



KEY POINTS:

- Many provisions of the bill have already been addressed by FDA regulatory changes that went into effect on January 1, 2017.
- The bill would require drug sponsors to seek re-approval from FDA for certain previously approved antimicrobials, including re-proving the safety and efficacy of the product when used for prevention purposes. This hardship and expense could result in increased costs or removal from the market of important veterinary medications.
- The legislation has the potential to significantly erode the medical discretion and oversight responsibilities of licensed veterinary professionals. It would diminish a veterinarian's ability to use his or her clinical skills and scientific knowledge in determining duration of therapy to ensure the best medical outcome for patients, and to protect public health and food safety.

What is the intent of this bill?

The stated purpose of the bill is to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention, control and treatment of animal diseases, in order to minimize the development of antibiotic-resistant bacteria. The legislation intends to address a perceived gap in the 2017 FDA regulations regarding prevention uses of antimicrobials in food animals. The concern is about products that were previously approved and labeled without a defined duration of administration or were approved for prevention at the same or similar dosage as they were for growth promotion. (Growth promotion and feed efficiency indications were removed from all feed labels on January 1, 2017.) The bill would require drug sponsors of these previously approved antimicrobial products to re-submit evidence to the Secretary proving that the drug is safe and effective for labeled prevention indications, which is a difficult and expensive process.

What is the problem?

The bill duplicates FDA's efforts through Docket No. FDA-2016-D-2635; Establishing Appropriate Durations of Therapeutic Administration; Request for Comments, which closed in March 2017. FDA has received input from a wide variety of stakeholders and is now deliberating on an approach to those few antimicrobials that aren't currently labeled with an explicitly defined duration of use.

Medically important antimicrobials that were approved for disease prevention at the same or similar dosage as they were for growth promotion have been addressed. As of January 1, 2017, there are no medically important antimicrobials that are approved and labeled for growth promotion. To be approved specifically for disease prevention, drug sponsors are required to demonstrate the efficacy and safety of the antimicrobial for that purpose at a given dose. It is already illegal to use any medicated feed in a manner different from the label directions; thus, a drug approve for disease prevention must be used for that purpose and cannot be used (even at the approved prevention dosage) for an alternate purpose.

Why is the AVMA opposed?

The onerous requirements of drug sponsors to provide additional evidence for safety and efficacy beyond what was required for the original New Animal Drug Application could greatly increase costs and/or result in loss of important veterinary medications from the market. It's important also to note that the lack of an explicitly defined duration of administration is not analogous to injudicious or unending antibiotic use. Medically important antimicrobials delivered to food animals in feed may only be used under the supervision of a licensed veterinarian who has issued a Veterinary Feed Directive (VFD). The duration of administration is required to be recorded on the VFD by the issuing veterinarian even if not given

on the drug label. Determining duration of therapy requires the medical judgement of a trained and licensed veterinarian, in the context of a veterinary-client-patient relationship. The passage of PARA would limit the ability of veterinarians to make the decisions necessary in their daily work to protect animal health and welfare.

Status of the bill:

- Sen. Dianne Feinstein (D-C.A.) introduced the bill on March 14, 2017, and it has been referred to the Committee on Health, Education, Labor and Pensions.