

February 25, 2013

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC

The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC

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

Dear Chairman Harkin, Ranking Member Alexander, and Members of the Senate Health, Education, Labor and Pensions Committee:

We write on behalf of a broad coalition of medical, public health, scientific, agricultural, consumer, environmental, humane, and other organizations, representing more than eleven million supporters, 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.

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 more than 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 (CDC) “top concerns.” Each year an estimated 900,000 cases of antibiotic-resistant infections cost society up to \$26 billion in additional healthcare costs and lead to tens of thousands of deaths. 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.

The Food and Drug Administration's (FDA's) response to the threat has been to propose recommendations (Guidance for Industry #213) that encourage industry to voluntarily phase-out the marketing of antibiotics to speed up animal growth and to also voluntarily phase out the over-the-counter marketing of antibiotics. This guidance does not require action and has no mechanism to track the adoption of these recommendations or to evaluate their effects on antibiotic use and resistance, nor does it address the routine feeding of antibiotics to food animals to keep them from getting sick in overcrowded, unsanitary, and high-stress conditions.

We need action to curb the overuse of antibiotics in food-producing animals. We also need the FDA to better track and publicly report data that can be used to verify the effectiveness of its efforts to curb antibiotic misuse and overuse or to 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 the data to the public. During the current reauthorization, we urge the Committee to enhance ADUFA further with provisions to:

- Improve existing requirements in ADUFA on the collection and reporting of information on sales of antibiotics for use in food producing animals, including:
 - requiring feed manufacturers to report to FDA on antibiotic sales in medicated feed to FDA by the antibiotic used, by animal species, and by indication (purpose of use) when available, and require FDA to make public summaries of these data available; and
 - requiring FDA to improve public summaries of data on sales of antibiotics for use in food producing animals, by reporting all information on amounts of antibiotic classes sold by different dosage forms (i.e., in feed, in water, or by injection), by different marketing status (e.g., over-the-counter or prescription), and by different approved purposes (i.e., growth promotion, disease prevention, disease control, and treatment).
- Require the FDA to track and publicly report on the response of drug manufacturers to FDA's voluntary plan so that Congress and the public can evaluate its effects on sales of antibiotics for use in food animal production.

We provide more detail on each of these recommendations below.

Improve existing requirements in ADUFA on the collection and reporting of information on the sales of antibiotics for use in food producing animals

Congress' requiring FDA to collect and publicly report on the sale of antibiotics in food producing animals for the first time in 2008 was a great step forward. However, it has become clear in subsequent years that there are significant gaps in both the data collected and the public reporting of that data by the FDA.

Currently, no reliable information is collected on the animal species in which the drugs are actually used except in the rare case where a drug is approved for a single species. Species-specific sales data are needed to compare with species-specific resistance trends that are identified through the National Antimicrobial Resistance Monitoring System. A 2011 report by the Government Accountability Office (GAO) recognized the limitations of the current sales and distribution data collection and recommended that federal agencies collect information on use by species.

FDA's reporting is similarly deficient. FDA does not currently publicly disclose information on antibiotic sales by method of antibiotic administration (i.e., by feed, water, or injection) although it acknowledges that group delivery of antibiotics to large numbers of animals, such as via feed or water, poses a qualitatively higher risk for antibiotic resistance. Furthermore, FDA does not disclose what information it has on purpose of use or on the amount of sales over-the-counter versus by prescription or other means. Finally, FDA does not break out information on antibiotic sales by the medical importance of the drugs.

To address these issues, ADUFA provisions should:

- Require feed manufacturers to report to FDA on antibiotic sales in medicated feed by the antibiotic used, by animal species, and by indication (purpose of use) when available, and require FDA to make public summaries of these data available.
- Require FDA to enhance public summaries of data on sales of antibiotics for use in food producing animals, by reporting all information on amounts of antibiotic classes sold by different dosage forms (i.e., in feed, in water, or by injection), by different marketing status (e.g., over-the-counter or prescription), and by different approved purposes (i.e., growth promotion, disease prevention, disease control, and treatment).
- Require FDA to organize its public summaries of collected antibiotic sales data by the medical importance of the drugs.
- Require FDA to make public summaries of the antibiotic sales data it has collected by no later than September 30 each year.

Require FDA to track and publicly report on implementation of its voluntary plan to address antibiotic misuse and overuse in food producing animals.

In addition to asking drug manufacturers to voluntarily phase-out sales of antibiotics for speeding up animal growth and over-the-counter sales of antibiotics, draft Guidance for Industry #213 allows drug manufacturers to seek new approvals to replace growth promotion use being phased out. This makes its ultimate impact on antibiotic use and resistance difficult to predict. However, FDA has not put forth a plan to track and report on the overall response to its guidelines so the public can evaluate the plan's effects on sales of antibiotics for use in food producing animals.

ADUFA provisions should require FDA to track and to report on the following:

- the number of antibiotic products currently approved for growth promotion along with the number of antibiotic products currently available over-the-counter;

- the number of drug manufacturers agreeing to participate in the voluntary program, including the number that agree to participate within 90 days of finalization of Guidance for Industry #213 as FDA has requested;
- the number of drug manufacturers not agreeing to participate;
- the number of products for which drug manufacturers have submitted applications for changes, broken out by type of change sought (i.e., removal of growth promotion claims, addition of new replacement claims, and removal of over-the-counter marketing status) and a list of these applications approved; and,
- the number of products for which drug manufacturers have not submitted applications to change approvals, broken out by type of change.

The number of products for which applications have and have not been submitted should be reported quarterly so the public has regular updates on the progress of the voluntary plan.

If you have any questions or would like to discuss this matter in detail, please contact Steve Roach at sroach@foodanimalconcerns.org, or (618) 457-6926.

Thank you for considering our views.

Sincerely,

Alliance for the Prudent Use of Antibiotics
 American College of Preventive Medicine
 American Public Health Association
 Assateague Coastkeeper
 Center for Food Safety
 Center for Science in the Public Interest
 Consumers Union
 Dignity Health
 Environmental Working Group
 FamilyFarmed.org
 Food Animal Concerns Trust
 Food & Water Watch
 Government Accountability Project
 Healthcare Without Harm
 Humane Society of the United States
 Humane Society Veterinary Medical Association
 Institute for Agriculture and Trade Policy
 Infectious Diseases Society of America
 Johns Hopkins Center for a Livable Future
 Keep Antibiotics Working
 March of Dimes

National Research Center for Women & Families
Natural Resources Defense Council
Pamlico-Tar River Foundation
The Pew Charitable Trusts
Physicians for Social Responsibility, San Francisco Bay Area Chapter (CA)
School Food FOCUS National Office (New York, NY)
STOP Foodborne Illness
Trust for America's Health
Union of Concerned Scientists
Wabash Riverkeeper
Waccamaw Riverkeeper
Waterkeeper Alliance
Waterkeepers Carolina
Yadkin Riverkeeper