PAMTA has the potential to severely limit the ability for veterinarians to ensure optimal animal health and welfare at production facilities.

**KEY POINTS:**

- The AVMA supports the Food and Drug Administration’s recommended approach (Guidance for Industry No. 152) for assessing the safety of new antimicrobial drugs for use in animals with regard to their potential effects on human health.
- Provisions in the bill conflict with legal requirements for veterinarians to adhere to FDA-approved drug label instructions.
- The AVMA disagrees with how the bill defines “therapeutic use.” Although there are provisions for disease control, some medically necessary antimicrobial therapies could still be deemed unlawful.
- If the bill were implemented, the FDA would need additional resources to fulfill its requirements within the two-year time frame, which could potentially cause drugs currently in use to be withdrawn, putting the health and welfare of animals at risk.

**What is the problem?**

The AVMA believes disease prevention is essential to protecting food safety and animal health and welfare. However, this bill defines several uses of antimicrobials in food animals as unlawful, making it nearly impossible for veterinarians to care for their animal patients and ensure a safe food supply.

The bill defines “therapeutic use” of antimicrobials in food animals as only “for the specific purpose of treating an animal with a documented disease or infection.” This definition excludes disease prevention and is contrary to other definitions by the AVMA, Codex Alimentarius, World Organization for Animal Health (OIE), and the Food and Drug Administration.

Under the stated definition for “non-therapeutic use,” which is inconsistently defined throughout the bill, H.R. 1552 calls for the withdrawal of “any repeated or regular pattern of use of medically important antimicrobials for purposes other than “therapeutic use or non-routine disease control.” The definition of “non-routine disease control” is problematic because it excludes “normal or standard production practices and conditions that facilitate the transmission of disease.” Disease transmission occurs via multiple routes, including indirect contact and noncontact routes (e.g., airborne). These routes are normal and standard in virtually any environment.

**Why is the AVMA opposed?**

This legislation is not in alignment with the FDA’s Guidance for Industry No. 209, which states that the therapeutic uses (i.e., for treatment, control and/or prevention purposes) of antimicrobials through feed or water are necessary for ensuring the health and welfare of food-producing animals. The AVMA agrees with the principles of GFI 209, and believes that administering antimicrobials...
through the animal’s food or water may be the most appropriate and effective way to use the drugs and eliminating the ability to treat animals in this way would pose a significant risk to their health.

The legislation eliminates the ability for veterinarians to prevent disease through the judicious use of antimicrobials. Some prohibitions among the provisions would also restrict a veterinarian’s ability to control diseases. The bill stipulates that antimicrobials cannot be used in a “repeated or regular pattern” that “facilitates the transmission of a disease.” Nearly all practices of administering antimicrobials in food animal production could be included in these provisions; thus, many antimicrobial therapies in food animal production would likely be interpreted as unlawful.

When administering medications, veterinarians are required by law to follow the FDA’s approved drug labels for food animals, unless the patient’s medical status dictates that the veterinarian may treat in an extralabel fashion. When using drugs extralabely, the use must be in line with the requirements within the Animal Medicinal Drug Use Clarification Act, which strictly prohibits extralabel use in feed among other restrictions specific to food-producing animals. Some medications are approved and required to be used for a specific period of time, which could extend beyond the resolution of clinical signs in an animal. However, provisions within H.R. 1552 would direct veterinarians to act illegally by deviating from FDA-approved label instructions.

The bill would require the FDA to determine, within a two-year time frame, that there will not be harm to human health through certain uses of antimicrobial drugs. This is problematic because no post-approval process or mechanism exists by which a drug sponsor can demonstrate “reasonable certainty” of no harm to human health. Also, without additional resources, it is unlikely that the FDA could meet this requirement, meaning drugs would be withdrawn from the market and the approval of new drugs would be stymied, putting the health and welfare of food-producing animals at risk.

Status of the bill:
- Rep. Louise Slaughter (D-N.Y.-25) introduced the bill on March 23, 2015, and it has been referred to the House Energy and Commerce Committee.