114TH CONGRESS
1ST SESSION

S. 621

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 and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

IN THE SENATE OF THE UNITED STATES

MARCH 2, 2015

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mrs. GILLIBRAND, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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 and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preventing Antibiotic Resistance Act of 2015''.

SEC. 2. PURPOSE.

The purpose of this Act is to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

SEC. 3. EVIDENCE OF SAFETY OF MEDICALLY IMPORTANT VETERINARY ANTIMICROBIALS.

(a) APPLICATIONS PENDING OR SUBMITTED AFTER ENACTMENT.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended—

(1) in the first sentence—

(A) in subparagraph (H), by striking ''or'' at the end;

(B) in subparagraph (I), by inserting ''or'' at the end; and

(C) by inserting after subparagraph (I) the following:

''(J) with respect to a medically important antimicrobial (as defined in subsection (q)), the applicant has failed to demonstrate that a New Animal Drug Application for an antimicrobial labeled for disease prevention or control fails to meet the criteria in subsection (q)(2)(A);''; and

(2) in the second sentence, by striking ''(A) through (I)'' and inserting ''(A) through (J)''.

(b) ENSURING JUDICIOUS USE IN ANIMALS OF MEDICALLY IMPORTANT ANTIMICROBIALS.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) ENSURING JUDICIOUS USE IN ANIMALS OF MEDICALLY IMPORTANT ANTIMICROBIALS.—

''(1) APPLICABILITY.—This subsection applies to medically important antimicrobials approved for use in a food-producing animal—

''(A)(i) for which there is in effect an approval of an application or an exemption under subsection (b), (i), or (j) of section 505; or

''(ii) that is otherwise marketed for human use;

''(B) for which the Food and Drug Administration has initiated or completed withdrawal or modification of an approved label for growth promotion, feed efficiency, or other production use or over-the-counter use, in accordance with the Guidance for Industry entitled, 'New Animal Drugs and New Animal Drug Combination Products, Administered in or on Medicated Feed or Drinking Water of Food-Producing

Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209', published in December 2013; and

''(C) for which the Food and Drug Administration has approved a label—

''(i) for disease control or prevention at the same or similar dosage level as applicable for the approved production use described in subparagraph (B);

''(ii) that does not specify an explicitly defined duration of therapy; or

''(iii) specifying a dosage that is not expected to treat a specific bacterial pathogen.

''(2) REVIEW OF DISEASE PREVENTION AND CONTROL APPROVALS.—

''(A) IN GENERAL.—Not later than January 1, 2017, the Secretary shall initiate a process whereby—

''(i) not later than January 1, 2018, a sponsor of an antimicrobial drug described in paragraph (1) shall submit to the Secretary evidence demonstrating that, with respect to such drug—

"(I) there is evidence of effectiveness in controlling or preventing bacterial disease;

"(II) an approved use is consistent with accepted veterinary practice;

"(III) an approved use is linked to a specific etiologic agent;

"(IV) an approved use is appropriately targeted to animals at risk of developing a specific bacterial disease;

"(V) an approved use has an explicitly defined duration of therapy; and

"(VI) there is reasonable certainty of no harm to human health due to the development of antimicrobial resistance; and

"(ii)(I) if the Secretary determines that the evidence submitted under clause (i) is sufficient to demonstrate that the drug meets the requirements described in subclauses (I) through (VI) of such clause, not later than December 31, 2018, the Secretary shall issue a revised label ap-

proval for the antimicrobial drug, as necessary; or

''(II) if the Secretary determines that the evidence submitted under clause (i) is insufficient to demonstrate that the drug meets the requirements described in subclauses (I) through (VI) of such clause, not later than December 31, 2018, the Secretary shall withdraw approval of any indication claims described in paragraph (1)(C) for which the Secretary determines the evidence is insufficient and, as necessary, issue a revised label approval.

''(B) WITHDRAWAL OF CLAIMS.—On or before January 1, 2018, the sponsor of a drug described in paragraph (1) may request the approval of the Secretary to remove any label claim described in paragraph (1)(C), and the Secretary shall approve any such request and, as necessary, issue a revised label. The sponsor shall not be required to submit the evidence required under subparagraph (A)(i) with respect to any claim so withdrawn.

''(3) EXEMPTIONS.—In the case of a drug that is a medically important antimicrobial for which the

Secretary grants an exemption under section 505(i), the withdrawal of indication claims in a food-producing animal in accordance with paragraph (2)(B) shall be effective on the date that is 2 years after the date on which the Secretary grants the exemption, unless, not later than 2 years after the date on which the Secretary grants the exemption, the Secretary provides a written determination of intent to extend the exemption.

''(4) DEFINITION.—In this subsection, the term 'medically important antimicrobial' means a drug that—

''(A) is intended for use in food-producing animals; and

''(B) is composed wholly or partly of—

''(i) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, sulfonamide, cephalosporin, or fluoroquinolone; or

''(ii) a drug from an antimicrobial class that is listed as 'highly important', 'critically important', or 'important' by the World Health Organization in the latest edition of its publication entitled 'Critically

Important Antimicrobials for Human Medicine' (or a successor publication).''.

SEC. 4. SENSE OF THE SENATE REGARDING VETERINARY OVERSIGHT OF USE OF MEDICALLY IMPORTANT ANTIMICROBIALS.

(a) IN GENERAL.—It is the sense of the Senate that a valid veterinarian-client-patient relationship should exist to ensure that medically important antimicrobials are used in food-producing animals in a manner that is consistent with professionally accepted best practices.

(b) VETERINARIAN-CLIENT-PATIENT RELATIONSHIP.—In this section, the term ''veterinarian-client-patient relationship'' means a relationship in which all of the following criteria are met:

(1) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the patient and the client has agreed to follow the veterinarian's instructions.

(2) The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of—

(A) a timely examination of the patient by the veterinarian; or

(B) medically appropriate and timely visits by the veterinarian to the premises where the animal or animals are kept.

(3) The veterinarian is readily available for follow-up evaluation or has arranged for veterinary emergency coverage and continuing care and treatment.

(4) The veterinarian provides oversight of treatment, compliance, and outcome.

(5) Patient records are maintained.

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