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## Testimony at US Stakeholder Listening Session June 7, 2010 Regarding Transatlantic Task Force on Antimicrobial Resistance: HHS Humphrey Bldg, June 9, 2010

Thank you for the opportunity to suggest priorities for the Transatlantic Task Force on Antimicrobial Resistance on behalf of The Alliance for the Prudent Use of Antibiotics (APUA). Established in 1981, APUA is a global scientific organization, with affiliated chapters in sixty countries working to improve antimicrobial access and use and contain antibiotic resistance. We see this Task Force as a uniquely powerful vehicle with regulatory leverage and funding sources at hand to enable concrete interventions.

The convergence of increasing antibiotic resistance, continuing antibiotic misuse, and a dwindling antibiotic pipeline has created a global public health crisis. A recent APUA sponsored study at Cook County Hospital estimated the cost of antibiotic resistance in US hospitals at greater than \$20 billion annually, adding 6.4 – 12.7 hospital days per patient stay. In addition to economic and health costs, resistant bacteria represent a national security risk as a potential resource for biological weapons. Since the best known way to curtail resistance is to use antibiotics appropriately and the need for new treatments is critical, we suggest that the Task Force adopt two overarching goals: 1. Reduce unnecessary selective pressure on existing antimicrobial agents and 2. Promote novel infectious disease products, including diagnostics, innovative antibiotics and alternative treatments.

### Need for Concrete Implementation Plan with Funding and Incentives

Despite over 30 years of expert reports and calls for action, the trend on both sides of the Atlantic has been continuing antibiotic misuse in all settings. While the US Interagency Planning Group and the EU Framework have made significant strides, the level of funding and coordination has not matched the advance of the resistant bugs. Multidrug resistance has emerged, MRSA has risen to alarming levels, and untreatable gram-negative infections have now appeared. This situation now requires an “Emergency Action Plan” noting leverage points and funding to be applied.

### Surveillance Systems to Monitor Antibiotic Use and Resistance in All Settings

The first activity for the Task Force should be establishing compatible surveillance systems to document both antibiotic use and resistance trends in all settings. In addition to pathogen surveillance, APUA’s ongoing international surveillance of commensal resistance should be used to provide complementary data and serve as an early warning of resistance emergence. (Surveillance needs are more fully discussed in the APUA 2005 GAARD report in CID.)

### The Need to Address Antibiotic Use on the Farm

Food animal production sites are a major contributor to the selection and transfer of dangerous resistance genetic elements, which promote resistance in human pathogens. The animals far outnumber humans; the volume of antibiotics used there is high; massive low dose levels are routinely applied; and infection control is inadequate. At a recent APUA scientific roundtable, top scientists from European countries evaluated the impact of the ten- year EU ban of growth promotion in food animal production there and noted the lessons learned from the surveillance and pilot interventions there. There is little sense in requiring responsible stewardship and data from the human medicine sector and not requiring the same from the food animal production sector where sludge and downstream waterways make for massive resistant gene pools. In the interest of public health and national security, the US should adopt the EU models of surveillance and reducing antibiotic misuse for growth promotion in food animals. Other countries would follow, resulting in a great reduction in global selective pressure.

### Integrating Infection Control Programs with Antibiotic Stewardship

The Task Force should identify regulatory and financial incentives to promote antibiotic stewardship programs in EU and US healthcare facilities and community medicine clinics. Also to be considered is testing more integration of environmental hygiene, infection control and antibiotic stewardship efforts to simultaneously address resistance emergence and spread. To control drug resistance in the developing world, leverage points should be identified in the EU and US aide programs, with the goal of improving antimicrobial access and use.

### Research Funding and Incentives to Promote Novel Infectious Disease Products

Promoting development of drugs with novel modes of action should be a priority. These approvals and incentives should be combined with concrete stewardship strategies as they come on line. Subsidies, patent extensions, and wild card incentives should be provided to companies, which meet priority infection needs and actively develop strong post-marketing surveillance and stewardship programs. Government agencies should ensure development of up to date treatment guidelines. At the same time, basic research on antibiotic resistance should be funded at much higher levels and a coordinated Transatlantic research agenda developed to accelerate answers.

Finally, one broad-brush strategy for the Task Force to consider would be designation of antibiotics as a special regulatory class (similar to orphan drugs or narcotics). Reclassification of antibiotics into a protected class would give these life saving agents the respect they deserve, allow special regulations and incentives to encourage pharmaceutical company investments and promote responsible stewardship and marketing. Since time is of the essence, government and private sector experts need to work together and fully use existing resources and expertise. As an independent global health organization with a dedicated network and over twenty years of experience, we look forward to partnering with you to address our mutual security interests in strengthening our society against infectious diseases and “preserving the power of antibiotics.” Thank you.

Kathleen T. Young, Executive Director, APUA

Cc Stuart B. Levy, President, APUA