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November 27, 2007

The Honorable Edward Kennedy  
317 Russell Senate Building  
Washington, D.C. 20510

Dear Senator Kennedy;

We write on behalf of the Alliance for the Prudent Use of Antibiotics (APUA) to request a meeting to discuss additional provisions needed in the STAAR (Strategies to Address Antimicrobial Resistance) Act, S.2313. The APUA board voted to conditionally endorse the bill, and related legislation such as S.2351, provided the following provisions are added to ensure the desired effect and mitigate unintended consequences.

Our major concern is the lack of sufficient international scope for surveillance, early warning, and interventions to protect the U.S. against untreatable infections. The recent scare concerning potential spread of XDR-TB via a U.S. air traveler highlighted the need for a strong international tracking and control of dangerous resistant organisms.

We would like to work with you to ensure any legislation on this topic including the following provisions:

- Governmental funding for private sector basic research on resistance in acute bacterial infections at a level comparable to that for other major threats such as HIV, H5N1, or breast cancer.
- Strong regulatory incentives for antibiotic stewardship in human medicine and food animal production, such as revising FDA guidance 152 to adequately protect vital human medicines from agricultural misuse.
- Stronger involvement of existing U.S. domestic-based organizations with the capacity to deal with the problem on a global basis.
- Provisions for collection and public access of real time (NOT annual summary reports) data on antibiotic resistance and use at the national and global levels. CDC efforts should be supplemented by those of private institutions. To adequately measure the scale of the problem, new coding may be required in U.S. health institutions.
- Data collection and behavioral research to determine ways to improve antibiotics use in agriculture and medicine.

Because the new antibiotic pipeline is dry, we 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 dual approach, we will face a future of unaffordable drugs and untreatable infections.

Since its founding in 1981, APUA has provided consultation to governmental organizations dealing with antibiotic resistance issues. We have provided leadership in the development and implementation of the WHO global strategy, the U.S. interagency plan, and the Antibiotic Preservation Act. We look forward to working with your office to strengthen the STAAR Act in collaboration with our partners in government, industry, academia and consumer groups. On behalf of our board of directors and our affiliated organizations in 60 countries, we thank you for your continuing leadership to improve national and international public health and contain global public health threats. We look forward to meeting with you.

Sincerely,

Stuart B. Levy, M.D.  
President

Kathleen T. Young  
Executive Director

cc: Congressman Stephen Lynch