Testimony of Dr. Richard Carnevale, Animal Health Institute on
SB 2598
Oregon House Committee on Agriculture and Natural Resources
March 24, 2015

Dear Chairman Witt and members of the Committee:

Thank you for this opportunity to present testimony and explain the significant changes taking place in the regulation and use of antibiotics to keep food animals healthy. My name is Dr. Richard Carnevale, and I am vice president of regulatory, scientific and international affairs with the Animal Health Institute (AHI) AHI is the national trade association representing companies that make medicine for animals, including the pharmaceuticals, vaccines and feed additives used to keep our pets and food animals healthy.

I am here to urge defeat of HB 2598, largely because the broad objectives of this bill are already being implemented in a consistent and orderly way by the U.S. Food and Drug Administration, with cooperation from our companies and all other stakeholders. State bills that are inconsistent in the details with the FDA policy – like this one – will only cause confusion and perhaps even delay.

In 2010 FDA announced its new judicious use of antibiotics in farm animals policy. Under this policy, FDA said all uses of medically important antibiotics for growth promotion uses were injudicious and should be eliminated. Additionally, FDA said that all remaining uses of medically important antibiotics used in feed should be under the direction of a veterinarian.

FDA had two ways to implement this new policy: The agency could seek the cooperation of stakeholders, including animal health companies; or the agency could use the administrative process set out in law to force label changes, or in some cases remove existing products from the market

FDA chose the former – work with the cooperation of stakeholders. A major reason for this is that FDA believed it would be a faster and more efficient way to implement this policy. They have been proven right.

In December, 2013, FDA published final Guidance 213, laying out the process that companies could use to bring their product labels into compliance with the new policy. As a part of that publication, FDA set a three-year timeline for implementation and asked companies with affected products to notify the agency by March 31, 2014 of their intention to cooperate.

All but two companies met this March deadline, and within another month FDA announced ALL companies had pledged in writing to work with the agency to bring their labels into compliance – meaning the removal of growth promotion claims and the addition of the veterinary feed directive requirement, meaning a veterinarian must grant permission for all uses of medically important antibiotics added to feed or water.

Some opponents of the FDA plan have suggested that because of the voluntarily nature of the program it will not happen. This is simply not true. I have been working for the past year with a coalition of

pioneer and generic animal drug companies to develop an implementation plan, which they are taking quite seriously. Most, if not all, of these companies are currently discussing with FDA the specifics of these changes. We believe the December, 2016 deadline for implementation will be met. Once those label changes are made, it will be unlawful to use medically important antibiotics for growth promotion. Products to do so will no longer be available because FDA regulations will be published establishing new conditions of use for each product. Feed mills will be obligated to mix antibiotics only according to those new conditions. It is important to understand that the FDA approved label on antibiotics generally dictates the dose and duration of use for a specific indication – meaning whether it is for prevention, control or treatment of disease. No one – including the prescribing veterinarian – can use a product intended for feed in any way not permitted on the label.

This bill undermines and confuses the FDA effort by using language that has no meaning in the current regulatory structure. The bill uses the term "non-therapeutic" and defines it to include both growth promotion and prevention. However, FDA (and the American Veterinary Medical Association) considers prevention claims to be therapeutic because they are targeted at a specific disease or pathogen. That means the label will list the specific disease or the specific pathogen the drug acts against, and the veterinarian's decision to administer the drug is based on his professional judgment that there is a real threat of that disease without the drug. So all of the provisions under Section 4 of HB 2598 will be met by federal regulation.

Another flaw in this bill is the data collection requirement. Applying this provision only to concentrated animal feeding operations is simply punitive against large farms. Small farms can and do use antibiotics as well; all uses of antibiotics can select for resistant bacteria, and there is no scientific evidence that resistant bacteria are more prevalent on larger than smaller farms.

This provision also ignores efforts at the federal level. FDA is working with the U.S. Department of Agriculture to gather additional data on antibiotic use but doing it in a more scientific way that will produce information that will help producers use antibiotics more judiciously. The agency intends to hold a public meeting this spring to address the need for more detailed on farm use information. The Obama Administration is seeking additional funding for this effort as part of its broad Combatting Antibiotic Resistant Bacteria (CARB) strategy. Simply requiring some farms in the state to report use data will not achieve any scientific purpose.

We object to the private right of action provisions of this bill. Section 5 allows data to be made public, and this section then allows these private parties to bring suit when they believe uses aren't warranted and the state does not act. Most egregiously, it allows plaintiffs to recover costs when they win. Farmer defendants cannot recover costs whether they win or lose. This section places a target on farmers and hands a gun and a bullet proof vest to plaintiffs against these unarmed farmer defendants. There is an elaborate federal system in place to ensure responsible and proper use of antibiotics. All marketed products must go through a rigorous FDA approval process to be proven safe and effective; the FDA approved label for feed products must be followed; USDA tests meet for violative residues. Not only has this USDA program shown extremely low levels of violative residues over time, but FDA recently released results of a milk sampling study with found only 15 of nearly 2000 samples with residues.

Finally, FDA, USDA and CDC all cooperate on the National Antimicrobial Resistance Monitoring System (NARMS) which tracks resistant bacteria in animals, meats and people.

There is no question that antibiotic resistance is a public health threat. The issue will only be effectively addressed as those in human health, animal health and public health come together and agree upon the sources of the problem and specific steps that can address these causes. Both the 2013 CDC threat report and last year's report from the President's Council of Advisors on Science and Technology (PCAST) on antibiotic resistance make it clear that the major antibiotic resistance challenges are unrelated to agricultural use. The CDC report listed 18 specific threats and said only 2 of those could have a source in agriculture. It is important we target our limited resources to real problems. HB 2598 ignores the work being done at the federal level, uses confusing terminology and seeks to punish a subset of Oregon farmers. We urge it be defeated.