



Contact

Stuart B. Levy, MD

President

617-407-5622 cell

Kathleen T. Young

Executive Director

617-610-3313 cell

Alliance for the Prudent Use of Antibiotics

75 Kneeland Street

Boston, MA 02111

Phone: 617-636-0966

Fax: 617-636-3999

Press Release: Tuesday, June 24, 2008 Congressional Hearing, Department of Health and Human Services Washington, D.C.

Urgent Federal Action Needed to Fill Antibiotic Pipeline and Curb Antibiotic Misuse

BOSTON, MA – June 24, 2008

In the face of escalating antibiotic resistant infections in the US, the Alliance for the Prudent Use of Antibiotics (APUA) supports new legislative proposals to curb antibiotic misuse in animals and accelerate new drug development. Antibiotic resistance is one of the major public health threats of the 21st century. In addition to posing a threat to the US healthcare system and our reliance on high tech medicine, resistant bacteria represent a potential resource for adversaries to exploit in building biological weapons. It is estimated that over \$20 billion is billed to Medicare annually for hospital-acquired infections, many of which are drug resistant. Increased funding is needed to support government agencies and engage private sector organizations working on antibiotic resistance.

Antibiotics are different from other drugs because their use in one human or animal has broad impacts on entire communities. Antibiotics exert a strong selective pressure on bacteria and these bacteria can then transfer resistance traits responsible for escalating multidrug resistant infections. "We need new drugs to treat these difficult resistant infections," says Dr. Stuart Levy, President of APUA and Professor at Tufts Medical School. One approach APUA favors would be to designate antibiotics as a special regulatory class of drugs. "This would enable unique economic incentives for antibiotic development and foster better stewardship once they are on the market," states Dr. Levy.

Since 1981, APUA has promoted basic research and education on antibiotic use and resistance as means to strengthen society's defenses against infectious disease. APUA advocates a three-pronged approach to containing antibiotic resistance. First, the US needs to institute data collection of human and animal antibiotic use and surveillance on resistance to serve as early warnings and guide interventions to protect the US against untreatable infections. Because the new antibiotic pipeline is dry, we also need incentives to entice pharmacy companies to stay in the antibiotic business. At the same time, we need stronger stewardship requirements to protect antibiotics already on the market and avoid the endless escalation in the battle with microbes. Without this three-pronged approach, "our society could soon face a future of unaffordable drugs and untreatable infections," claims Dr. Levy.

- **Economic incentives for new antibiotic development:** Priority antibiotics, diagnostics, and vaccines should qualify for tax relief for R&D, cost reduction and/or support of clinical trials, and extended market exclusivity. Government funding for applied research on antimicrobial resistance and antibiotic use should be instituted. Particularly strong incentives should be



established to facilitate development of antibiotics with a narrow spectrum and novel mechanisms.

- **Surveillance:** Better monitoring of resistance rates and antibiotic use in humans and animals is needed to extend the life of current antimicrobials.¹ Antibiotic use data collection should be required and international and local clinical antibiotic resistance electronic surveillance demonstrations should be funded to enable rapid dissemination of warnings.
- **Economic incentives:** APUA, IDSA, AMA, and other national health organizations are currently advocating immediate legislative action through the STAAR Act and PDUFA to provide incentives to new drug development and ensure better stewardship. APUA's FAAIR Report published in Clinical Infectious Diseases provides evidence for the need for risk assessment models to consider the full ecological impact of antimicrobial resistance and use of the precautionary principle in assessing human health risk associated with antimicrobial use in agriculture. Antibiotic use for growth promotion in animals should be disallowed.

References:

APUA's 2002 "Facts about Antimicrobials in Animals and the Impact on Resistance" (FAAIR) report titled "The Need to Improve Antimicrobial Use in Agriculture" and published in the medical journal Clinical Infectious Diseases, called for immediate action by government and the agriculture industry to reduce the human health risks identified in the report. The national experts involved in the APUA report also recommended elimination of antibiotic use for growth promotion and limiting farm use of critically important drugs which are needed for hard-to-treat human infections.

2005 Report of the Global Advisory on Antibiotic Resistance Data (GAARD): "Global Antimicrobial Resistance Alerts and Implications" published as a Supplement (2005;41) to Clinical Infectious Diseases, a publication of the University Chicago Press.

For more information on issues of antimicrobial resistance, please visit the APUA website: www.apua.org.