PARA 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?
S. 1256 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. The bill also includes the sense of the Senate that a valid veterinarian-client-patient relationship should exist to ensure that medically important antimicrobials are used in a manner consistent with professionally accepted best practices.

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, S. 1256 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 FDA Guidance for Industry No. 209. The AVMA agrees that the uses associated with the treatment, control and prevention (including administration through feed or water) as indicated in GFI No. 209 are necessary for ensuring the health and welfare of food-producing animals.
• 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 currently required by law to follow the
labels for drugs that have been approved by the FDA. 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 S. 1256 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:**

- Sen. Dianne Feinstein (D-Calif.) introduced the bill on June 27, 2013, and it has been referred to the Senate Committee on Health, Education, Labor and Pensions.