SB 920 & HB 2598

Sec. 1 (3) (a) Sulfonamides are not antibiotics they are antimicrobials which demonstrates the authors of this legislation are somewhat uninformed. Are floroquinolones not mentioned because they are not used for these purposes as directed by the FDA or is this another over site by a the authors.

SECTION 2. The Legislative Assembly finds and declares:(1) The World Health Organization has stated that "without urgent, coordinated action by many stakeholders, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill."

However WHO also states: "The development of AMR is a natural phenomenon. However, certain human actions accelerate the emergence and spread of AMR. The inappropriate use of antimicrobial drugs, including in animal husbandry, favors the emergence and selection of resistant strains, and poor infection prevention and control practices contribute to further emergence and spread of AMR." And: "WHO is working in collaboration with partners across many sectors to identify strategies and actions to mitigate AMR. WHO is already working closely with the World Organization for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO) to promote best practices to avoid the emergence and spread of antibacterial resistance, including optimal use of antibiotics in both humans and animals.

(2) The United States Food and Drug Administration and the Centers for Disease Control and Prevention have stated that there is a definitive link between the routine use of antibiotics for both disease prevention and growth promotion on industrial farms and the crisis of bacterial antibiotic resistance in humans.

Although this is true it is somewhat out of context the actual statement from FDA includes this: Because all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, it is important to use these drugs only when medically necessary. Governments around the world consider antimicrobial-resistant bacteria a major threat to public health. Illnesses caused by drug-resistant strains of bacteria are more likely to be potentially fatal when the medicines used to treat them are rendered less effective.

FDA is working to address the use of "medically important" antibiotics in food-producing animals for production uses, such as to enhance growth or improve feed efficiency. These drugs are deemed important because they are also used to treat human disease and might not work if the bacteria they target become resistant to the drugs' effects.

"We need to be selective about the drugs we use in animals and when we use them," says William Flynn, DVM, MS, deputy director for science policy at FDA's Center for Veterinary Medicine (CVM). "Antimicrobial resistance may not be completely preventable, but we need to do what we can to slow it down."

FDA has taken steps by changing the Veterinary Feed Directive (VFD) to address the issue, these changes were made bases on expert scientists, veterinarians, FDA research, and data available to them. Is the Oregon Legislature assuming that they are more educated on AMR than these experts that study the issue every day and therefore need to take additional action.

Here is another statement from the FDA concerning the twisting of a report to scare people:

Below is a statement from the FDA regarding the interpretation of antimicrobial resistance data:

"Recently, the Environmental Working Group issued a report of its interpretation of the 2011 Retail Meat Annual Report of the National Antimicrobial Resistance Monitoring System (NARMS). While FDA is always concerned when we see antimicrobial resistance, we believe the EWG report oversimplifies the NARMS data and provides misleading conclusions. We do not believe that EWG fully considered important factors that put these results in context, including:

- whether the bacterium is a foodborne pathogen. The report highlights resistance to *Enterococcus*, but this is not considered a major foodborne pathogen. Instead, we include it because its behavior is helpful in understanding how resistance occurs.
- which drug(s) the bacterium is naturally resistant to. For example, most *Enterococcus faecalis* is naturally resistant to the antibiotic class of lincosamides. Because we know and expect to see this resistance, we are not as concerned with resistance in this species the way we would be with resistance in true pathogens like *Salmonella* and *Campylobacter*.
- why NARMS includes certain drugs in its testing design. We include some antibiotics for epidemiology purposes-- to track the spread of certain bacteria or certain genes. But resistance to these antibiotics doesn't reflect a danger to public health.
- whether the antibiotics that are commonly used to treat patients are still effective. NARMS data indicates that first-line treatments for all four bacteria that we track (*Salmonella, Enterococcus, Escherichia coli* and *Campylobacter*) are still effective.
- what the 2011 data indicate relative to similar data reported for prior years.

"Additionally, we believe that it is inaccurate and alarmist to define bacteria resistant to one, or even a few, antimicrobials as "superbugs" if these same bacteria are still treatable by other commonly used antibiotics. This is especially misleading when speaking of bacteria that do not cause foodborne disease and have natural resistances, such as *Enterococcus*.

When taking such factors into account, FDA believes the notable findings in the 2011 NARMS Report include:

• In the critically important class of antimicrobials, the 2011 data showed no fluoroquinolone resistance in *Salmonella* from any source. This is the drug of choice for treating adults with *Salmonella*.

- Trimethoprim-sulfonamide is another drug used to treat *Salmonella* infections and resistance remains low (0% to 3.7%).
- Fluoroquinolone resistance in *Campylobacter* has stopped increasing and remained essentially unchanged since the FDA withdrew the use of this drug class in poultry in 2005.
- Macrolide antibiotic resistance in retail chicken isolates remains low, with 2011 results at 0.5% of *Campylobacter jejuni* and 4.3% of *Campylobacter coli*. The macrolide antibiotic erythromycin is the drug of choice for treating *Campylobacter* infections.
- Multidrug resistance is rare in *Campylobacter*. Only nine out of 634 *Campylobacter* isolates from poultry were resistant to 3 or more antimicrobial classes in 2011. However, gentamicin resistance in *Campylobacter coli* markedly increased from 0.7% in 2007 (when it first appeared in the NARMS retail meat report) to 18.1% in 2011. Gentamicin has been suggested as a possible second-line therapy for *Campylobacter* infections, although it is not commonly used.
- Resistance to third-generation cephalosporins, which are used to treat salmonellosis, has
 increased in *Salmonella* from chicken (10 to 33.5%) and turkey (8.1 to 22.4%) meats when
 comparing 2002 and 2011 percentages. FDA noted this development in previous years and has
 already taken action by prohibiting certain extra-label uses of cephalosporins in cows, pigs,
 chickens and turkeys, and is continuing to closely monitor resistance to these drugs.

"Antimicrobial resistance is a serious and challenging issue. It is critically important that we continue our efforts to minimize antimicrobial resistance, including promoting appropriate and judicious use of antimicrobials in both humans and animals.

"Based on a thorough review of the available scientific information, FDA has created a strategy for the judicious use of medically important antimicrobials in food-producing animals that states their use should be limited to situations where the drugs are necessary for ensuring animal health, and done so under veterinary guidance. It is the non-judicious use – for growth promotion and feed efficiency – that is of particular concern to FDA. This collaborative strategy is intended to provide the quickest way to achieve the greatest degree of public health protection, but it does not prevent FDA from initiating regulatory action in the future, if the agency finds it necessary. FDA welcomes all contributions in helping to understand and address the challenge of antibiotic resistance. However, it is very important to look at the NARMS data in the proper context, with a good understanding of the microbiology, epidemiology and genetics of antibiotic-resistant foodborne pathogens and their clinical management."

For more information, visit <u>FDA.gov</u>.

(4) Up to 70 percent of all antibiotics sold in the United States are given to food-producing animals, often for the nontherapeutic purpose of promoting growth or for the purpose of compensating for the effects of insanitary and overcrowded conditions.

As previously mentioned any nontherapeutic uses of medically important antibiotics will be eliminate by the change to the VFD by next year. FDA statement: "In 2010, FDA called for a strategy to phase out

production use of medically important antimicrobial products and to bring the remaining therapeutic uses under the oversight of a veterinarian. The guidance document that FDA is issuing on Dec. 11, 2013, which was previously issued in draft form in 2012, lays out such a strategy and marks the beginning of the formal implementation period.

The agency is asking animal pharmaceutical companies to notify FDA within the next three months of their intent to voluntarily make the changes recommended in the guidance. Based on timeframes set out in the guidance, these companies would then have three years to fully implement these changes."

Since there is approximately 495 million people and pets in the US and somewhere in the neighborhood of 10 billion or more farm animals (20 times the people and pet population) it is not overly surprising that 95% of the us animal and human population would utilize "up to 70% of all antibiotics sold", I actually would have expected the number to be higher.

(5) Many of the antibiotics provided to food-producing animals are identical to, or from the same family as, drugs used in human medicine to cure serious diseases. According to the Centers for Disease Control and Prevention, because the antibiotics are similar, bacteria resistant to the antibiotics provided to food-producing animals will also be resistant to the antibiotics used in humans.

This is very true and there is nothing the Oregon Legislature could possibly due to change it. R & D is very expensive and when a pharmaceutical company creates or finds a new drug they will market it wherever they can prove safety and efficacy.

Section 4 is already basically in practice due to the changes in the VFD.

Section 5: Lets create more busy work for small business so they can spend less time tending to their livestock and then have to give them antibiotic when they find problems created by the neglect while they were filling out forms.

Section 8: There is zero scientific evidence that an emergency exists. If in doubt re-read the FDA response to the EWG.

Perhaps we should leave medical issues to the trained scientific community including the medical and veterinary professionals working on the issue and not legislate based on emotion not science.

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