November 30, 2015

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Docket No. FDA-2015-N-2768

Dear Acting Commissioner Ostroff:

Consumer Federation of America (CFA) appreciates the opportunity to submit comments in response to the Food and Drug Administration’s request for public input on possible approaches for collecting additional on-farm antimicrobial drug use and resistance data. [Docket No. FDA-2015-N-2768]. CFA is a nonprofit association of over 250 consumer groups that was established in 1968 to advance the consumer interest through research, education and advocacy.

CFA agrees with FDA that the agency needs to gather more information about the way livestock growers use medically important antimicrobials on animals. More specifically, CFA supports efforts to gather quantitative, comprehensive, ongoing, and unbiased data, as described in the comments we submitted jointly with the Keep Antibiotics Working coalition. CFA writes separately to emphasize consumers’ need for better data to evaluate the risks associated with consuming meat and poultry.

There is broad scientific consensus that overuse of antibiotics in animals causes antibiotic resistance, which in turn compromises food safety.1 According to the most recent National Antimicrobial Resistance Monitoring System Reports, the incidence of antibiotic resistant foodborne pathogens like *Salmonella* and *Campylobacter* remains stubbornly high, and for some strains, multidrug resistance continues to rise at an alarming pace.2 Current food inspection rules do not keep meat and poultry tainted with these superbugs off of store shelves, and consumers bear responsibility for neutralizing these food safety threats through strict 

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1 See, e.g., Centers for Disease Control and Prevention. “Antibiotic Resistance from the Farm to Table” available at: http://www.cdc.gov/foodsafety/challenges/antibiotic-resistance.html#two; World Health Organization. “Tackling antibiotic resistance from a food safety perspective in Europe” (2011) available at: http://www.euro.who.int/__data/assets/pdf_file/0005/136454/e94889.pdf?ua=1. “Food products of animal origin are often contaminated with bacteria, and thus likely to constitute the main route of transmitting resistant bacteria and resistance genes from food animals to people.” Id. at 13 (emphasis added).

adherence to safe handling and cooking guidelines. Even highly conscientious home cooks may become seriously ill as a result of cross-contamination.

Consumers now have limited options to minimize the risk of contracting a foodborne illness caused by antibiotic resistant bacteria. Some research indicates that organic and other meat products from animals raised without antibiotics are less likely to harbor antibiotic resistant Salmonella, Campylobacter, and other pathogens.\(^3\) But these product lines currently command a significant price premium. Moreover, they do not eliminate the threat of resistant bacteria. The evidence from countries like Denmark and Sweden show that widespread action is necessary to reverse resistance trends. FDA will need reliable, comprehensive data to identify which uses, with which species, in which places, give rise to the most serious threats.\(^4\)

These efforts should begin with collecting data from feed mills and from large meat and poultry companies. FDA already requires feed mills to maintain records specific to species and production class, and producers administer some 70% of animal antibiotics through feed. To complement feed mill data, FDA should collaborate with USDA’s Animal and Plant Health Inspection Service (APHIS) to implement APHIS’ proposal of collecting proprietary data from “large companies raising feedlot cattle, poultry, or swine.”\(^5\) These large operators now produce the vast majority of meat and poultry in the United States.\(^6\) APHIS has proposed relying on these companies’ on-farm antibiotic use data as “an alternative source of data on national estimates of antibiotic use in livestock and poultry operations.” However, de-identified data could also help to gauge the success of antibiotic stewardship efforts, and to assess associations between antibiotic use practices and resistance, without sacrificing the confidentiality of company data. APHIS has expressed the concern that “not all companies may want to share proprietary data,” but the agency has authority under the Animal Health Protection Act (APHA) to require reporting, and it should exercise it if necessary.\(^7\)

Robust on-farm data collection will also be critical for the agency to assess whether encouraging voluntary use reductions—rather than simply banning all prophylactic use of antibiotics—results in unjustifiable risks to consumers. CFA believes that it does. In part,

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\(^6\) A recent USDA report on the hog industry, for example, shows that large farms holding 5,000 head or more accounted for 93% of the pig crop in 2014. USDA. Overview of the United States Hog Industry. (Oct. 29, 2015) available at: http://usda.mannlib.cornell.edu/usda/current/hogview/hogview-10-29-2015.pdf

\(^7\) In particular, the APHA gives USDA authority to “promulgate such regulations, and issue such orders, as the Secretary determines necessary to carry out” the Act, including “operations and measures to detect, control, or eradicate any pest or disease of livestock.” 7 U.S.C. 8308, 8315.
this is because recent research reveals that the food safety hazards from antibiotic resistant bacteria go beyond just “food poisoning” cases that affect the gastrointestinal tract. For example, scientists have linked foodborne *E. coli* with urinary tract infections (UTIs), dubbed “foodborne UTIs” or FUTIs. The lag time between when an affected person consumes contaminated food and the onset of a FUTI may extend up to several months, making it impossible to demonstrate a direct transmission event, or to hold a producer accountable for the foodborne illness that its product causes. Adequate data—including species specific information on actual use—will help public health authorities to determine which antibiotic practices are most associated with these types of foodborne illnesses, and help to reduce them.

Many large meat producers have already begun aggressively phasing out antibiotics use in response to consumer demand. We are optimistic that FDA will be able to provide informational support for these efforts, and to use data to demonstrate their benefits to the public. CFA recognizes that any effective data collection effort will require significant agency resources, and for that reason we support increased funding for FDA. However, we urge the agency to make collection of on-farm antibiotic use data a budget priority irrespective of how much Congress decides to appropriate to the agency.

Thank you for your consideration and for the agency’s efforts to move forward on controlling antibiotic resistance.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

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