

**Center for Science in the Public Interest • Food Animal Concerns Trust • Health Care Without Harm
Keep Antibiotics Working • Natural Resources Defense Council • Union of Concerned Scientists**

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

Re: Public Health Enhancements to the Animal Drug User Fee Act

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

We write on behalf of a broad coalition of medical, public health, scientific, consumer, and environmental organizations, to urge that the reauthorization of the Animal Drug User Fee Act (ADUFA) include provisions to help preserve the efficacy of antibiotics vital to protecting public health. Specifically, we urge you to enact the data collection and reporting requirements in the Delivering Antimicrobial Transparency in Animals (DATA) Act (H.R. 820), introduced by Representatives Waxman and Louise Slaughter, as part of the Animal Drug User Fee Act (ADUFA).

Antibiotics, the miracle drugs of the last century, are losing their effectiveness as a result of misuse and overuse in human medicine and food animal production. We must continue to pursue efforts to address resistance related to human use of antibiotics, but antibiotic use in animal agriculture constitutes the overwhelming majority of antibiotic use (accounting for over 70% of total sales of medically important antibiotics in the United States) and must also be addressed. A focus on human use alone cannot address the problem.

Antibiotic resistance is an expensive and critical public health threat – one of the Centers for Disease Control and Prevention’s “top concerns.” Each year an estimated 900,000 cases of antibiotic-resistant infection cost society up to \$26 billion in additional healthcare costs, and lead to tens of thousands of deaths as well. The Director General of the World Health Organization has warned that we face a “post-antibiotic era . . . in effect, an end to modern medicine as we know it” and that “[t]hings as common as strep throat or a child’s scratched knee could once again kill.”

As the CDC and others note, strong science – more than 147 studies to date – links antibiotic use in animals to antibiotic resistance and risks to human health. Leading medical, public health, and scientific organizations have called for an end to the unnecessary use of antibiotics in animals that are not sick—a key contributor to the rising tide of antibiotic resistance—and for better tracking and reporting of data on antibiotic sales and use to address the threat.

We need action to curb the overuse of antibiotics in food producing animals. We also need the Food and Drug Administration (FDA) to better track and publicly report data that can be used to track trends in antibiotic resistance, design appropriate interventions, and fine-tune those efforts if they have not been effective.

In 2008, Congress through ADUFA reauthorization required drug manufacturers to report antimicrobial sales to FDA and directed FDA to release a summary of these data to the public. The FDA's 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 nature and purpose of their use. Scientists need this data to better understand geographic and temporal trends in antibiotic resistance. Unfortunately, standalone summary sales data, without more detail, are insufficient to track these trends and develop appropriate interventions. 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.

Therefore, during the current reauthorization, we ask the committee to enhance ADUFA further with the DATA Act's provisions to:

- Require large-scale live poultry dealers, swine contractors, and feed lot operators to report to the FDA information on the amount of antibiotics used by animal species and require drug sponsors to report antibiotic sales broken down by animal species
- Require FDA to include in its public summaries information on amounts of antibiotics sold (including for feed sold pursuant to a Veterinary Feed Directive)
 - by different dosage forms (i.e. in feed, in water, or by injection),
 - by different marketing status (e.g. over-the-counter or prescription),
 - by percentages sold for different approved purposes (i.e. growth promotion, disease prevention, disease control, and treatment),
 - by differing medical importance, and
 - by each food-producing animal species
- Require FDA to include in its public summaries information on quantities of antibiotic sold and distributed by state.

Again, we urge you to support stronger data collection and reporting for agricultural antibiotic sales and distribution by amending ADUFA to include these requirements. These provisions will help scientists better understand and track current use patterns, explain resistance trends, and monitor progress in reducing antibiotic use and resistance. This information can help ensure that these essential medicines continue to be effective and to protect children and families well into the future.

Thank you for considering our views.

Sincerely,

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