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113TH CONGRESS
1ST SESSION

H. R. 820

To amend the Federal Food, Drug, and Cosmetic Act to enhance the reporting requirements pertaining to use of antimicrobial drugs in food animals.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 2013

Mr. WAXMAN (for himself and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to enhance the reporting requirements pertaining to use of antimicrobial drugs in food animals.

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 ''Delivering Antimicrobial Transparency in Animals Act of 2013''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Antimicrobials are of critical importance to public health and to the American economy.

(2) Use of antimicrobials, whether in human medicine or in agriculture, contributes to the development and spread of antimicrobial resistance.

(3) Data from the Food and Drug Administration (FDA) indicate that approximately 80 percent of all antimicrobials sold in the United States, over 29,000,000 pounds in 2009, were sold for use in food animals.

(4) A study published in September, 2012, in Proceedings of the National Academy of Sciences of the United States of America found that even low doses of antimicrobials in animal feed for short periods of time increased the prevalence of the bacteria E. coli and the prevalence and diversity of antimicrobial resistance genes in bacteria in pigs.

(5) Public Law 110–316, the Animal Drug User Fee Amendments of 2008, requires producers of drugs used in food animals to provide specified information annually to the FDA on the sales and indications for use of such drugs.

(6) A September 2011 study by the Government Accountability Office found that the data provided to the FDA under the Animal Drug User Fee Amendments Act of 2008 lacked sufficient details necessary to analyze trends in antimicrobial resist-

ance, such as information on actual drug use in specific food-producing animal species.

SEC. 3. PURPOSE.

The purpose of this Act is to provide the Food and Drug Administration and the public with better information on the use of antimicrobial drugs in animals used for food to—

(1) enable public health officials and scientists to better understand and interpret trends and variations in rates of microbial resistance to such antimicrobial drugs;

(2) improve the understanding of the relationship between antimicrobial drug use in animals used for food and antimicrobial drug resistance in microbes in and on animals and humans; and

(3) identify interventions to prevent and control such antimicrobial drug resistance.

SEC. 4. ENHANCED REPORTING REQUIREMENTS.

(a) REPORTS.—Section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) is amended by striking paragraph (3) and inserting the following:

''(3)(A) In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on

the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

''(B) Each report under this paragraph shall specify the amount of each antimicrobial active ingredient—

''(i) by container size, strength, and dosage form;

''(ii) by quantities distributed to each State domestically and by quantities exported; and

''(iii) by dosage form, including (for each dosage form) the known or estimated amounts of the antimicrobial active ingredient sold or distributed for use in each food-producing animal for which the new animal drug is approved, including a description of the methods used to determine or estimate the amounts.

''(4)(A) Subject to subparagraph (B), in the case of animal feed in final formulation bearing or containing a new animal drug for which reporting is required under paragraph (3), a live poultry dealer, swine contractor, or feed lot operator who purchases, contracts, or manufactures such feed shall submit to the Secretary an annual report that specifies, by

food-producing animal for which the new animal drug is approved and, where applicable as determined by the Secretary, by production class of such animal—

''(i) the amount of each antimicrobial active ingredient contained per kilogram of each such feed sold or distributed for that animal and, where applicable, production class;

''(ii) the quantity of such feed sold or distributed for that animal and, where applicable, production class; and

''(iii) for each such feed sold or distributed under a veterinary feed directive—

''(I) the indications for which the feed was sold or distributed and the quantities of such feed that were sold or distributed per each such indication;

''(II) the number of individuals of the food-producing animal and, where applicable, the production class to which the feed was intended; and

''(III) the length of time over which the feed was intended to be provided to the animals and the dose of the active anti-

microbial ingredient the animals were intended to receive.

''(B)(i) Subparagraph (A) does not apply to a live poultry dealer, swine contractor, or feed lot operator if the total value of the live animals owned, purchased, sold, contracted for, or otherwise controlled by the dealer, contractor, or operator, directly or through subsidiaries or affiliates, per year, does not exceed—

''(I) $10,000,000; or

''(II) such other sum as the Secretary may specify through regulation.

''(ii) The Secretary may specify through regulation alternative reporting requirements, including via pilot programs or based on the results of pilot programs—

''(I) to improve the accuracy of reports;

''(II) to lessen the burden of reporting;

''(III) to facilitate the Secretary's ability to provide public summaries of the reports; or

''(IV) to improve the Secretary's ability to use the reports, or the public's ability to use the summaries under paragraph (5), to understand the relationship between sales, distribution, and end-use practices with respect to feed con-

taining new animal drugs described in paragraph (1) and antimicrobial resistance trends in microbes in animals, animal food products, and humans.

''(5)(A) Each report under paragraph (3) or (4) shall—

''(i) be submitted electronically not later than March 31 each year;

''(ii) cover the period of the preceding calendar year;

''(iii) include separate information for each month of such calendar year; and

''(iv) be in such format as the Secretary may require.

''(B) In specifying a format under subparagraph (A)(iv), the Secretary shall seek to ensure that such format enables the data reported to be integrated or otherwise easily associated and compared with data from other Federal databases containing data on—

''(i) drug sales for human use; and

''(ii) rates of antimicrobial resistance in bacteria in and on animals, animal food products, and people.

''(C) The Secretary may share information reported under paragraph (3) or (4) with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act.

''(D)(i) Not later than November 30 each year, the Secretary shall make publicly available summaries of the information reported under paragraphs (3) and (4).

''(ii) For each summary under clause (i), except as provided in clause (iii), the Secretary shall—

''(I) report data by antimicrobial drug class;

''(II) for each such antimicrobial drug class, specify—

''(aa) the quantity of drugs sold or distributed per dosage form;

''(bb) the percentage of drugs sold or distributed with labeled indications that fall within each of the following categories: growth promotion, feed efficiency, or other production purposes; disease prevention; disease control; and disease treatment;

''(cc) the quantity of drugs sold or distributed per each of the following mar-

keting categories: over-the-counter, prescription, and veterinary feed directive;

"(dd) the quantity of drugs sold or distributed per State of sale or distribution; and

"(ee) the known or estimated quantity of drugs sold or distributed for each food-producing animal and, where feasible, production class of such animal; and

"(III) for each feed sold or distributed under a veterinary food directive for which reporting is required under paragraph (4), include the information reported pursuant to subclauses (I), (II), and (III) of paragraph (4)(A)(iii).

"(iii) For any antimicrobial drug class with fewer than 3 sponsors of approved new animal drugs, instead of reporting data under clause (ii), the Secretary shall for each such class—

"(I) report data by category of importance of the antimicrobial drugs within that class to human medicine, as determined by the Secretary; and

"(II) to the extent feasible for each such category, specify—

''(aa) the quantity of drugs sold or distributed per dosage form;

''(bb) the percentage of drugs sold or distributed with labeled indications that fall within each of the following categories: growth promotion, feed efficiency, or other production purposes; disease prevention; disease control; and disease treatment;

''(cc) the quantity of drugs sold or distributed per each of the following marketing categories: over-the-counter, prescription, and veterinary feed directive; and

''(dd) the quantity of drugs sold or distributed per State of sale or distribution.

''(iv) In carrying out this subparagraph, the Secretary shall report data in a manner consistent with protecting both national security and confidential business information.

''(E) In this paragraph, the terms 'live poultry dealer' and 'swine contractor' have the meanings given to those terms in section 2 of the Packers and Stockyards Act, 1921.''.

(b) RULE OF APPLICATION.—The amendment made by this section applies to reports under paragraphs (3)

and (4) of section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) (as amended by subsection (a)) that cover the period of calendar year 2014 or any subsequent calendar year. The provisions of section 512(l)(3) of such Act, as in effect the day before the date of enactment of this Act, apply to reports that cover the period of calendar year 2013.

SEC. 5. ENHANCED COLLABORATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE DEPARTMENT OF AGRICULTURE.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall increase collaboration and coordination with the Secretary of Agriculture to expand and coordinate the collection of data on the use of antimicrobial drugs in or on cattle, swine, chickens, turkeys, and such other food-producing animal species as agreed to by the Secretary of Health and Human Services and the Secretary of Agriculture, including by providing information to the Secretary of Agriculture for use by—

(1) the Animal and Plant Health Inspection Service to help inform its collection of data through the National Animal Health Monitoring System; and

(2) the Economic Research Service to help inform its collection of data through the Agricultural Resource Management Survey.

SEC. 6. ACTION BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) PUBLICATION OF FINAL GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish a final version of draft guidance #213, 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''.

(b) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 3 years after the publication of final guidance pursuant to subsection (a), the Comptroller General of the United States shall commence a study to evaluate—

(A) the voluntary approach used by the Food and Drug Administration to eliminate injudicious use of antimicrobial drugs in food-producing animals; and

(B) the effectiveness of the data collection activities conducted by the Food and Drug Administration regarding antimicrobial resistance.

(2) REPORT.—Not later than 1 year after commencing the study required by paragraph (1), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of such study.

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