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

What will this bill do?

H.R. 1150 will amend the Federal Food, Drug and Cosmetic Act to require drug manufacturers that hold approvals for animal drugs that are “medically important antimicrobials” to demonstrate with reasonable certainty that no harm to human health will be caused due to the development of antimicrobial resistance attributable to certain uses of that particular drug. The legislation defines “medically important antimicrobials” as drugs intended for use in food-producing animals and composed wholly or partly of any kind of specified antimicrobials, including penicillin, cephalosporins, and macrolides or drugs from an antimicrobial class on the World Health Organization’s list of antimicrobials important to human health.

What is the problem?

AVMA believes disease prevention is essential to protecting food safety and animal health and welfare. However, the bill defines “therapeutic use” 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 Food and Drug Administration.

Under the stated definition for “non-therapeutic use,” which is inconsistently defined throughout the bill, H.R. 1150 calls for the withdrawal of “any repeated or regular pattern of use of medically important antimicrobials for purposes other than therapeutic use or nonroutine disease control.” The definition of “nonroutine 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 recommendations for the judicious use of antimicrobials (Guidance for Industry No. 209).

- 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.

- Provisions in the bill conflict with legal requirements for veterinarians to adhere to FDA-approved label instructions.

- 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.

- The AVMA supports the FDA’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.

Key points:

- This legislation is not in alignment with the FDA’s recommendations for the judicious use of antimicrobials (Guidance for Industry No. 209).

- 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.

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American Veterinary Medical Association Governmental Relations Division
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clinical signs in an animal. However, provisions within H.R. 1150 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 15, 2013, and it has been referred to the House Energy and Commerce Committee, Subcommittee on Health.