfer of antibiotic resistance genes in the environment from plant genomes to animals and by fruit consumption. This practice would be especially harmful in this case, considering gentamicin is a critically important life-saving antibiotic in human medicine.

The EPA decision is contrary to the scientific evidence presented in APUA's CID report as well as arguments made by the Infectious Diseases Society of America (IDSA, and The American Society for Microbiology (ASM)) against misuse of this antibiotic. This had previously been addressed when a Mexican company wanted to use it on a variety of fruits and vegetables in the U.S. The American Society for Microbiology and others then persuaded the EPA that fruits and vegetables treated with gentamicin should not be imported, and a tolerance level for gentamicin in food should not be considered because of the importance of gentamicin in human medicine. Further, that any unnecessary residues on food could compromise the use of this antimicrobial (gentamicin), which is the last economically feasible drug for some human bacterial infections.

The consensus among the experts in the scientific and clinical communities indicates that the EPA action is a major threat to the US medical system and country's health security. We respectfully request reconsideration of this action.

Sincerely,

Stuart B. Levy, MD, President, APUA

Kathleen T. Young, Executive Director, APUA