Talking Points
“Preservation of Antibiotics for Medical Treatment Act”

• Risk assessment is the proper tool for making policy decisions about the use of antibiotics in animals. Decisions made without risk assessment are likely to result in unintended consequences including increased animal death and disease and increased risks to public health.

• The bill undermines the Food and Drug Administration process of reviewing the human health impacts of individual animal drugs based on science and risk assessment. All antibiotics used to keep animals healthy have passed the FDA process and have been shown to be safe and effective and have undergone review for their potential to cause increased antibiotic resistance. The bill removes seven of these antibiotics from the market unless sponsors can demonstrate what has already been proven in the review process – that they are safe and effective.

• Two-thirds of previous PAMTA bills have been enacted into law and should be allowed to work before removing products from market. Provisions requiring more USDA research into the causes and solutions of antibiotic resistance were passed as part of the Farm Bill in 2008. The Animal Drug User Fee Amendments of 2008 require FDA to collect antibiotic sales data from companies and make a summary of that data public. The provisions were designed to provide better information to researchers conducting risk assessments and should be allowed to yield information before products are removed from market.

• The bill overlooks the legitimate veterinary need to preserve these antibiotic classes for use in food animals to ensure that healthy animals enter the food chain. With few new antibiotics anticipated for approval by FSDA, the removal of the products and antibiotic classes listed will only serve to increase the use of the remaining products, thus increasing the selective pressure for resistance to those antibiotic classes. This result will defeat the intended “preservation” for both veterinary and human medicine.

• The bill attempts to mislead and confuse the public and their elected officials by mixing the problem of antibiotic resistance in general with the portion that might be related to antibiotic use in animals. Most informed scientists and public health professions acknowledge that the problem of antibiotic resistance in humans is overwhelmingly an issue related to human drug use.

• While citing Europe as a model, the bill would remove from market a broader range of products than those banned in Europe. The result of the non-scientific removal of antibiotics used as growth promoters in Europe is clear: increased animal disease, increased use of therapeutic antibiotics, and no improvement in human antibiotic resistance patterns. Recent published, peer-review articles document these impacts and warn that broad political decisions not based on science – like this legislation – carry unintended consequences.

• Many voluntary and regulatory actions to ensure safe use of antibiotics in animals are in place. Species-specific Judicious Use principles are widely observed; voluntary risk assessments have been done by sponsors, and FDA is now requiring specific risk assessments for new and existing antibiotic products; surveillance programs are in place at the farm, marketplace and public health levels, and can be strengthened. Data from USDA, CDC and FDA shows these efforts are working and we should not risk undermining animal health by passing this bill.
Analysis of provisions of S. 1260

Section 1. Short Title

Section 2. Findings

Congress finds that--
(1)(A) in January 2001, a Federal interagency task force released an action plan to address the continuing decline in effectiveness of antibiotics against common bacterial infections, referred to as antibiotic resistance;
(B) the task force determined that antibiotic resistance is a growing menace to all people and poses a serious threat to public health; and
(C) the task force cautioned that if current trends continue, treatments for common infections will become increasingly limited and expensive, and, in some cases, nonexistent;

All of this is true. The Federal action plan includes a section on use of veterinary antibiotics. The task force found, in agreement with most scientists, that the greatest bug/drug combinations that pose an antibiotic resistance threat are the result of human use, and not related to veterinary use.

(2) antibiotic resistance, resulting in a reduced number of effective antibiotics, may significantly impair the ability of the United States to respond to terrorist attacks involving bacterial infections or a large influx of hospitalized patients;

This is an attempt to place animal use of antibiotics in the context of an issue of concern to all – but it doesn’t work. Terrorists can attack using bacterial infections manufactured to be resistant – this is not resistance that arises from veterinary use of antibiotics.

(3)(A) any overuse or misuse of antibiotics contributes to the spread of antibiotic resistance, whether in human medicine or in agriculture; and
(B) recognizing the public health threat caused by antibiotic resistance, Congress took several steps to curb antibiotic overuse in human medicine through amendments to the Public Health Service Act (42 U.S.C. 201 et seq.) made by section 102 of the Public Health Threats and Emergencies Act (114 Stat. 2315), but has not yet addressed antibiotic overuse in agriculture;

The act referred to “took several steps to curb antibiotic overuse in human medicine” by creating a Federal interagency task force and authorizing grants for research. In fact, the report of the Federal interagency task force did examine the use of veterinary and human antibiotics. The plan presented in that report is currently being implemented and is referred to in Finding 1. In other words, the
provisions of the Public Health Service Act had the same effect on veterinary use of antibiotics as on human use. Congress has addressed them both.

Of course, neither the legislation nor the report of the task force recommended the dangerous and far-reaching act of removing FDA-approved products from the market, as this bill does.

Congress took two additional steps in 2008 specifically aimed at veterinary drugs. The Farm Bill authorizes research and education grants on antibiotic resistant bacteria that may be transferred from livestock to humans, and the Animal Drug User Fee Amendments requires FDA to collect annual data on the amount of antibiotics used in animal agriculture. The results of these efforts should be known before further steps are taken.

(4) in a March 2003 report, the National Academy of Sciences stated that--
(A) a decrease in antimicrobial use in human medicine alone will have little effect on the current situation; and
(B) substantial efforts must be made to decrease inappropriate overuse in animals and agriculture;

This statement flies in the face of the body of scientific opinion and is a misquote of the NAS report. The state from the report reads “Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough.” Even CDC and medical experts agree that human resistance problems are largely due to use or abuse of antimicrobials in humans, not animals. There is serious debate about the contribution of animal use to the problem of antibiotic resistance in humans, but it is clearly much smaller than the impact of human use. This is borne out by the European experience – where a phase-out of antibiotics use for growth promotion has had no impact on reducing antibiotic resistance in human clinical infections.

(5)(A) an estimated 70 percent of the antibiotics and other antimicrobial used in the United States are fed to farm animals for nontherapeutic purposes, including--
(i) growth promotion; and
(ii) compensation for crowded, unsanitary, and stressful farming and transportation conditions; and
(B) unlike human use of antibiotics, these nontherapeutic uses in animals typically do not require a prescription;

That estimate is outdated (1999), is inaccurate, and ignores evidence to the contrary. Figures released by the Animal Health Institute’s annual survey of makers of antibiotics shows about 15 percent of veterinary antibiotics are used to promote growth. These uses of antibiotics make producers more efficient and keep animals from getting sick, contrary to the purposes stated by the authors.
(6) (A) large-scale, voluntary surveys by the Department of Agriculture’s Animal and Plant Health Inspection Service in 1999, 2001, and 2006 revealed that 84 percent of the grower-finisher swine farms, 83 percent of cattle feedlots, and 84 percent of sheep farms administer antimicrobials in the feed or water for health or growth promotion reasons, and many of the antimicrobials identified are identical or closely related to drugs used in human medicine, including tetracyclines, macrolides, Bacitracin, penicillins and sulfonamides; and

(B) these drugs are used in people to treat serious diseases such as pneumonia, scarlet fever, rheumatic fever, venereal disease, skin infections, and even pandemics like plague, as well as bioterrorism agents link anthrax.

Except for anthrax, the bacteria causing these diseases in humans do not infect food producing animals. Therefore, antibiotic use in animals can have no direct effect on the treatment of these diseases in humans. Anthrax that naturally occurs in livestock is an acute and frequently fatal disease that is never treated with antibiotics. If anthrax is found on a farm, the premises are depopulated and disinfected.

(7) many scientific studies confirm that the nontherapeutic use of antibiotics in agricultural animals contributes to the development of antibiotic-resistant bacterial infections in people;

(8) (A) the periodical entitled ‘Clinical Infectious Diseases' published a report in June 2002, based on a 2-year review by experts in human and veterinary medicine, public health, microbiology, biostatistics, and risk analysis, of more than 500 scientific studies on the human health impacts of antimicrobial use in agriculture; and

(B) the report recommended that antimicrobial agents should no longer be used in agriculture in the absence of disease, but should be limited to therapy for diseased individual animals and prophylaxis when disease is documented in a herd or flock;

Numerous scientific studies have been done over the past thirty years exploring the potential link between animal use of antibiotics and antibiotic resistance in humans. None “confirm” that the “nontherapeutic” use contributes to human antibiotic resistance. It is clear this potential exists, and the debate is over the actual incidence rate of such transfer and the risk to humans. The level of this risk, which reasonable experts agree is small, should dictate the risk management response.

(9) (A) the United States Geological Survey reported in March 2002 that antibiotics were present in 48 percent of the streams tested nationwide; and

(B) almost half of the tested streams were downstream from agricultural operations;
The finding leaves out the important information that most of the drugs found were clearly from human waste. It’s true that streams downstream from agricultural operations were oversampled. However, those downstream segments were found to have less incidence of antibiotics than other, more urban influenced waters.

(10) An April 1999 study by the General Accounting Office concluded that resistant strains of 3 microorganisms that cause food-borne illness or disease in humans—Salmonella, Campylobacter, and E. coli—are linked to the use of antibiotics in animals;

This is the fact that gives the lie to most of the rest of this bill. These are the three food-borne microorganisms that can transfer antibiotic resistance from animals to humans. They also are not major bugs of concern in the debate over antibiotic resistance. All of the “growing menace” findings (see above) relate to other organisms. In addition, most of the illness caused by these three is not treated with antibiotics.

(11) Epidemiological research has shown that resistant Salmonella and Campylobacter infections are associated with increased numbers of ill patients and bloodstream infections, and increased death;

Salmonella bloodstream infections occur at a rate of 0.4% in North America based on data from the SENTRY Antimicrobial Surveillance System. Salmonella isolates from these infections are routinely susceptible to antibiotics such as the fluoroquinolones and cephalosporins used to treat Salmonella. Bloodstream infections with Campylobacter are extremely rare and have not been reported in the SENTRY program. However, a paper published in 2007 in the International Journal of Antimicrobial Agents examined 11,000 cases of enteric Campylobacter infections and indicated that there was no difference in severity between fluoroquinolone-resistant infections and fluoroquinolone-susceptible infections. Fluoroquinolones are frequently used to treat foodborne infections in humans.

(12)(A) In January 2003, Consumer Reports published test results on poultry products bought in grocery stores nationwide showing disturbingly high levels of Campylobacter and Salmonella bacteria that were resistant to antibiotics used to treat food-borne illnesses; and
(B) further studies showed similar results in other meat products;
(C) In December 2007, the USDA issued a fact sheet on the recently recognized link between antimicrobial drug use in animals and the MRSA infections in humans;

What “further studies?” In fact, there are two problems with the Consumer Reports findings. First, finding bacteria on meat in grocery stores tells us nothing about the source of that bacteria. The bill makes an assumption it is the
result of on-farm practices, but there are many steps between the farm and the supermarket where the bacteria can be introduced. Second, the findings are out of sync with broader Federal databases. FDA’s retail meat sampling program is finding resistance levels far lower than the grab-bag sample used by Consumer Reports.

The USDA fact sheet cited two references to support the “recognized” link between antimicrobial use in animals and MRSA infections. In fact, the two references cited were unrelated to MRSA and provided no data to support this statement. Furthermore, the CDC does not currently recognize a connection between human disease and MRSA that has been found in animals.

(13) in October 2001, the New England Journal of Medicine published an editorial urging a ban on nontherapeutic use of medically important antibiotics in animals;

There are individuals, including some editorial writers, who believe this. Editorials are not science, and as Europe has learned, making non-scientific decisions can lead to unintended consequences.

(14) in 1998, the National Academy of Sciences noted that antibiotic-resistant bacteria generate a minimum of $4,000,000,000 to $5,000,000,000 in costs to United States society and individuals yearly;
(13) a year later, the National Academy of Sciences estimated that eliminating the use of all antibiotics as feed additives would cost each American consumer less than $5 to $10 per year;

This is a breathtaking misuse of numbers. The $4 to $5 billion in costs is not attributed to veterinary use of antibiotics, but applies to all antibiotic resistance and is stated in the aggregate. The next statement, in the particular, would be $2.7 billion if stated the same way as the cost numbers.

(15) the American Medical Association, the American Public Health Association, the National Association of County and City Health Officials, and the National Campaign for Sustainable Agriculture, are among the more than 300 organizations representing health, consumer, agricultural, environmental, humane, and other interests that support enactment of legislation to phase out nontherapeutic use in farm animals of medically important antibiotics;

In fact, the American Medical Association resolution calls for phasing out certain antibiotic uses based on a risk assessment. FDA has recently mandated risk assessments be done for all new and existing animal drugs. In addition, the Coalition for Animal Health, representing animal producers and veterinarians, as well as the Council of State Governments and the American Legislative Exchange Council, all oppose this action. The National Conference of State Legislators also defeated a resolution supporting action like that called for in this bill.
(16) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)--
(A) requires that all drugs be shown to be safe before the drugs are approved; and
(B) places the burden on manufacturers to account for health consequences and prove safety;

That’s right. All of the drugs that this bill proposes to remove from the market have been proven to be safe and effective by the manufacturers. They could not be marketed otherwise. So why does the bill override the FDA process that requires sponsors to demonstrate safety and efficacy?

(17)(A) the Food and Drug Administration recently modified the drug approval process for antibiotics to recognize the development of resistant bacteria as an important aspect of safety;
(B) however, most antibiotics currently used in animal production systems for nontherapeutic purposes were approved before the Food and Drug Administration began giving in-depth consideration to resistance during the drug-approval process; and
(C) the Food and Drug Administration has not established a schedule for reviewing those existing approvals;

The FDA has implemented requirements that all drug sponsors must do a risk assessment to gauge the threat of antibiotic resistance. This new requirements applies to all new antibiotic drug applications and existing products. All antibiotics currently used in animal production systems have been given in-depth consideration to resistance, either during the drug-approval process or later when new requirements were put into place. In a recent Federal Register notice, FDA outlined the entire history of antibiotic resistance requirements, making it clear that all antibiotic drugs have been examined. The latest risk assessment requirement is simply the latest and most advanced method of examining this potential risk.

(18) certain non-routine uses of antibiotics in animal agriculture are legitimate to prevent animal disease;

(19)(A) an April 2004 study by the General Accounting Office concluded that Federal agencies do not collect the critical data on antibiotic use in animals that they need to support research on human health risks; and
(B) the report recommends that the Department of Agriculture and the Department of Health and Human Services develop and implement a plan to collect data on antibiotic use in animals.

Again, this has been done. In addition to the annual data provided to FDA in the drug event reports, the Animal Drug User Fee Amendments of 2008 requires drug
sponsors to provide calendar year data to FDA on antibiotic sales. The first such report is due in March 2010, and FDA is required to make a public summary of the data.

Section 3. Purpose

Section 4. Proof of Safety of Critical Antimicrobial Drugs

Definition of Critical Antimicrobial Animal Drug – means a drug that is

1. Intended for use in food producing animals; and
2. Is composed wholly or partly of –
   (A) Any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, or sulfonamide; or
   (B) Any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

Not only have products in these classes already met the safety and efficacy tests, but recent risk assessments have confirmed their safety:

Penicillin – FDA says its review of penicillin is complete although results of not been made public. It is reasonable to assume that if safety concerns had arisen in that review, FDA would have initiated regulatory action under current authority to do so.

Tetracycline – Review currently underway; quantitative risk assessments will soon be published documenting extremely low risk.

Macrolide – Published, peer-reviewed quantitative risk assessments document extremely low risk;

Streptogramin – FDA conducted a quantitative risk assessment on the one approved streptogramin product and did not even find that a hazard exists.

The very broad ‘any other drug used in medicine’ paragraph demonstrates the aim is to remove products from the market, not to address resistance issues. The potential risk associated with antibiotic use in animals is that foodborne pathogens that could otherwise be treated with antibiotics would be untreatable due to resistance. Very few foodborne illnesses are treated with antibiotics. Treatment of other human diseases are highly unlikely to be compromised by animal antibiotic use – which is exactly why risk assessment should be used to made policy decisions about the use of these products.
Definition of “nontherapeutic use:” means any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animals for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.

In addition to conflicting with finding #18, it fails to recognize existing terminology used by US and international regulatory bodies as well as the veterinary and medical communities. FDA approves products for disease treatment, disease prevention, disease control and productivity, or growth. Treatment, prevention and control are considered “therapeutic” uses by FDA, AVMA, Codex Alimentarius, OIE and others.

This section rescinds the approval of a list of seven “critical antimicrobial animal drugs” unless the sponsor demonstrates there is a reasonable certainty of no harm to human health from the development of antimicrobial resistance from “nontherapeutic” use of the drug. The Secretary would rescind these approvals within 2 years of enactment of the bill unless the Secretary determines there is a demonstration of reasonable certainty of no harm.

This provision undermines FDA’s authority to implement the Federal Food Drug and Cosmetic Act (FFD&CA). The Act requires sponsors to demonstrate safety and efficacy of all antimicrobials, including those listed in the bill. Thus, any antimicrobial currently marketed has gone through the process where safety and efficacy have been demonstrated already.

In addition, the standards by which FDA evaluates the safety of antimicrobials and their potential to give rise to antibiotic resistance has changed as science has advanced. In 2003 year FDA again upgraded these standards, requiring that sponsors perform a risk assessment to assess the potential of a drug contributing to antibiotic resistance. This new risk assessment standard will be applied to all new drugs and to all existing drugs. According to FDA, they have completed this review for products in one class listed in the bill – penicillin. In addition, FDA has done a more comprehensive risk analysis on another compound listed, (virginiamycin, a streptogramin, and found no hazard exists. Published, peer reviewed risk assessments exist for other compounds listed, including tetracycline and macrolides – which also show risk levels that are extremely low and may even be zero.