Testimony before the

House Committee on Energy and Commerce, Subcommittee on Health

United States House of Representatives

April 9, 2013

Lance B. Price, Professor, Department of Environmental and Occupational Health,

The George Washington University

Chairman Pitts, Ranking Member Pallone and members of the Health Subcommittee, thank you for the opportunity to give testimony about the steps Congress must take to shine a light on antibiotic use.

I am grateful that today's hearing on the Animal Drug User Fee Act (ADUFA) will include a discussion of the issue of antibiotic resistance and, more specifically, Section 105 of the 2008 ADUFA amendments, which requires the Food and Drug Administration (FDA) to collect and report data from animal-drug manufacturers on the sale of antibiotics intended for use in food animal production. As a public health researcher with years of experience examining the relationship between antibiotic use in food animals and antibiotic-resistant infections in people, I strongly believe the public needs to know more about how and why antibiotics are used on food animals to produce meat and poultry. For this reason, I support the Delivering Antimicrobial Transparency in Animals (DATA) Act (H.R. 820), introduced by Representatives Waxman and Slaughter, to broaden and deepen understanding regarding this public health threat, and to inform the policymaking process at FDA and in Congress.

As a microbiologist, I have dedicated my career to studying bacteria. I'm fortunate to be doing so during a golden age of DNA sequencing technology. Quickly and cheaply, we can now map the entire

genomes of bacteria that infect people and use that information to determine where they are coming from. And the results tell us conclusively that using antibiotics on industrial farms is a danger to human health. My colleagues and I have published numerous journal articles showing that exposing bacteria to antibiotics breeds drug-resistant superbugs, that these bacteria are prevalent on our meat and poultry, and that the germs do in fact spread from animals to people where they cause infection.

It is undisputed that using antibiotics—appropriately or inappropriately—is the single most powerful force leading to the development of antibiotic-resistant bacteria that poses an immediate threat to the public's health. We cannot stop using antibiotics altogether because we need them to treat infections. What we can do, however, is reduce inappropriate use and slow the evolution of resistant bacteria. Hospitals across the country are implementing stewardship programs with the goal of reducing antibiotic use and curbing resistance. For years, the Centers for Disease Control and Prevention (CDC) has been undertaking a campaign called Get Smart About Antibiotics to promote more responsible prescribing and use among people. A key component of these programs is data collection. Doctors, pharmacists and hospital administrators are tracking antibiotic use prescription by prescription, noting when, where and for what diseases these drugs are being used. Because there is good data in human medicine, they know how antibiotic use is changing, how use contributes to resistance, where problems persist, and what targeted interventions will work best to address remaining issues. According to the CDC National Center for Emerging and Zoonotic Infectious Diseases, in 2011, there was a 25 percent reduction in the number of people developing healthcare-associated invasive MRSA infections[i]. And the American Academy of Pediatrics recently reported on a 40 percent reduction in cephalosporin-resistant *Klebsiella* infection and a 70 percent reduction in intensive care units.

But even if every hospital and every doctor participated in a stewardship program and tracked the use of all human antibiotics, we still would fail to understand the vast majority of antibiotic use taking place in this country—that is, the use of these drugs on industrial farms.

About two months ago, the Food and Drug Administration reported that, in 2011, drug companies sold nearly 30 million pounds of antibiotics for use in food animal production—the highest amount the agency has reported. The agency broke down these sales into eight drug classes and an "other" category aggregating the sales of several additional classes. While this information is helpful in illustrating the overall scope of antibiotic sales for meat and poultry production, it does not provide enough detail. In order to protect public health and animal well-being, we must also know why, how and in what animals these vital drugs are used.

First, we need to know to which animals antibiotics are being administered. Each year, the FDA measures the prevalence of superbugs on retail meat and poultry and finds considerable differences between what's on ground turkey, retail chicken, pork chops and ground beef. Bacteria on some products exhibit much higher rates of resistance than the same kinds of bacteria on other products. Understanding how antibiotics are intended to be used in each species can shed light on the superbugs that vary so significantly by product.

Second, we need to know why antibiotics are being used—that is, how often they are sold for non-therapeutic production purposes like growth promotion and disease prevention or for therapeutic purposes like disease control and treatment. Last April, the Food and Drug Administration issued a draft set of voluntary guidelines designed to eliminate the use of antibiotics to accelerate the growth of healthy animals. The agency's deputy commissioner for food, Mike Taylor, said in a *USA Today* op-ed to critics who thought this voluntary approach had no teeth that the FDA would "trust, but verify" that these policies are working. But if the FDA does not know how often antibiotics are being used to promote growth or compensate for overcrowded and unsanitary living conditions, it cannot verify progress. Complicating matters, the animal-drug industry has stated explicitly that it would seek replacement indications for product labels, essentially swapping "growth promotion" indications for "disease prevention," which could be virtually identical in practice. These practices pose a particular threat to human health because they involve low-dose antibiotics, which can do more harm than therapeutic doses.

They create an environment for bacteria that is just hostile enough to prompt them to develop resistance but not so harsh that they are killed off. Only with more data can the FDA truly verify that its policies are having a real effect on actual usage and not just on labeling.

Drug manufacturers should have some estimates of this species and intended use information. But the best information might come from feed mills, which are responsible for mixing antibiotics into animal feed for various purposes, either by order of a veterinarian, or per the request of producers or large-scale meat production companies. Congress should explicitly authorize FDA to require uniform annual reporting of these data from the largest feed mills or, if easier, from top meat production companies who are purchasing the antibiotics to be distributed to their growers in feed.

Third, we need more precise data that provides details on antibiotics important in human medicine. In the FDA's reports, it includes an "other" category that aggregates sales of antibiotic classes in which there are fewer than three companies selling products. This is intended to protect proprietary data, but it is unnecessarily broad. The FDA should divide this category into two components—one tallying sales of antibiotics used only in animals and another for sales of drugs used in humans and animals.

Fourth, the FDA should report how antibiotics are intended to be administered—such as, in feed, in water or by injection—both in total and by drug class. The FDA provided this information at the request of Representative Slaughter after the agency released its 2009 sales report and it should become a standard element of the agency's annual sales summary. It was from this information that we learned that 74 percent of antibiotics are administered in feed and 16 percent in the water. Route of administration does not definitively indicate why drugs are used, but the widespread administration of antibiotics in feed suggests that large groups of animals are routinely and indiscriminately being fed antibiotics they may not need, which may indicate that there are deeper, underlying production problems needing to be addressed.

As a microbiologist who is committed to public health, I must express deep frustration with the Food and Drug Administration. The agency's core mission is to protect the public's health, yet it is not doing nearly enough to monitor antibiotic practices that it knows are dangerous and injudicious. It negotiated an agreement to collect fees from drug makers in exchange for expediting drug approvals, while missing a prime opportunity to seek some common-sense provisions to simply measure—not restrict, just measure—the use of antibiotics. The agency has been in possession of data that would shed more light on how antibiotics are being used on industrial farms, but it has declined to share it in 2010 and 2011. FDA notes that it has the authority to collect more data but has not exercised it. Instead, the agency has initiated a years-long potential rulemaking process to further explore the question of data collection, a process that, unfortunately, will keep the public in the dark for at least a few more years, with no clear light at the end of the tunnel. Congress has the opportunity to direct FDA to do a better job, and to prioritize data collection and stewardship of antibiotics the agency approves.

I am grateful to this committee for considering the issue and I ask you to hold the FDA accountable. As this committee did five years ago, please seize this opportunity and allow the public to know more about how our food is produced and how antibiotics needed to safeguard human and animal health are being used on industrial farms. Please include additional antibiotics data collection provisions in the Animal Drug User Fee Act.

Thank you.

[i] http://www.cdc.gov/ncezid/pdf/annual-report.pdf; accessed 3/3/13.