April 5, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn Building
Washington, D.C. 20515

The Honorable Joe Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn Building
Washington, D.C. 20515

Dear Chairmen Upton and Pitts and Ranking Members Waxman and Pallone:

On behalf of the undersigned organizations representing medical, public health, scientific, agricultural, environmental, animal protection, and other organizations, we urge you to include H.R. 820, the Delivering Antimicrobial Transparency in Animals (DATA) Act, as part of the final Animal Drug User Fee Act (ADUFA). This legislation provides a reasonable, common-sense approach to better understanding antibiotic use in agriculture.

There is substantial scientific evidence supporting the claim that non-judicious use of antimicrobials in both humans and food animals leads to development of antimicrobial resistance in human pathogens. Given the increasing proportion of highly-resistant pathogens that are causing human disease today, improved antimicrobial stewardship will have a significant positive impact on human health. Unless we are able to significantly change the way we use antimicrobials in both clinical medicine and in agriculture, we risk entering a "post-antibiotic" era, where people die of common infections that previously had been treatable.

The DATA Act would provide the Food and Drug Administration (FDA) and the public with better information on the use of antimicrobial drugs in food animals. Such data will enable public health officials and scientists to better understand and interpret trends and variations in antimicrobial resistance, to improve the understanding of the relationship between animal uses of these drugs and antimicrobial resistance in animals and humans, and to identify interventions to prevent and control resistance.

FDA's current data collection efforts are insufficient to detect correlations between antibiotic use and the development of resistance.

The Animal Drug User Fee Act of 2008 (ADUFA) authorized FDA to collect and publish data from pharmaceutical companies on antibiotics sold for use in food animals, but unfortunately it stops short of requiring public reporting of critical details that would be needed to effectively interpret trends in resistance. ADUFA requires drug sponsors to report to the FDA basic

information about their antimicrobial products, including 1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; 2) quantities distributed domestically and outside the United States; and 3) dosage form, including a listing of the target animals, indications, and approved production classes. Despite being collected by the FDA, data publicly reported under ADUFA have been substantially limited. The Summary Reports for 2009, 2010 and 2011 report only total antimicrobial sales volumes by drug class, aggregated to the national level, without any information on animal species in which antibiotics are used or the purpose of their use. Unfortunately, standalone summary sales data, without additional granularity, is insufficient to effectively study and understand the relationship between antibiotic use and the development of resistance and to consider appropriate interventions.

In September 2011, the Government Accountability Office (GAO) published a report titled *Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*[1], which highlighted shortcomings in the current FDA regulations on antimicrobial animal drug sales and distribution reporting. Indeed, the current lack of adequate U.S. antibiotic consumption data impedes our understanding of geographic and temporal trends in antibiotic resistance. In the agricultural context, a more complete and accurate dataset on antibiotic consumption will make information currently collected under the National Antimicrobial Resistance Monitoring System (NARMS) more effective, because it could be used to show possible correlations between antibiotic use and the development of resistance.

The DATA Act will ensure that U.S. experts have access to reliable, standardized data on the scope of antibiotic consumption in animals by species.

To effectively control the antibiotic resistance epidemic, both governmental and non-governmental animal health and infectious disease experts need ongoing access to reliable data on the scope of antibiotic consumption in animals, by species, and in a unit of measure that can be compared across species and localities. The DATA Act accomplishes this goal by requiring:

- drug sponsors to include in their annual FDA reports the dosage form and the known or estimated amounts of the antimicrobial ingredients in new animal drugs sold or distributed for use in each food-producing animal species for which the new animal drug is approved.

- large-scale live poultry dealers, swine contractors, and feed lot operators to submit annual reports to FDA on the antimicrobials used in their animal feed. For antimicrobials in feed under a Veterinary Feed Directive (VFD), the reports would be required to include information on quantities, dosages, and duration of time that the feed may have been provided to the animals.

- FDA to report data on the percentage of antimicrobials sold for growth promotion/feed efficiency, disease prevention, disease control, and disease treatment.

[1] U.S. Government Accountability Office, *Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*, GAO-11-801, September 7, 2011.

- FDA to provide the quantity of drugs sold or distributed state-by-state, as well as the quantity of drugs sold or distributed for each type of animal.

- for feed sold pursuant to a VFD, FDA to provide data on the indication for which the feed was sold or distributed, the quantities of feed sold or distributed for each such indication, the number of individual animals to which the feed was intended to be given, and the dosage and length of time for which such feed was intended to be given.

Again, we urge you to support stronger reporting requirements for agricultural antibiotic sales and distribution by amending ADUFA to include the DATA Act. This important legislation will help illustrate current use patterns, explain resistance trends, and monitor progress in assuring responsible animal antibiotic use. The American public needs assurance that these essential medicines will be effective in protecting children and families well into the future. Should you have any questions, please contact Amanda Jezek at 703-740-4790 or ajezek@idsociety.org.

Signed,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Public Health Association
Association for Politics and the Life Sciences
Food & Water Watch
Humane Society Veterinary Medical Association
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Johns Hopkins Center for a Livable Future
Pediatric Infectious Diseases Society
School Food FOCUS National Office
Society of Infectious Diseases Pharmacists
The Humane Society of the United States
Trust for America's Health
The Pew Charitable Trusts

cc: Members of the Committee on Energy and Commerce
Rep. Louise Slaughter