REAUTHORIZATION OF ANIMAL DRUG USER FEES: ADUFA AND AGDUFA

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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WITNESSES

SUBMITTED MATERIAL

REAUTHORIZATION OF ANIMAL DRUG USER FEES: ADUFA AND AGDUFA

TUESDAY, APRIL 9, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 4 p.m., in room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Burgess, Shimkus, Gingrey, Lance, Guthrie, Griffith, Ellmers, Upton (ex officio), Pallone, Capps, Green, Barrow, Christensen, Waxman (ex officio).

Also present: Representative Gardner.

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Matt Bravo, Professional Staff Member; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; John O'Shea, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Tom Wilbur, Digital Media Advisor; Alli Corr, Minority Policy Analyst; Eric Flamm, Minority FDA Detailee; Karen Lightfoot, Minority Communications Director and Senior Policy Advisor; Karen Nelson, Minority Deputy Committee Staff Director for Health; and Rachel Sher, Minority Senior Counsel.

Mr. PITTS. Time of 4 o'clock having arrived, this subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing focuses on the reauthorization of two successful programs, the Animal Drug User Fee Act, ADUFA, and the Animal Generic Drug User Fee Act, AGDUFA.

[The bills follow:]

.....

(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. SHIMKUS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs.

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

SECTION 1. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This Act may be cited as the "Animal Drug User Fee Amendments of 2013".

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug ap-

plications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 2. DEFINITIONS.

Section 739 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11) is amended to read as follows:

"SEC. 739. DEFINITIONS.

"For purposes of this part:

"(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

"(2) The term 'supplemental animal drug application' means—

"(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

"(B) a request to the Secretary to approve a change to an application approved under section 512(e)(2) for which data with respect to safety or effectiveness are required.

"(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

"(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

"(5) The term 'investigational animal drug submission' means—

"(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an

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animal drug application or a supplemental animal drug application; or

"(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

"(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

"(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

"(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal

drug applications, supplemental animal drug applications, and investigational animal drug submissions:

"(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

"(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements, or submissions in condition for approval.

"(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

"(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applica-

tions, and investigational animal drug submissions.

"(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

"(F) Development of standards for products subject to review.

"(G) Meetings between the agency and the animal drug sponsor.

"(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.

"(9) The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses in connection with the process for the review of animal drug applications for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental

animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

"(B) management of information and the acquisition, maintenance, and repair of computer resources;

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

"(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

"(10) The term 'adjustment factor' applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.

"(11) The term 'person' includes an affiliate thereof.

"(12) The term 'affiliate' refers to the definition set forth in section 735(11).".

SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) is amended to read as follows:

"SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

"(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

"(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

"(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

"(i) A fee established in subsection (c) for an animal drug application, except an animal drug application described in section 512(d)(4).

"(ii) A fee established in subsection (c), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

"(I) a supplemental animal drug application for which safety or effectiveness data are required; and

"(II) an animal drug application described in section 512(d)(4).

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

"(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

"(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or

supplemental animal drug application which is refused for filing.

"(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

"(2) ANIMAL DRUG PRODUCT FEE.—

"(A) IN GENERAL.—Each person—

"(i) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

"(ii) who, after September 1, 2003, had pending before the Secretary an ani-

mal drug application or supplemental animal drug application,

shall pay for each such animal drug product the annual fee established in subsection (c).

"(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

"(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

"(ii) January 31 of each year.

"(C) LIMITATION.—Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

"(3) ANIMAL DRUG ESTABLISHMENT FEE.—

"(A) IN GENERAL.—Each person—

"(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

"(ii) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

"(iii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

"(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product

during the fiscal year. The fee under this paragraph for a fiscal year shall be due upon the later of—

"(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

"(ii) January 31 of each year.

"(C) LIMITATION.—

"(i) IN GENERAL.—An establishment shall be assessed only one fee per fiscal year under this section, subject to clause (ii).

"(ii) CERTAIN MANUFACTURERS.—If a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

"(4) ANIMAL DRUG SPONSOR FEE.—

"(A) IN GENERAL.—Each person—

"(i) who meets the definition of an animal drug sponsor within a fiscal year; and

"(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual sponsor fee as established under subsection (c).

"(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due upon the later of—

"(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

"(ii) January 31 of each year.

"(C) LIMITATION.—Each animal drug sponsor shall pay only one such fee each fiscal year.

"(b) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g)—

"(A) for fiscal year 2014, the fees required under subsection (a) shall be established to generate a total revenue amount of $23,600,000; and

"(B) for each of fiscal years 2015 through 2018, the fees required under subsection (a) shall be established to generate a total revenue amount of $21,600,000.

"(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

"(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

"(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

"(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

"(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

"(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

"(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

"(2) INFLATION ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

"(A) one;

"(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3

years of the preceding 4 fiscal years for which data are available; and

"(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under this paragraph.

"(3) WORKLOAD ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, after the revenue amounts established in subsection (b) are adjusted for inflation in accordance with paragraph (2), the revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review

of animal drug applications. With respect to such adjustment—

"(A) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary;

"(B) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies; and

"(C) under no circumstances shall such adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (2).

"(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is

necessary to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

"(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

"(d) FEE WAIVER OR REDUCTION.—

"(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—

"(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;

"(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person;

"(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

"(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

"(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

"(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or

"(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

"(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

"(3) RULES FOR SMALL BUSINESSES.—

"(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

"(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

"(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

"(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application, or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

"(f) ASSESSMENT OF FEES.—

"(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after

fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments, and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

"(ii) shall be available to defray increases in the costs of the resources allo-

cated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

"(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

"(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

"(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

"(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

"(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the

cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

"(B) RECOVERY OF COLLECTION SHORTFALLS.—

"(i) FISCAL YEAR 2016.—For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

"(ii) FISCAL YEAR 2017.—For fiscal year 2017, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under

this section and appropriated for fiscal year 2015 falls below the amount of fees authorized for fiscal year 2015 under paragraph (3).

"(iii) FISCAL YEAR 2018.—For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section (including any reduction in the authorized amount under subparagraph (A)), shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2016 and 2017 (including estimated collections for fiscal year 2017) falls below the cumulative amount of fees authorized under paragraph (3) for fiscal years 2016 and 2017.

"(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for

a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

"(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

"(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

"(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.".

SEC. 4. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) is amended to read as follows:

"SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1(b) of the Animal Drug User Fee Amendments of 2013 toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

"(b) FISCAL REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

"(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

"(d) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2018, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) veterinary professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization;

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall

hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2018, the Secretary shall transmit to Congress the revised recommenda-

tions under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 5. SAVINGS CLAUSE.

Notwithstanding the amendments made by this Act, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of the enactment of

this Act, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. 6. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after October 1, 2013, regardless of the date of the enactment of this Act.

SEC. 7. SUNSET DATES.

(a) AUTHORIZATION.—Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall cease to be effective October 1, 2018.

(b) REPORTING REQUIREMENTS.—Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2019.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 108 of the Animal Drug User Fee Amendments of 2008 (Public Law 110–316) is repealed.

(2) CONFORMING AMENDMENT.—The Animal Drug User Fee Amendments of 2008 (Public Law 110–316) is amended in the table of contents in section 1, by striking the item relating to section 108.

(d) TECHNICAL CLARIFICATION.—Effective November 18, 2003, section 5 of the Animal Drug User Fee Act of 2003 (Public Law 108–130) is repealed.

.....

(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to generic new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. GARDNER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to generic new animal drugs.

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

SECTION 1. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This Act may be cited as the "Animal Generic Drug User Fee Amendments of 2013".

(b) FINDING.—The fees authorized by this Act will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated

applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 2. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) is amended to read as follows:

"SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

"(a) TYPES OF FEES.—Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

"(1) ABBREVIATED APPLICATION FEE.—

"(A) IN GENERAL.—Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (c) for such an application.

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

"(C) EXCEPTIONS.—

"(i) PREVIOUSLY FILED APPLICATION.—If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

"(ii) CERTAIN ABBREVIATED APPLICATIONS INVOLVING COMBINATION ANIMAL DRUGS.—An abbreviated application for an animal drug described in section 512(d)(4) (commonly referred to as a 'combination animal drug') and submitted on or after October 1, 2013, shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

"(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

"(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

"(2) GENERIC NEW ANIMAL DRUG PRODUCT FEE.—

"(A) IN GENERAL.—Each person—

"(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 510; and

"(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (c).

"(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

"(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

"(ii) January 31 of each year.

"(C) LIMITATION.—Such fee shall be paid only once for each generic new animal drug

product for a fiscal year in which the fee is payable.

"(3) GENERIC NEW ANIMAL DRUG SPONSOR FEE.—

"(A) IN GENERAL.—Each person—

"(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

"(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c).

"(B) PAYMENT; FEE DUE DATE.—Such fee shall be due each fiscal year upon the later of—

"(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

"(ii) January 31 of each year.

"(C) AMOUNT OF FEE.—Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

"(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

"(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

"(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

"(b) FEE AMOUNTS.—Subject to subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

"(1) TOTAL FEE REVENUES FOR APPLICATION FEES.—The total fee revenues to be collected in abbreviated application fees under subsection (a)(1)

shall be $1,832,000 for fiscal year 2014, $1,736,000 for fiscal year 2015, $1,857,000 for fiscal year 2016, $1,984,000 for fiscal year 2017, and $2,117,000 for fiscal year 2018.

"(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be $2,748,000 for fiscal year 2014, $2,604,000 for fiscal year 2015, $2,786,000 for fiscal year 2016, $2,976,000 for fiscal year 2017, and $3,175,000 for fiscal year 2018.

"(3) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in generic new animal drug sponsor fees under subsection (a)(3) shall be $2,748,000 for fiscal year 2014, $2,604,000 for fiscal year 2015, $2,786,000 for fiscal year 2016, $2,976,000 for fiscal year 2017, and $3,175,000 for fiscal year 2018.

"(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

"(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue

amounts established under subsection (b) and the adjustments provided under this subsection.

"(2) WORKLOAD ADJUSTMENT.—The fee revenues shall be adjusted each fiscal year after fiscal year 2014 to reflect changes in review workload. With respect to such adjustment:

"(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

"(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b).

"(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

"(4) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds

that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

"(e) EFFECT OF FAILURE TO PAY FEES.—An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

"(f) ASSESSMENT OF FEES.—

"(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees

appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug sponsors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

"(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of

Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

"(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

"(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

"(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $7,328,000 for fiscal year 2014;

"(B) $6,944,000 for fiscal year 2015;

"(C) $7,429,000 for fiscal year 2016;

"(D) $7,936,000 for fiscal year 2017; and

"(E) $8,467,000 for fiscal year 2018;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees.

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years

2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

"(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

"(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of abbreviated appli-

cations for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(k) DEFINITIONS.—In this section and section 742:

"(1) ABBREVIATED APPLICATION FOR A GENERIC NEW ANIMAL DRUG.—The terms 'abbreviated application for a generic new animal drug' and 'abbreviated application' mean an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2). Such term does not include a supplemental abbreviated application for a generic new animal drug.

"(2) ADJUSTMENT FACTOR.—The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

"(A) for purposes of subsection (f)(1), such Index for October 2002; and

"(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

"(3) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term 'costs of resources allocated for the proc-

ess for the review of abbreviated applications for generic new animal drugs' means the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

"(B) management of information, and the acquisition, maintenance, and repair of computer resources;

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

"(D) collecting fees under this section and accounting for resources allocated for the re-

view of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

"(4) FINAL DOSAGE FORM.—The term 'final dosage form' means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

"(5) GENERIC NEW ANIMAL DRUG.—The term 'generic new animal drug' means a new animal drug that is the subject of an abbreviated application.

"(6) GENERIC NEW ANIMAL DRUG PRODUCT.—The term 'generic new animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

"(7) GENERIC NEW ANIMAL DRUG SPONSOR.—The term 'generic new animal drug sponsor' means

either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

"(8) INVESTIGATIONAL SUBMISSION FOR A GENERIC NEW ANIMAL DRUG.—The terms 'investigational submission for a generic new animal drug' and 'investigational submission' mean—

"(A) the filing of a claim for an investigational exemption under section 512(j) for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

"(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

"(9) PERSON.—The term 'person' includes an affiliate thereof (as such term is defined in section 735(11)).

"(10) PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term 'process for the review of abbreviated applications for generic new animal drugs' means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

"(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

"(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

"(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

"(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

"(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

"(F) Development of standards for products subject to review.

"(G) Meetings between the agency and the generic new animal drug sponsor.

"(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

"(11) SUPPLEMENTAL ABBREVIATED APPLICATION FOR GENERIC NEW ANIMAL DRUG.—The terms 'supplemental abbreviated application for a generic

new animal drug' and 'supplemental abbreviated application' mean a request to the Secretary to approve a change in an approved abbreviated application.".

SEC. 3. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) is amended to read as follows:

"SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1(b) of the Animal Generic Drug User Fee Amendments of 2013 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

"(b) FISCAL REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

"(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

"(d) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2018, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) veterinary professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization;

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 4. SAVINGS CLAUSE.

Notwithstanding the amendments made by this Act, part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this Act, shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. 5. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2013, regardless of the date of enactment of this Act.

SEC. 6. SUNSET DATES.

(a) AUTHORIZATION.—Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall cease to be effective October 1, 2018.

(b) REPORTING REQUIREMENTS.—Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) shall cease to be effective January 31, 2019.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 204 of the Animal Generic Drug User Fee Act of 2008 (Public Law 110–316) is repealed.

(2) CONFORMING AMENDMENT.—The Animal Generic Drug User Fee Act of 2008 (Public Law 110–316) is amended in the table of contents in section 1, by striking the item relating to section 204.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. In 2003, ADUFA I was authorized to help the Food and Drug Administration review of animal drugs. Similar to the prescription drug user fee for human drugs, under ADUFA, FDA collected funds to expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors. The program was authorized for 5 years, and Congress renewed the program for an additional 5 years in ADUFA II in 2008.

In fiscal year 2012, FDA completed 747 ADUFA reviews. And according to FDA, the agency has exceeded all performance goals outlined in ADUFA I and II. However, absent congressional action, FDA's ability to collect these user fees will expire September 30, 2013.

FDA and industry have negotiated an agreement regarding the size and scope of ADUFA III, which would extend the program through fiscal year 2018, and these recommendations were delivered to the committee in February. Under the negotiated proposal industry would pay approximately $23.6 million in fiscal year 2014 and similar amounts adjusted for inflation for fiscal years 2015 to 2018. Twenty percent of this total would come from application fees, 27 percent from product fees, 27 percent from sponsor fees, and 26 percent from establishment fees. The ADUFA III proposal also includes an annual offset adjustment based on any collection shortfall in previous years.

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for 5 years in order to improve the review of abbreviated new animal drug applications, eliminate application backlogs and reduce review times. To date, according to the FDA, the agency has exceeded all performance goals but one from AGDUFA I. This program also expires September 30, 2013, unless it is reauthorized, and FDA and industry have negotiated an agreement for AGDUFA II.

Under the proposed AGDUFA II agreement, industry would pay $7.3 million in fiscal year 2014, which allows for hiring of 22 FTEs and includes a one-time cost of $850,000 for information technology; $6.9 million for fiscal year 2015; $7.4 million for fiscal year 2016; $7.9 million for fiscal year 2017; and $8.4 million for fiscal year 2018. These fees would be paid through application fees, 25 percent of the total; product fees, 37½ percent; and sponsor fees, also 37½ percent of the total.

The legislation to reauthorize ADUFA III was introduced today by Congressman John Shimkus, and the AGDUFA II reauthorization sponsored by Representative Cory Gardner was also introduced today.

I want to welcome all of our witnesses, thank them for being here today, look forward to your testimony. We have a new set of lights, and so green is go with your statement, a 5-minute statement. Yellow I think there is 30 seconds left. Red is you are over time. So thank you.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing focuses on the reauthorization of two successful programs—the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

In 2003, ADUFA I was authorized to help the Food and Drug Administration's (FDA) review of animal drugs.

Similar to the Prescription Drug User Fee for human drugs, under ADUFA, FDA collected funds to help expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors.

The program was authorized for 5 years, and Congress renewed the program for an additional 5 years in ADUFA II in 2008.

In FY2012, FDA completed 747 ADUFA reviews, and, according to FDA, the agency has exceeded all performance goals outlined in ADUFA I and II.

However, absent Congressional action, FDA's ability to collect these user fees will expire September 30, 2013.

FDA and industry have negotiated an agreement regarding the size and scope of ADUFA III, which would extend the program through FY2018, and these recommendations were delivered to the Committee in February.

Under the negotiated proposal, industry would pay approximately $23.6 million in FY2014, and similar amounts, adjusted for inflation, for FYs 2015–2018.

Twenty percent of this total would come from application fees, 27% from product fees, 27% from sponsor fees, and 26% from establishment fees.

The ADUFA III proposal also includes an annual offset adjustment based on any collection shortfall in previous years.

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for 5 years, in order to improve the review of abbreviated new animal drug applications (ANADAS), eliminate application backlogs, and reduce review times.

To date, according to FDA, the agency has exceeded all performance goals but one from AGDUFA I.

This program also expires September 30, 2013 unless it is reauthorized, and FDA and industry have negotiated an agreement for AGDUFA II.

Under the proposed AGDUFA II agreement, industry would pay:

- $7,328,000 in FY2014 (which allows for the hiring of 22 FTEs and includes a one-time cost of $850,000 for information technology);
- $6,944,000 in FY2015;
- $7,429,000 in FY2016;
- $7,936,000 in FY2017; and
- $8,467,000 in FY2018.

These fees would be paid through application fees (25% of the total), product fees (37.5%), and sponsor fees (also 37.5% of the total).

The legislation to reauthorize ADUFA III was introduced today by Rep. John Shimkus, and the AGDUFA II reauthorization, sponsored by Rep. Cory Gardner, also was introduced today.

I want to welcome all of our witnesses and thank them for being here today. I look forward to your testimony.

Thank you. At this time, I would like to request unanimous consent for Congressman Gardner to participate in the subcommittee hearing. Without objection so ordered. I now yield the remainder of my time to Rep. Gardner.

Mr. PITTS. At this time I would like to request unanimous consent for Congressman Gardner to participate in the subcommittee hearing. Without objection, so ordered.

I now yield the remainder of my time to Representative Gardner.

OPENING STATEMENT OF HON. CORY GARDNER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. GARDNER. Thank you, Mr. Chairman, and I thank you for allowing me to be here today; Ranking Member Pallone and other colleagues on the subcommittee for the opportunity to participate today. And I would also like to congratulate Congressman Shimkus

for his introduction of the Animal Drug User Fee Amendments Act of 2013.

My congressional district is home to over 2.8 million head of cows, 450,000 hogs and pigs, and close to 160,000 sheep and goats. There is far more livestock in my district than there are people. At least that is what they tell me in Colorado. But, in fact, the State of Colorado is the fifth largest State in the Nation when it comes to cattle on feed.

The ADUFA and AGDUFA programs have been a success at FDA, and the continuation of these important programs will ensure that livestock producers in Colorado and indeed throughout the country will continue to have access to safe and effective animal drugs to treat their herds.

In particular, the Animal Generic and Drug User Fee Program at FDA has achieved noteworthy success since first being authorized in 2008. FDA decreased a significant backlog of applications and reduced the review time for new animal drug applications. The reauthorization of AGDUFA will continue this progress at FDA and other—and our producers with cost-effective generic products that are available to the market on the market faster.

It is an honor to have the opportunity to lead the reauthorization of AGDUFA through this committee, and I look forward to working with my colleagues to ensure its passage and to hearing from the witnesses today. And with that, Mr. Chairman, thank you, and I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentlemen, and now recognizes the ranking member of the subcommittee Mr. Pallone for 5 minutes for his opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE JR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

I am pleased that the committee is having a hearing on two important bills today, the Animal Drug User Fee amendments and the Animal Generic Drug User Fee amendments, both of which I have cosponsored. Without congressional action the current agreements will expire at the end of this fiscal year, which would have a serious and harmful impact on the ability of FDA's Center for Veterinary Medicine to review new and generic drug applications in a timely manner.

Prior to 2003, FDA's review of animal drug submissions was taking over a year and a half to be completed, and this obviously led to serious concerns that new and innovative pharmaceutical products were not making their way on to the marketplace in order to treat our Nation's pets, as well as food animals that help sustain the Nation's food supply. Accordingly in 2003, Congress first enacted ADUFA to help improve the FDA review of new animal drugs.

Like other user fee programs for human drugs, ADUFA authorized the FDA to collect fees to help ensure that the agency had the resources it needed to help expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors.

In 2008, because of the success of this program, Congress reauthorized ADUFA for 5 years—that is ADUFA II—and so here we are again 5 years later. In order for the FDA to continue the success of this program, Congress must act to reauthorize these user fees.

Under the proposed ADUFA III agreement, the industry would pay approximately $23.6 million in fiscal year 2014 and similar amounts in the remaining 4 years based on inflation adjusters. This includes some resources for technology infrastructure in the first year. These fees will continue to allow the agency to more efficiently and effectively review an animal drug applications and provide industry with predictability and speedier reviews.

In 2008, Congress authorized the AGDUFA program for 5 years in order to improve the review of abbreviated new animal drug applications or generic versions of animal drugs. AGDUFA enabled the agency to eliminate its application backlog and reduce review times. Similar to ADUFA, FDA and industry negotiated an agreement regarding the size and scope of an agreement for generic animal drugs, or AGDUFA.

Under the new proposal before us today, the industry would pay $7.3 million in fiscal year 2014, which includes technology funding; 6.944 million in fiscal years 2015; 7.429 million in fiscal year 2016; 7.936 million in fiscal year 2017; and, finally, 8.467 million in fiscal year 2018. Once implemented, AGDUFA will continue to speed lower-cost animal drugs to the marketplace and bring significant savings to ranchers, farmers, and pet owners.

I think we can all agree that these programs have been particularly effective. This project should not be interrupted, and so, Mr. Chairman, I stand ready to work with you so that this process will be expeditious, and we can pass these agreements into law as soon as possible.

Let me close by saying that I recognize that there is a growing concern among stakeholders and some members of the subcommittee about the use of antibiotics in food animals. Clearly we face significant challenges when it comes to maintaining the effective use of antibiotics. With fewer and fewer innovative antibiotic products coming down the pharmaceutical pipeline, it is even more important that we keep antibiotics that are currently on the market working. So I look forward to hearing from our second panel about how bacteria that are resistant to antibiotics begin to proliferate, and what type of threat this poses to humans.

So thank you again for all the witnesses for being with us, and we are looking forward to your testimony.

Nobody wants my time, right? No. I yield back.

Mr. PITTS. The chair thanks the gentlemen.

I now recognize the chairman of the full committee Mr. Upton for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman. I appreciate today's hearing on the reauthorization of the Animal Drug User Fee Act, as well as the Animal Generic Drug User Fee Act.

You know, Congress first created ADUFA back in 2003 and AGDUFA back in 2008, and together these programs have yielded many benefits for the American people, and they have ensured that veterinarians, livestock producers, poultry producers, pet owners have access to new and affordable animal drugs to keep their animals healthy. They have assisted animal drug producers by fostering a stable and predictable FDA review process. And finally, they have helped American consumers by keeping that food supply safe. For companies like Zoetis, which employs over 700 people in my district, these programs are essential for them to keep producing top-of-the-line drugs for pets and livestock.

I was fortunate enough to be the lead House sponsor of the original ADUFA bill back in 2003, and it is great to see how successful it has been and how many Americans it has, in fact, helped. I believe that there is a bipartisan, bicameral interest in getting these user fees reauthorized well before they expire at the end of September of this year, and I intend to do all that I can to make sure that that effort happens. So I look forward to working with all of our colleagues on those bills. I want to particularly thank Mr. Gardner and Mr. Shimkus for their leadership on both of these pieces of legislation respectively, and I yield the balance of my time to John Shimkus.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Thank you for holding today's hearing on the reauthorization of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

Congress first created ADUFA back in 2003 and AGDUFA in 2008. Together, these programs have yielded many benefits for the American people. They have ensured that veterinarians, livestock producers, poultry producers and pet owners have access to new and affordable animal drugs to keep their animals healthy. They have assisted animal drug producers by fostering a stable and predictable FDA review process. Finally, they have helped American consumers by keeping the food supply safe.

For companies like Zoetis, which employs over 700 folks in my district, these programs are essential for them to keep producing top of the line drugs for pets and livestock.

I was fortunate enough to be the lead House sponsor of the original ADUFA legislation in 2003, and it is great to see how successful it has been and how many Americans it has helped.

I believe there is bipartisan, bicameral interest in getting these user fees reauthorized well before they expire at the end of September. I intend to do all I can to make this reauthorization effort bipartisan, and I look forward to working with my Democratic colleagues on these bills.

I thank John Shimkus and Cory Gardner for their leadership on ADUFA and AGDUFA, respectively.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman. Thank you also, Chairman Pitts, and I appreciate holding this hearing on the user fee reauthorization bills that are important to our agriculture community and the consumers they serve.

Today I am pleased to introduce legislation reauthorizing the Animal Drug User Fee Act, along with companion legislation to reauthorize generic drug user fees, introduced by my colleague from Colorado Cory Gardner. Together these bills will provide the FDA

with critical resources to improve the animal drug approval process and allow drug manufacturers to bring innovative products to the market, improving food safety and animal health. These are the same tools the FDA has successfully utilized to reduce application backlogs and provide a more predictable process since ADUFA was first signed into law over 10 years ago.

ADUFA is important to many of my constituents in southern Illinois as well as rural and agricultural communities across the country. It is a fact of life that animals get sick, and it is important for veterinarians to have the ability to provide the best drugs and treatment available. H.R. 1407 and 1408 provide veterinarians access to products to prevent, control and treat animal diseases in our pets and livestock.

Livestock producers benefit as well. Last week when I announced the introduction of ADUFA reauthorization, I stood with beef and pork producers from my district who spoke on the importance of this legislation to their businesses and livelihoods. They rely on the timely availability of these drugs to provide a safe food product to maintain the health of their herds.

At the end of the day, all American consumers benefit from the availability of safe and affordable food. This will have positive impact on everyone in our district, from producers on family farms to pet owners and consumers in major urban cities and suburbs around the country.

I want to thank Chairmen Upton and Pitts, along with Ranking Member Waxman and Pallone for becoming original cosponsors of these reauthorizations, and I look forward to working with them to move these bills through the committee. I believe the hearing today will be a productive next step for us to move forward on swift bipartisan passage of H.R. 1407 and 1408 through the House.

Thank you to our witnesses from the FDA and the animal health community for being here today. I look forward to hearing your input on the importance of a clean reauthorization process.

With that, Mr. Chairman, I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the ranking member of the full committee Mr. Waxman, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Our hearing today is going to examine FDA's animal drug user fee programs, which have been successful at speeding both brand and generic drugs for animals to the market, and that is very important. But the reauthorization of these user fee programs also gives us an opportunity to look at providing FDA with new tools to address a glaring public health crisis, the problem of antibiotic resistance.

Antibiotics are truly a lifesaving gift. Unfortunately the more they are used, the less they work. Untold numbers of Americans die or are infected each year by antibiotic-resistant bugs. To remain effective, antibiotics must be used judiciously. To be sure, antibiotics are overprescribed for use in humans. That is a real and

difficult problem and one that requires our attention. But we have to look at all areas in which antibiotics are used and reduce all unnecessary uses.

We know that most antibiotic use occurs on the farm, and much of this use is not to treat sick animals, which everyone agrees is important, but for disease prevention or growth promotion. Unfortunately we don't know exactly how much because it isn't reported anywhere.

We now have an overwhelming body of evidence showing that the overuse of antibiotics in industrial meat production is threatening to destroy the effectiveness of our most important antibiotics for human use. In recent years reports from the Institute of Medicine, GAO and the World Health Organization all describe the global public health threat generated by bacteria that had become resistant as a result of antibiotic use on the farms.

There is a bill that would take steps to curtail the inappropriate use of important human antibiotics. Representative Slaughter's Preservation of Antibiotics for Medical Treatment Act, or PAMTA. We always take these things and put them down as acronyms. This bill has a long history. Congressman Dingell and I introduced the very first version back in 1980 as The Antibiotics Preservation Act.

I think this legislation makes good sense, but it has, unfortunately, never moved very far. At least part of the reason it has failed to move is that industry claims there is not enough data to show a link between the use of antibiotics on the farm and the development of resistant bugs that harm people. That is why we need to ask industry to give us more data on how these drugs are being used. Industry should provide evidence to document its assertion that there is no link. Industry should not be able to have it both ways. We know a lot about how antibiotics are being used in humans thanks to our healthcare system infrastructure. We know very little about the use of antibiotics on farms and ranches.

In the 2008 reauthorization of the animal drug user fee legislation, we took a sensible step by requiring drug companies to make certain limited reports to FDA on their animal antibiotics sales data, but we need to go further. Earlier this year I introduced the Delivering Antibiotic Transparency in Animals Act, or DATA. The DATA Act would enhance the information FDA gets about how these drugs are used by putting modest requirements on the drug companies and the major industrial meat product companies like Tyson or Smithfield Farms.

This is a commonsense bill. There is no prohibition on the use of these drugs. We are simply asking that industry tell us more about the way these drugs are used so that we can learn more about how resistant bugs which are harming Americans every day are bred.

The issue of antibiotic resistance is not new to this committee. In the 111th and 112th Congresses, we held several hearings on this issue. Now is the time for the next step by moving the DATA Act as we work to combat the public health crisis.

I understand the argument for keeping the Animal Drug User Fee Acts free of controversy, but I do think we need to find a way to address this issue soon. We need to ensure that FDA has not only the resources and procedures for speeding safe and effective

animal drugs to market, but also the information to ensure that they are being used judiciously.

I thank you, Mr. Chairman, for holding this hearing today. I look forward to the hearing, hearing from our witnesses, and I yield back a second, the 3, 4 seconds I don't have any longer.

Mr. PITTS. The chair thanks the gentlemen.

That concludes the opening statements by the Members. We have two panels today. I will ask the first panelist to please come forward to the witness table and introduce her at this time.

Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine, U.S. Food and Drug Administration, is our first witness. Thank you for coming. You will have 5 minutes to summarize your written testimony. Your written testimony will be made part of the record. And so at this time, Dr. Dunham, you are recognized for 5 minutes.

STATEMENT OF BERNADETTE DUNHAM, DIRECTOR, CENTER FOR VETERINARY MEDICINE, U.S. FOOD AND DRUG ADMINISTRATION

Dr. DUNHAM. Thank you very much.

Good afternoon, Chairman Pitts, Ranking Member Pallone and members of the subcommittee. I am Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine at the Food and Drug Administration. Thank you for this opportunity to discuss FDA's proposals for reauthorization of the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act.

As you know, these fee programs are designed to expedite access to new therapies for food-producing animals and companion animals, and foster innovation in drug development by enabling FDA to maintain a stable workforce to provide a predictable and timely review process.

These programs have been highly successful and have enabled FDA to eliminate a backlog in application, dramatically reduce the time needed to review animal drug applications and other submissions, improve timely communications with drug sponsors, and achieve other efficiencies in the drug approval process, while still ensuring the drugs are safe and effective.

In my testimony today I will provide the status of FDA's reauthorization activities. I will also provide some information about each program, our achievements to date, and our proposed changes.

The user fee provisions of ADUFA II and AGDUFA I will sunset on October 1st, 2013, if not reauthorized. Timely reauthorization is needed to ensure there is it no disruption to these important programs.

FDA began the reauthorization process with the public meeting held November 7th, 2011, and began discussions with stakeholders in February 2012. FDA published the negotiated recommendations in the Federal Register on December 5th, 2012, and solicited public comment. Another public meeting to get input on the recommendations was held December 18th, 2012. The final recommendations transmitted to Congress include for each program the goals letter outlining the performance metrics, the proposed legislative language, and a summary of public comments.

FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the agency's mission to protect and promote public health. Under the original Animal Drug User Fee Act enacted in 2003, the agency agreed to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of new animal drug review process. The additional funding enabled FDA to increase the number of review staff by approximately 30 percent.

In 2008, before ADUFA I expired, Congress passed ADUFA II, which included an extension of the program for an additional 5 years. And I am pleased to report that FDA has exceeded all of the performance goals established under ADUFA for each year of this critical program.

During the first 5 years of the program, the agency was able to dramatically reduce review times from 500 days to 180 days and completely eliminate the backlog of 833 submissions within the first year.

Due to the current success of the program, FDA and industry agree that only minor refinements to the performance goals that ADUFA II established were necessary. Our recommendations relating to the financial enhancements of this program include a new statutory inflation adjuster, a new provision for recovering collection shortfalls, and a modification of the workload adjuster.

To increase revenue stream stability, reduce application fee costs and minimize the potential for collection shortfalls, the recommendations also modify the fee revenue distribution. FDA's recommendation to Congress after consultation with the regulated industry is that the total fee revenue estimate for fiscal year 2014 will be $23.6 million, which includes a one-time information technology funding in the amount of $2 million.

AGDUFA I authorized FDA's first-ever generic animal drug user fee program, and the additional funding enabled FDA to increase the number of review staff by approximately 45 percent. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic animal drug products are safe and effective, and provided pet owners, ranchers and farmers with greater access to lower-cost therapeutic drugs. FDA agreed to meet performance goals to expedite the review of generic applications and submissions without compromising the quality of the agency's review.

During the 4 years of AGDUFA I, FDA has exceeded every goal every year, with one minor exception. We missed a performance goal by 1 day for one submission of an investigational generic new animal drug in 2009.

The additional resources provided under AGDUFA I enabled FDA to completely eliminate a backlog of 680 submissions in 22 months. In addition, the agency has been able to dramatically reduce review times from 700 days to 270 days.

FDA's goals for AGDUFA II are to sustain and enhance the core program's operation and performance, while providing predictable review times and resources sufficient to keep pace with actual costs. FDA and industry agreed to shorter review times for certain reactivations and resubmissions and to implement a process for timely foreign inspections.

Our recommendations for financial enhancements for AGDUFA II include a fixed inflation adjuster of 4 percent each year to achieve the proposed revenue levels, and modification of the workload adjuster to ensure that it adequately captures FDA's workload. We also recommend modifying the fee revenue distribution to increase the stability of the revenue stream and reduce application fee costs.

The total 5-year revenue for AGDUFA I was $27.1 million. The proposed total 5-year revenue for AGDUFA II will be $38.1 million, which includes a one-time IT funding for $850,000 for fiscal year 2014 for the first year planned of a total of $7.328 million.

FDA's ADUFA and AGDUFA legislative proposals represent considerable input from and agreement of stakeholders, the public, and the agency. ADUFA and AGDUFA are widely regarded as extremely successful programs. The recommendations we have submitted for reauthorization of these programs will ensure FDA has a stable workforce to provide the predictable and timely review process the drug sponsors need in order to foster innovation. They will also provide for expedited access to new therapies for food-producing animals and companion animals, while ensuring the drugs are safe and effective.

Thank you for the opportunity to discuss ADUFA and AGDUFA programs, and I am happy to answer any questions.

Mr. PITTS. Thank you, Dr. Dunham, for your opening statement.

[The prepared statement of Dr. Dunham follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

BERNADETTE M. DUNHAM, D.V.M., PH.D.

DIRECTOR, CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

APRIL 9, 2013

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. I am Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine (CVM) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss FDA's proposals for the reauthorization of the Animal Drug User Fee Act (ADUFA III) and the Animal Generic Drug User Fee Act (AGDUFA II).

As you know, these fee programs are designed to expedite access to new therapies for food-producing animals and companion animals and foster innovation in drug development by enabling FDA to maintain a stable workforce to provide a predictable and timely review process. These programs have been highly successful and have enabled FDA to eliminate a backlog in applications, dramatically reduce the time needed to review animal drug applications and other submissions, improve timely communications with drug sponsors, and achieve other efficiencies in the drug approval process, while still ensuring that the drugs are safe and effective.

In my testimony today, I will provide the status of FDA's reauthorization activities. I will also provide some information about each program, our achievements to date, and our proposed changes.

STATUS OF FDA'S REAUTHORIZATION ACTIVITIES

The user fee provisions of ADUFA II and AGDUFA I will sunset on October 1, 2013, if not reauthorized. Timely reauthorization is needed to ensure there is no disruption to these important programs. FDA began the reauthorization process with a public meeting held on November 7, 2011. In February 2012, FDA began discussions to get input from our stakeholders to help us develop our recommendations for reauthorization. FDA consulted with representatives of patient and consumer advocacy groups, veterinary professionals, scientific and academic experts, and industry associations. FDA then published the negotiated recommendations in the *Federal Register* (FR) on December 5, 2012, and solicited public comment. We also held a second public meeting to get input on the recommendations on December 18, 2012. The final recommendations transmitted to Congress include, for each program, the goals letter outlining the performance metrics, the proposed legislative language, and a summary of public comments.

ADUFA BACKGROUND

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADA) to be central to the Agency's mission to protect and promote public health. One way we protect animal and human health is by approving safe and effective and properly labeled new animal drugs. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. The original Animal Drug User Fee Act enacted in 2003 (ADUFA I) authorized FDA to collect user fees that were to be dedicated to expediting the review of NADAs in accordance with certain performance goals and to expand

and modernize the new animal drug review program. The Agency agreed, under ADUFA I, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the review of animal drug applications by approximately 30 percent since 2003.

In 2008, before ADUFA I expired, Congress passed ADUFA II, which included an extension of the program for an additional five years (FY 2009 to FY 2013), as well as several enhancements to the program.

ADUFA ACHIEVEMENTS

I am pleased to report that FDA has exceeded all of the performance goals established under ADUFA for each year of this critical program. Under the performance goals of ADUFA, FDA agreed to review and act on submissions within shorter periods of time each successive year. During the first five years of this program, the Agency was able to dramatically reduce review times from 500 days to 180 days and completely eliminate a backlog of 833 submissions within the first year.

With ADUFA II, FDA agreed to further enhance the review process. A key improvement under ADUFA II is the "end-review amendment" (ERA) process that allows FDA reviewers to work with the drug sponsor to amend certain pending submissions. By enhancing communication early in the process, the ERA process allows FDA to decrease the number of

review cycles, which ultimately leads to a shorter time to approval and significant cost-savings for the sponsor. The greatest impact of this new tool has been with submissions of investigational new animal drug (INAD) studies and study protocols. Greater than 90 percent of ERAs resulted in a favorable outcome in the first cycle.

Also as part of ADUFA II, FDA developed an electronic submission tool, which has enabled sponsors to submit applications and submissions electronically, allowing FDA reviewers to evaluate the submissions and correspond with sponsors electronically. Electronic submissions have provided substantial cost savings for both FDA and animal drug sponsors. Approximately 18 percent of submissions were electronic in 2011, the program's first year, and over 50 percent were electronic in 2012. Submissions are received by FDA in minutes rather than days, and correspondence back to sponsors occurs in minutes rather than the several days required for mailing responses.

Further, FDA and the regulated industry participated in eight joint public workshops on mutually agreed-upon topics. This collaboration enhanced communication and transparency on topics critical to the animal drug review process. The workshops discussed in detail the data requirements necessary for drug evaluation and explored scientific approaches to challenges in pharmacokinetics, new emerging issues relative to antiparasitic resistance, and a novel question-based-review (QbR) process for certain reviews. The final two public workshops for FY 2013 will address the evaluation of drugs for use in animal production and data quality for animal drug submissions from sponsors.

ADUFA II also enabled FDA to improve the animal drug review and business processes by facilitating the timely scheduling and conducting of foreign pre-approval inspections. Because of processes developed under ADUFA II, sponsors are now able to voluntarily submit an annual facilities list and notification 30 days prior to submitting an NADA, a supplemental NADA, or an INAD submission to inform FDA that the application or submission includes a foreign manufacturing facility. This advance notice gives FDA more time to plan for any necessary foreign inspections, thus helping to reduce costs and prevent delays during the review of an application or submission.

PROPOSAL FOR ADUFA III

FDA is proposing changes to the performance goals that ADUFA II established to further enhance the process for review of animal drug applications. Due to the current success of the program, FDA and industry agreed that only minor refinements were necessary.

The ERA procedure implemented as part of ADUFA II resulted in an increase in the number of one-cycle reviews; however, certain challenges associated with the process restricted its full utilization. The Agency is proposing, among other changes, to further improve the review process by replacing the ERA with shorter review times for certain resubmissions and reactivations beginning in FY 2015. To allow time for the programming and information management system changes required to make this and other changes, we are proposing to maintain the ADUFA II ERA process and associated review performance goals for FY 2014 for most applications.

FDA agrees to maintain the ADUFA II performance goals regarding work queue procedures, timely meetings with industry, review of administrative NADAs, and pre-approval foreign inspections. To enhance the exchange of scientific information, the Agency and industry agree on the need for industry to submit information earlier in development to enable the parties to reach agreement at a pre-submission conference or begin the review of study protocols. Additionally, FDA will provide increased flexibility for sponsors to submit scientific data or information concurrent with study protocol review.

Our recommendations relating to the financial enhancements of this program include a new statutory inflation adjuster that accounts for changes in FDA's costs related to payroll compensation and benefits as well as changes in non-payroll costs through use of a prescribed methodology that uses the Consumer Price Index as a guide. We also recommend modifying the base years for calculating the workload adjuster to ensure that it adequately captures changes in FDA's workload during ADUFA III.

Additionally, ADUFA III offers the following financial recommendations:

- A new provision for recovering collection shortfalls to ensure adequate funding for the animal drug review process. For example, when FDA sets fees for FY 2016, it may add to the fee revenue the amount of any shortfall in fees collected in FY 2014. This process would follow in subsequent years through the final year adjustment.
- A modified fee revenue distribution to increase revenue stream stability, reduce application fee costs, and minimize the potential for collection shortfalls. The proposed distribution will shift from 25 percent for each fee type in ADUFA II to 20

percent for application fees, 27 percent for product fees, 27 percent for sponsor fees, and 26 percent for establishment fees.

FDA's recommendation to Congress, after consultation with the regulated industry, is that the total fee revenue estimate for FY 2014 will be $23,600,000, which includes one-time Information Technology (IT) funding in the amount of $2,000,000. The proposed statutory language specifies annual revenue of $21,600,000 for each of FY 2015 through FY 2018; however, this amount is subject to a number of possible adjustments, including for inflation, workload, and collection shortfall.

AGDUFA BACKGROUND

AGDUFA I authorized FDA's first-ever generic animal drug user fee program. AGDUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new generic animal drug application review process by approximately 45 percent. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic animal drug products are safe and effective and provided consumers with greater access to lower-cost therapeutic drugs.

Under AGDUFA I, FDA agreed to meet performance goals for certain submissions over five years from FY 2009 through FY 2013. The purpose of establishing these performance goals was to expedite the review of abbreviated new animal drug applications (ANADA) and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions without compromising the quality of the Agency's review.

AGDUFA ACHIEVEMENTS

AGDUFA I established increasingly stringent review performance goals. In the four years of AGDUFA I review performance evaluated to date (FY 2009 to FY 2012), FDA has exceeded every performance goal every year with one minor exception. During the program's first year, the Agency missed the performance goal by one day for one submission of an investigational generic new animal drug. Most importantly, the additional resources provided under AGDUFA I enabled FDA to completely eliminate a backlog of 680 submissions in 22 months. In addition, the Agency has been able to dramatically reduce review times from 700 days to 270 days. The timely approval of generic new animal drugs continues to be a critical component of animal health because it provides quicker access to additional sources of animal drugs at lower cost for ranchers, farmers, and pet owners.

PROPOSAL FOR AGDUFA II

FDA's goals for the legislative proposal to reauthorize AGDUFA I are to sustain and enhance the core program's operation and performance while providing predictable review times and resources sufficient to keep pace with actual costs. The Agency is proposing to maintain the AGDUFA I goals regarding work queue procedures, timely meetings with industry, review of administrative ANADAs, review of protocols without substantial data, and amendments of similar applications and submissions.

FDA and industry agreed to shorter review times for certain reactivations and resubmissions. The Agency also agreed to increased communication and transparency with industry through

timely meetings and question-based-review (QbR) for bioequivalence submissions, which are most often used when a sponsor proposes manufacturing a generic version of an approved off-patent product. The QbR incorporates the most important scientific and regulatory review questions that focus on critical pharmaceutical attributes essential for ensuring generic drug product quality. In addition, FDA further agreed to implement a process for timely foreign inspections as provided in ADUFA II.

Similar to AGDUFA I, our recommendations for financial enhancements for AGDUFA II include a fixed inflation adjuster of four percent each year to achieve the proposed revenue levels. We also recommend modifying the base years for calculating the workload adjuster to ensure that it adequately captures changes in FDA's workload during AGDUFA II. Additionally, the fee revenue distribution has been modified from 30 percent for application fees, 35 percent for product fees, and 35 percent for sponsor fees under AGDUFA I to 25 percent for application fees and 37.5 percent for both product fees and sponsor fees under AGDUFA II. The purpose of changing the fee distribution is to increase the stability of the revenue stream and reduce application fee costs.

The total five-year revenue for AGDUFA I was $27,100,000. The proposed total five-year revenue for AGDUFA II will be $38,100,000, which also includes one-time IT funding in the amount of $850,000 for FY 2014 for a first year planned total of $7,328,000.

CONCLUSION

FDA's ADUFA and AGDUFA legislative proposals represent considerable input from and agreement of stakeholders, the public, and the Agency. ADUFA and AGDUFA are widely regarded as extremely successful programs. The recommendations we have submitted for reauthorization of these programs will ensure FDA has a stable workforce to provide the predictable and timely review process that drug sponsors need to foster innovation. They also will provide for expedited access to new therapies for food-producing animals and companion animals, while still ensuring that the drugs are safe and effective. FDA looks forward to working with you and your staff to achieve a timely reauthorization of these important human and animal health programs.

Thank you for the opportunity to discuss the ADUFA and AGDUFA programs. I would be happy to answer any questions.

Mr. PITTS. I will begin the questioning and recognize myself 5 minutes for that purpose.

Dr. Dunham, Congress first enacted ADUFA in 2003 and AGDUFA in 2008. Would you explain how ADUFA and AGDUFA improved FDA regulations of new animal drug, generic animal drugs as far as benefit to public health is concerned? And then tell us what the new improvements, the improvements in the new proposed ADUFA and AGDUFA agreements, how they would improve that.

Dr. DUNHAM. Yes, sir. These programs have enabled us to adequately have the scientific staff that we need to do our reviews and to afford us the opportunity to bring innovative products to our review process, thereby enhancing and protecting both the health of the animals and from that, very specifically looking at food-producing animals, to ensuring their health is sustained, and therefore any product that you are going to consume should be safe. And the extensive review we have to assure that is something that we have benefited from with this program.

And continuing along that line, that also applies then to the AGDUFA, or generic animal drugs, where, again, the safety, effectiveness and availability of these products which are needed because of the diversity of the species that we have, these programs have both been successful.

And the public health side is both sides, companion animal medicine to ensure they are safe and effective and keeping animals healthy, because, as you know, even with zoonotic medicine, there is an opportunity for problems there. So this is one thing we value very much when we cross over the lines of public health in everything we do for our review process.

The changes that we will be looking at are to further enhance our interaction with our sponsors in working with them earlier as they come forward with innovative products. The more that we can partner with them in regards to reviewing the science behind their innovation, we can address issues of concerns and help them work through this and provide data that can hopefully bring us to a single review. This will allow the expedition of an approved product that is meeting all of our standards for safety and effectiveness, and get those drugs to the veterinarians for them to be able to take care of all the species. And I think the diversity of the species that we deal with is challenging, and for that reason these programs have helped us tremendously.

Mr. PITTS. Thank you.

Why are the ADUFA and AGDUFA agreements so important to livestock, and poultry producers, and veterinarians, and pet owners and consumers? And what are the consequences of the not reauthorizing the animal drug user fee programs?

Dr. DUNHAM. Again, with the success that we have had and the capability of bringing forth more safe and effective products to address the plethora of diseases that we have because we have so many species that we need to look at, this program has led to that success. And there are still many, many more diseases that we need to address with our sponsors.

The program, if we were not to continue this, would, in fact, set us back. The way in which we have been able to have expedited

reviews, i.e., work with our companies to address and review the science, if we don't have the staff to complete that, we are going to be turning back and having slower reviews, and that is going to, I think, lead to harm because we are not going to have the needed products that we want out there to address the concerns of the health of the animals that we take care of every day.

And I do believe that with the programs sustaining us, there is a lot of new science coming forward, and the challenges for having these review processes will bring the best of the best together and, I think, open more venues that we see information that we gather on the animal side many times transmits over for information on the human side.

And so I think together we can be a force to reckon with, because this is what we need in this day and age. And more importantly, I think it is something that we understand these drugs that we develop, although we need many of them, there is innovative science coming onboard, and we have to be very judicious in how we use the products, as you mentioned earlier in the testimony coming forth with the Members. And I think the more that we are aware of the complexity of the challenging reviews that we have, the more we can work together to ensure public health.

Mr. PITTS. All right. How do ADUFA and AGDUFA take small businesses into account? What accommodations do these programs make for them? And then finally I want to ask how does ADUFA foster innovation in drug development?

Dr. DUNHAM. With the opportunity to give waivers for sponsors where they are small businesses, we can work with them. And many times on the first round through, we will work very closely with them to help minimize the cost factor the first time around.

We are also able to give waivers, as we have always done, for anything from minor species. And at the same time that we do this, we work very closely with the sponsors to bring them in earlier, as I said, to be able to address what they propose to do and understand the procedures they have to go through in order to get there.

For generic drugs, where they will copy your pioneer, we have an opportunity there on the fee system that we can address the small businesses so that if it is the first time in and they haven't had any approvals, it is a much lower fee, and once they get above six applications approved, it will be an increase in the fee on that one, and when they have had more than that. So we give a break on the finances in order to help them, and all of our sponsors have benefited from that.

When the sponsors are able to have recovery of not only the efficacy and the speed with which drugs are approved, then when you get it to market, the benefit comes back always for research. When we can do that, they are able to break ground with innovation. And what we do now is we try to meet with them very, very early on, even before they are coming with the application, so that we can understand where they are going to be going. And with these opportunities we can then fine-tune issues or be able to flag something that is going to be very challenging, and work with them to review sooner, and be able then to hopefully have all of these various technical sections that they have to meet be met thoroughly and effectively, and hopefully with one cycle review.

So having our staff be able to engage in interaction with them has been a real success rate. I think the sponsors have also improved, because the more that they can understand what it takes to have a really good application coming in the front door, the quicker we are going to have a single review, and that is the goal, and that is the time saving across the board.

Mr. PITTS. The chair thanks the gentlelady, and my time is expired. I now recognize the ranking member of the subcommittee Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman, and thank you, Dr. Dunham, for being here today.

I know you are not likely to answer the question, but I have to ask you really just to alert the FDA to an issue that I am concerned about, and that is implementation of an e-labeling or a paperless labeling system for drug products. And I would like to quickly use this opportunity to go on record with a question and look forward to hearing back from the FDA in a timely manner.

Three successive FDA unified agendas starting in the spring of 2009 have contained notice of a proposed rule signaling to me that electronic distribution of required drug product prescribing information is an FDA priority. E-labeling would ensure that most up-to-date prescription drug product, safety and efficacy information is available to healthcare providers, something I think we all agree is critical. In addition, it would also provide significant gains to patients, manufacturers and dispensers. In today's world current technology makes e-labeling a viable alternative that has tremendous value and could hopefully also lower costs.

So my two questions are given the need for e-labeling, is there a date that the agency can commit in regards to completing the rulemaking process in implementing e-labeling? And second, is there any update on your process moving forward that you can share? And I don't expect you to answer this, but if you want to; if not, through the chairman, you know, have the FDA get back to us.

Dr. DUNHAM. I would be delighted to pass that question over to the key members in the agency that can address that and have them get back to you as soon as possible.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Now, getting back to the Animal Drug User Fee legislation, Dr. Dunham, I want to thank you for your testimony about these important programs. It is clear they have been every bit the success that the other user fee programs at FDA have been. They have allowed the agency to move efficiently and effectively to review animal drug applications, and have provided industry with predictability and, of course, speedier reviews. And I am glad to be a cosponsor of the legislation. We will work to see that it moves through this committee in a timely way.

Another topic at today's hearing which has come up is antibiotic resistance and its relationship to the use of these important life-saving drugs in food-producing animals. As this committee well knows, antibiotic resistance is a grave public health threat. I recognize that there is a growing concern among stakeholders and some members of the subcommittee about the use of antibiotics in food

animals. Specifically they say that there is a lack of data on how antibiotics are used and in what quantities. But in the 2008 ADUFA reauthorization legislation, we did include some provisions to address this knowledge gap.

So my first question is can you tell us about what those provisions did? Then what kind of information did you get as a result? And do you think it has been successful overall? In 2 minutes.

Dr. DUNHAM. Actually, in fact, it was very successful. I think section 105 allowed us to be able to report out what the sponsors did with regards to sales of their drugs and distribution. And when we did this, it was really good because we had a lot of comments coming back, and, in fact, the comments have said, can we do more, and can we make this even more useful?

And I think always we would appreciate the opportunity in ways to work with everybody to get the best data. And what we have done is we have now also put out an advanced notice of proposed rulemaking just to do that, to gather information from many stakeholders as to additional ideas for how to improve, what this data would look like. There are areas that we would like to refine, and we hope with the 2012 report we are going to see the format change.

And further, based upon receiving some additional input, one of the areas that you know is important is how do we gather information on use data, and this is something that extends way beyond. And we do want to be able to work with our other agencies, such as USDA and CDC, and academia to figure out some ways to do this. And we have also been looking at different programs internationally. People are embracing how to do this.

So I think this is a very good way for us to reach out and improve this, and we look forward to reviewing the comments and coming back with some proposals. But I think this is something that we all want to work together on.

Mr. PALLONE. Well, you still have 30, 40 seconds here. What kind of information did you actually get, though?

Dr. DUNHAM. We are talking fast.

We were able to put out exactly what—the actual indication for the groups of animals. We do it in aggregate, and they will be able to say what the dosage is, what the form of administration is, their sales distribution.

The issue there has been could we have more, can we refine this, and I think that there are areas that we can, and this is what we do with working with our stakeholders to be able to fine-tune this so we can have a little bit more information.

I think what is really critical is we are also very nicely at the same time doing two other things. We have a proposal out there right now, which is Guidance 209, which we did finalize to say we do want to phase out growth promotion and feed efficiency use of medically important antibiotics and bring back in oversight by veterinarians. And Guidance 213 is how we work with our pharmaceutical companies to make the label changes appropriate to do just that and to change that authorization on the labeling as well. And the veterinary feed directive is one of the key tools that will come back in with the hands of a veterinarian to do all of that. That is happening simultaneously.

What would be really good now is as we fine-tune all of this, what does that look like when you really do see these strengths occurring and you are getting feedback from what the distributions are, and how we can further enhance this reporting schedule. And I do think everything is coming together in a way that I really appreciate with collaboration in addressing the very important issue, because, as you said earlier, it is a very important issue internationally. Everybody is involved. Judicious use is critical no matter what the antimicrobial. And I think together now you are finding everybody rallying, and I think in the spirit of collaboration, this is the best I could ever have. I am very grateful to work with so many fabulous folks coming up with new ways of addressing this very important issue.

Mr. PALLONE. All right. Thank you. Thanks very much.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Illinois Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. I think I am going to be following up on my friend Mr. Pallone's question. But before I do that, Dr. Dunham, I see you got your Ph.D. In cardiovascular physiology from Boston University; is that correct?

Dr. DUNHAM. Yes, sir.

Mr. SHIMKUS. Is that animal cardiovascular physiology, or is it one and the same or——

Dr. DUNHAM. Believe it or not, it was actually in a medical program that I was doing with my basic science Ph.D. So it was done at Boston University and Harvard Medical School. So we were dealing with patients, and we had then some opportunity for live-animal medicine.

Mr. SHIMKUS. Obviously with the University of Illinois close to my district and knowing folks who have gone into veterinarian medicine, it is a pretty stringent, obviously, path to get there and sometimes more difficult, some would say——

Dr. DUNHAM. Yes, it is.

Mr. SHIMKUS [continuing]. Than some other aspects. So I just noticed that on your bio and wanted to ask about that.

And you have been with the FDA for a long time.

Dr. DUNHAM. Yes, since 2002.

Mr. SHIMKUS. And the other point is that in this day and age, when we question role of government, I think the FDA and really the history with this program, it really does talk about the benefits of some government activity involved in protecting the safety and advocacy of our food supply for our public. So it is—I mean, even conservative Republicans have to talk to some of our friends in the district and say, yes, there is a role for government, and this is one, and this has been helpful, and why.

But can you walk us through what you have done and the FDA actions have been over the past few years when it comes to this whole debate on the animal use—antibiotic use in animals?

Dr. DUNHAM. What we have done is we have always had a very detailed review requirement on safety and effectiveness for drugs being used in food animals, and we have developed one important document, Guidance 152, which really did take a look at the very important drugs and to put those into a category of those that are very critical and most important. And with that the majority of all

our antimicrobials are, in fact, under prescription. It is the very old drugs that you know have these particular labels on them that were not as specific as we would like them.

Anymore now it is really important that we understand what the pathogen is, what the disease is that it caused, how do you have the correct label, and then working with the veterinarian and the producers together, because everybody is engaged in this to make sure we have a very healthy animal and, from that, a safe food product. Working together they are able then to assimilate exactly what would be the requirement for a drug to be used and to follow through.

And now anymore we are able to fine-tune, working with laboratories and also our national antimicrobial resistance monitoring system, to really be able to understand what these pathogens are doing and where is the resistance occurring.

Number one, I don't want the drug to develop resistance in the animal, and I certainly don't want to have a problem with resistance in people, and that is why everybody has a role to play in judicious use of these very important drugs. And these programs now bring us together so that we can track and follow through to see what is happening. And the more that we have the veterinarian back overseeing and working closely, this will be another way of enhancing that judicious use, which is really important.

And in combination, that data comes back that we are looking at for our review process so that we can be able to see what is happening with resistance and follow that across the board. And I think this way, if there are three or four drugs, it will be a veterinarian to work at that program, understand that particular production site, and be able to select the best antimicrobial, and be able to follow that.

Mr. SHIMKUS. My time is running short. And you were talking about older drugs and stuff. What authority currently does the FDA have to restrict the use of any antibiotic that my have adverse impact on human health?

Dr. DUNHAM. I am sorry, could you repeat that one more time?

Mr. SHIMKUS. What authority does FDA have today on—you know, if there was an old antibiotic that they might suggest might have an adverse impact on human health, what can FDA do today?

Dr. DUNHAM. Right now, as I mentioned, we have taken a very active approach to be able to work a collaborative procedure to be able to phase those out. We have identified them. We have said these older drugs that are medically important will be phased out. We have 213, which is the guidance we would like to see finalized and approved this year. Within the first 3 months the sponsors will let us know their intention, and we have given them 3 years to make those changes, and this allows us to then go to a mandatory process if they don't.

Mr. SHIMKUS. So this all debate occurred in your discussions with the, obviously, stakeholders in the industry and yourself.

Dr. DUNHAM. Yes. This is one thing that I am very proud of to think that we have reached out and said, you know, we have a problem, we all know this. How can we all work together through this? And I think when everybody rolls up their sleeves and comes to the table and addresses this issue, you bring the best of the best

out of everybody and many solutions. And not one size fits all, so how do we do this? And doing it together I think is a real success. So I am looking forward to that.

Mr. SHIMKUS. Thank you very much.

I yield back, Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from California Mrs. Capps for 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman, for holding this hearing.

I know my colleagues have heard me talk a great deal about the beauty of an innovation that takes place in my district. One of our biggest agricultural sectors is cattle production, so having a working Center for Veterinary Medicine at the FDA is very important to the central coast of California as well.

I want to thank the agency and industry partners for working together to come up with their agreement. I am pleased that we are here working on this topic today, and thank you, Dr. Dunham, for your testimony.

It seems clear that over the years FDA has recognized that the use of antibiotics in food-producing animals can lead to the development of drug-resistant infections in humans. In 1999, FDA released a framework to evaluate the potential impact antibiotic use in food-producing animals could have on the development of antibiotic resistance in humans. 2005, FDA withdrew the approval of one such antibiotic, fluoroquinolone, for use in poultry because a significant increase in resistance to that drug was observed in humans after it became widely used in chickens.

More recently FDA has announced that it is unwise and irresponsible to use important human antibiotics for growth promotion in animals, and the agency has taken a number of steps to encourage the industry to voluntarily stop such uses.

Dr. Dunham, can you and will you now tell us a bit more about what went into the withdrawal of fluoroquinolone and the human health concerns that led FDA to take this extraordinary step?

Dr. DUNHAM. Thank you, Representative Capps—we had an opportunity to, again, bring the best science forward and to follow this along. And with the data that we had at that time, one of the problems that we have seen is Campylobacter is a problem within poultry. And when we had an opportunity to watch what was happening, when exposed then to the drug, at that time the data was being collected so that we could see there really was not only the hazard, but then once there was further exposure, then we had a problem that we were able to identify. And upon doing so and collecting the best science and review, then we were able to take action.

And I think once we know the risk, the hazard, the exposure, that is the time when you have all the science that can be behind you when you make a decision like that. And then we went forth with that proposal at that time, and a few years later it was taken off the market.

Mrs. CAPPS. I appreciate your response and this example, which I was hoping that would be addressed in this way, because it really highlights a troubling glimpse, I believe, into the dangers to human health from the overuse of important antibiotics on farms. And I

am glad that we can see as a committee that you are in your Department attempting to build cooperation from industry in eliminating unnecessary uses of these drugs through a voluntary approach. But I do hope, and I guess this is the cautionary note, that if the voluntary approach fails, that FDA will either take a leadership role with regulatory action, or come back to us to let us know that you need new authority.

I believe we really—this is scratching the surface here with this one example. Antibiotic overuse does pose a harmful public health threat, and we need our preeminent public health regulatory agency to do all it can to protect American people and preserve the effective of these lifesaving drugs by overuse, and they become less effective when they are really needed for something else that is serious.

Last Congress we had numerous debates right here in this room about the shortages in the antibiotic pipeline and about the numerous potential superbugs that are resistant to our current antibiotic arsenal. These are human causes like overprescription and improper use. There are—one of things contributing to this is overprescription and improper use that contribute to the resistance for sure. But as FDA's actions now have shown, animal uses also contribute, and I wanted to get that on the record so that we could highlight the importance. These issues are related, and I urge this committee and my colleagues to work together on this aspect of this issue so that we can address the full causes of antibiotic resistance. I appreciate your testimony and your being here today.

I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the gentleman from Virginia Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you so much for being here today; do appreciate it very, very much.

You know, we look at these issues, and I am very concerned about the ag issues in my district, and it is one of largest industries in my district. I have been looking for ways to promote it and ways to expand it, and, of course, these issues that you bring up today are very important.

According to the National Cattlemen's Beef Association, there are approximately 7,600 beef farmers and 220,000 head of cattle in the Ninth District, and that is not counting our lambs and our goats and everything else that we have. For this reason development and approval of new animal drugs and generic drugs, including antibiotics, are very important to the farmers that I represent.

I do appreciate your being here and the positive relationship that I am told exists between your office and the stakeholders in the ag and pharmaceutical industry. So I do appreciate that.

I am concerned about large-animal vets and the shortage we have of those. I understand that there is a big concern about that shortage, and I am just wondering if the FDA is taking those concerns into consideration when proposing new guidance documents.

Dr. DUNHAM. Thank you very much. And, yes, we are. We have been meeting with the American Veterinary Medical Association because this issue of do we have sufficient food-animal veterinarians available has been an issue for a number of years.

And the other thing that is happening while we address those issues is to understand the plethora of veterinarians and where they are located versus where they are not, and how things have changed with regard to the practice of veterinary medicine as we have seen even with human medicine, and the technologies are enabling a tremendous amount of change that we want to embrace.

Just for example, we have the capability of smartphones. We have the capability of labs talking to each other much better and correlating and very quickly turning things around. So you think about all of that, and you say, well, how can I do this even more effectively? We need to hear from the producers and the veterinarians as to how we can coordinate this. The opportunity for veterinary technicians has been looked at. The universities are all embracing where advancements in medicine have taken us and how then are we using those in practice.

The coordination with some of our producers are state-of-the-art with how, as you know, they are set up, their track record, their records of medical references, their access to laboratories, and, again, a veterinarian to be there, which is so important, to oversee and work through this and be able to prescribe and know what is happening with those herds to ensure their health is there, again, to make sure we are protecting public health and any food item.

And I think as we talk through them, there is a variety of different ways of addressing concerns as we work through these, where I said, again, not one-size-fits-all and we learn from each other, and certain things that work in one State can work in another State.

The opportunity, again, for communication is going to be critical as we establish the veterinary-patient relationship in a way that embraces today's technology, where we are located and how we interact. And I have been very, very pleased. We had a committee that was brought together through the American Veterinary Medical Association for just that purpose, how do we work through these challenging issues right now. And, in fact, there are a number of students that I am very pleased are continuing to seek their careers in the food-animal production side of veterinary medicine.

Mr. GRIFFITH. Well, I have got two questions arising out of your answer. One, do you think that we should be working to see that we get either larger enrollment in our existing schools, or should we be looking to maybe expand and have some new veterinary medicine schools open up in the country?

Dr. DUNHAM. Well, actually there are a few more schools that I think will be opening up. I think the most important thing is for us, when we are talking to the next generation, is to encourage them, I think, to a stellar occupation in veterinary medicine. I can't be prouder to be a veterinarian because of the plethora of issues that we get to be challenged with. It is fantastic, and it is so rewarding to encourage them and let them know there are careers in the field. That is one thing I would love to see us do more of.

The schools themselves are actually top notch. And you mentioned a minute ago that it is oftentimes more challenging, Representative Shimkus, to get into veterinary medicine. That is true. But I think the rewards that you get afterwards in the public

health mission that we accomplish every day is outstanding. So that would be part and parcel of what I would encourage.

Mr. GRIFFITH. And then the other question I would have, we had some hearings about medical devices before we left, and there were some interesting cheap fixes that we saw, and there were other issues involved that wouldn't affect the veterinary side. But I am just wondering if FDA is prepared to move a lot of those things forward fairly quickly, because we learned about a device that was being used for children in the African Continent, but it was an $8 hack onto a smartphone. And it would seem to me, you know, as the FDA prepared—I know you can't answer for people—but on the animal side, are we prepared to get that stuff out into the field as fast a possible when it is something as simple as an $8 hack on a smartphone?

Dr. DUNHAM. As long as we can keep things and make sure it doesn't impinge on safety and effectiveness, we are going to work through a number of these opportunities to be able to further enhance how we can share information that is so rapid and moving so quickly, and also tracking. And I think with that there is that capability of, you can pull up an X-ray or lab report.

You could have our veterinarians, which are first responders, getting back to us very, very quickly right now, and I think that alone says so much when you realize how quickly everything moves in this day and age. Internationally we travel, animals travel, microbes travel. It is incredible. Food is already across countries before you can blink your eye. The more that we need to embrace technology for all the benefits, it is also quintessential in protecting animal health and public health to be able to enhance those communications.

Mr. GRIFFITH. Thank you so much, and I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from Virgin Islands Dr. Christensen for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and thank you for your answers as well and your testimony.

I also want to follow up on the resistance issue, and I think just to step back for a moment and make sure that we all understand what we are talking about. And for the record, could you give us a brief overview of how antibiotic resistance developed, and why it is a particular problem with continual long-term administration of antibiotics in feed or water as is done for growth-promotion purposes?

Dr. DUNHAM. I think the question of antimicrobial resistance is challenging. It is incredibly complex, and I don't have the answer. But I do know that there are incredible minds internationally working on this, as we all need to, every day, because it touches all of us, not just humans and not just animals; everything, plants as well. So the more that we are able to understand the complexity of this, we have the opportunity to intervene.

No matter what, judicious use of any antimicrobial, anywhere, from a dentist, physician or veterinarian, is quintessential. That being said, then that is why it is so important that we have the veterinarians overseeing and using these drugs with their medical

training, and working closely with the producers who absolutely then know their animals and how we can coordinate this and track it.

I think that part is happening more and more, and the recognition that if you use an antimicrobial, you are putting pressure back on that pathogen. You want to make sure you have eliminated that pathogen. So knowing the right antimicrobial to choose based upon what the pathogen is and the disease that it has caused, and to follow that through or to work up your lab to be able to decide that, that is the kind of stuff that we all have to embrace, and that is what we are seeing.

So one thing we have chosen, as I mentioned, was to recognize that I think growth promotion and feed efficiency were very, very older claims on antimicrobials way back, and what was missing was exactly the pathogen, and the disease and the dosage. Now we want to come fast forward, and all of these very important drugs need to have that, and they need to be under veterinary oversight. So where they would have been in the past, we are now looking to do that; phase out, labels will be changed, identification is on the label. So now when a physician or a veterinarian is looking at this label, it will identify that, and then they can do the proper workup. That brings us back again to developing judicious use across the board.

Mrs. CHRISTENSEN. As a physician, you know, we are always pressured to give antibiotics for viruses, for flus and so forth. Sometimes that is quite unpopular because you just don't do that unless you have a pathogen. So it is important, as you said, in human health as well as in animal.

But when we held a hearing on antibiotic use on animals back in 2010, one thing we heard from some animal producers was that growth promotion was actually a manifestation of disease prevention; and that is, the reason why antibiotics could make animals grow faster and use feed more efficiently was that the low chronic doses of antibiotics actually were preventing disease. The question that raises, of course, is whether when the industry says it phasing out growth-promotion uses of medically important antibiotics, maybe it simply intends to change the label, but not its practices.

So could you help address this question for us: How does FDA define disease "prevention"? And is it possible for industry to essentially switch a growth-promotion claim to a disease-prevention claim with just some data showing that the same dose of a drug that promotes growth will also prevent a disease?

Dr. DUNHAM. That is why with Guidance 213, which we certainly hope will be finalized this year, it will have us work very closely with the pharmaceutical company, because now they really do have to come back. And if there is going to be a prevention claim, it has to be able to identify everything we just talked about very clearly, because that is what was missing before.

Mrs. CHRISTENSEN. So you don't have a definition for "disease prevention" in this instance?

Dr. DUNHAM. You will see that in 213. But basically if you want to control something, that means you already have a problem. You can see within a herd there is a group of animals that have a prob-

lem, and you want to see to be able to prevent and control that from further expanding.

If you want to prevent, you would need to have, again, an awareness of the history of the animal, the herd, and whether or not as a veterinarian everything you have seen indicates that you can be expecting something to happen. But you would still have to now very much understand what that pathogen is to be able to make that call. And only the veterinarian, in pulling everything together in their medical history, would make that decision, and it would have to be then, as far as the drug sponsor coming in and have a label, that if they are going to put that claim on, what are they preventing, and what is the surrounding circumstances that a veterinarian would need to make it happen.

So you would have treatment, control and prevention in each one to be fine-tuned and explained, and now those labels would have to meet this new criteria before they could have that on them.

Mrs. CHRISTENSEN. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentlelady. And now recognize the gentlelady from North Carolina, Ms. Ellmers, for 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman.

And thank you, Dr. Dunham. And a moment ago you were speaking with my colleague, Mr. Griffith, about the excellent veterinarian schools in the country. And being a member representing District 2, North Carolina, I have to speak up for the NC State School of Veterinary Medicine; excellent school. And I will just have to add, as I have told everyone that I have come in contact with over the last 2 weeks, that my son has been accepted to NC State in the agriculture business school.

Dr. DUNHAM. Fantastic.

Mrs. ELLMERS. So I am very excited about that.

I am concerned. You know, in North Carolina, agriculture is the number one industry, and, you know, ag and our farmers, so important. Some of the larger farms, entities, you know, doing great and certainly have their issues to deal with. Some of the smaller farm entities, obviously any of these, you know, any more regulation or any more burden we put on them just makes it harder for them do what they need do. And, you know, I am particularly concerned about those farmers in the administration of any of these, you know, any of the jeopardy that we put them in.

You know, how would you explain to them that they can use the FDA? And I will just talk about the veterinary feed directive. How can we speak to them and know that this is something that is going to be feasible for them, something that is going to be workable, that they will be able to take advantage of, but at the same time be able to afford cost-wise?

Dr. DUNHAM. That is a great question. And I am actually able to tell you right now we are very pleased because we have just teamed up with the USDA. We are having five very special outreach listening sessions to address and listen from folks that are in either very remote locations or their concerns as to what this will do and mean for them. So right now we have our first one, which actually took place in Bowling Green, Kentucky today.

Mrs. ELLMERS. Great.

Dr. DUNHAM. And then we will be doing Olympia, Washington, Fort Collins, Colorado, Pierre, South Dakota, and College Station, Texas. And it is for that whole purpose, both listening to veterinarians as we have been doing, but also the producers, what are some of the hurdles they think they will be facing and how will we help them move through this, because it is not one size fits all. And you are absolutely correct, a smaller group versus a big producer that has everything they need, how do we help them understand those issues and how can we work with them.

The aspect of the veterinarian and how can they establish their veterinary patient-client relationship, they can set that up, and they have now a lot more latitude of what does that look like. And how you and I can set it up would be different to how I would set it up with somebody else. That is going to help. And the more that we dialogue them, that is going to bring us together to address their concerns so that we are not going to be adding further to their challenging days, because we need them, be they small or large, they are all a part of what we want with agriculture. And I am very pleased to know that we have been having some good feedback with them.

And they share their concerns already. We have had a lot of meetings with different producers. They have come in or they have actually come into D.C. and they have come from different States, and we have had a chance to meet with them, explain what this all looks like, what will the veterinary feed directive be, and how a veterinarian now has the opportunity to fine-tune and be responsive for this and to work with them. And I have been really, really impressed with the willingness to say, well, I have this issue, maybe we could do this, what about this. That brings out the best, and the solutions are going to be terrific coming forward.

Mrs. ELLMERS. Great. Well, thank you. And, you know, I am glad you mentioned coupling with the USDA, because my next question has to do with, you know, the veterinary shortages that of course across the country we are faced with. And, you know, one of the things that we are looking at here in Congress are the possibility of, you know, basically veterinarian medicine loan repayment programs. And, you know, from your perspective, I don't want to put you on the spot, you know, but there is a high basically tax that is associated with that, as high as 39 percent of repayment. In your opinion, coming from the FDA and having to do with our farmers and agriculture across this country, to me, I mean, that is pretty straightforward. That is a pretty negative effect, especially when you are talking about trying to serve underserved areas. What is your opinion on that? And I mean, just in the 40 seconds you have left, if you can just give me a little idea of what you think.

Dr. DUNHAM. That is definitely a challenge. I think all of our students, no matter where they are, are facing tremendous, tremendous burdens with the student loans. Any possible way we can assist is going to be welcomed, and they appreciate that. And yet when I meet with the students, they are absolutely dedicated and thrilled to be doing what they want to do, and yet they are willing to take on these loans. So anything we can do to help is what we have to do, and to show them that there is still a way to have a

career that is incredibly rewarding while, as you said, paying off these loans.

So I do welcome that. I know all of the associations are trying to do something. We would like very much to even have a student loan repayment program ourselves. Haven't quite got all the money for that, but I would love to do that. But anything that we can do and encourage would be a real positive, because we need them, it is a career that we have to have and sustain. Veterinary medicine is so important. I know many times we look at those as just being the ones that take care of the animals, but veterinary medicine crosses so many areas.

Mrs. ELLMERS. Absolutely.

Dr. DUNHAM. And they come with the most incredible dedication. And then their experience, maybe they will be members of Congress. It will be fantastic what they can continue to do.

Mrs. ELLMERS. Great. I truly appreciate your testimony. Thank you.

Dr. DUNHAM. Thank you.

Mr. PITTS. The chair thanks the gentlelady. I know the gentleman just walked in. We are about to wrap up questions.

Dr. Gingrey, do you have any questions you would like to ask?

Dr. GINGREY. Mr. Chairman, I think I will just pass at this time. Thanks.

Mr. PITTS. All right.

All right, at this time, then, with unanimous consent, we will recognize Representative Gardner, 5 minutes for questions.

Mr. GARDNER. Thank you, Mr. Chairman. And thank you, members of the committee.

Dr. Dunham, thank you for your testimony today. And just a couple of quick questions for you. Everybody has bragged about their vet school, so I will throw in a word for Colorado State University and the aforementioned Fort Collins, Colorado, where you will be having a clinic here, at least a forum, very soon. So thank you for your participation in that.

In your testimony you described the significant backlog on generic applications prior to the authorization of AGDUFA. What caused that backlog in the first place? And if you don't mind maybe talking a little bit about the causes. Was it simply a matter of resources? Go into that a little bit.

Dr. DUNHAM. It was actually resources and just not having the resources to have the dedicated people we need to do that review. And I can't echo enough how appreciative we are of this program, because once you get a chance to fill the resources and have staff that can do the review, it is incredible what you can accomplish. And to have that sustained reliability, then, on not only keeping our FTEs, but you are able to then give back to the companies to know exactly what these performances are. And together we can enhance and get those drugs reviewed. And so that is why this program and its reauthorization is critical, because we have established so much, and I would hate to see us go back. And the success story exemplifies that.

Mr. GARDNER. I think in your testimony, I believe you were talking about, was it was AGDUFA or ADUFA? I think you talked about hitting every single performance goal except for the one——

Dr. DUNHAM. That was on AGDUFA.

Mr. GARDNER [continuing]. By one day. And that was AGDUFA, correct, as a result of this?

Dr. DUNHAM. Yes.

Mr. GARDNER. And in your discussions with farmers and ranchers, I know you spoke with my colleague a little bit about this, can you describe the importance of having generic drugs on the market?

Dr. DUNHAM. I think it is really important. As we all know, we always value what the cost factors are. And just like on the human side, it is an opportunity to have a safe and effective drug that would be able to give you some cost savings. And I think, as you said earlier, with the plethora of animals and species we have, you can see how much more diversity we are going to have to deal with all of that.

So the more that we can have generic drugs come through and have their approval, it is going be helping everybody. We need so many drugs approved for so many different diseases in so many species, it is constantly challenging us. So this is another plus, and I have been very impressed with what they have done.

Mr. GARDNER. About 2 months ago, Jennifer Johansson, who is the vice chair of the Generic Animal Drug Alliance, testified before the Senate HELP Committee stating that the number of generic new animal drug applications decreased after the implementation of AGDUFA. Are you aware of a reason for this? Do you feel at the present time that the submissions are adequate to provide available generics to producers?

Dr. DUNHAM. I think we are seeing that. I think at the time we were also going through some economic turmoil and I think there was a little bit of hesitancy, we even saw that, as to how many applications were actually coming in, and that is something that goes along with what happens in the market. But that seems to have leveled out right now, and I would have to say that I think we are going to continue to see more coming forward.

Mr. GARDNER. You mentioned some of the feedback, the forum, the information you are getting from stakeholders. We have talked about what you are getting from veterinarians, what you are talking about getting from people in the livestock industry. Could you describe the stakeholder process with other people who may be outside of the industry itself but who are interested in the pharmaceutical issues as it pertains to the animal side?

Dr. DUNHAM. Yes. And we have a number of stakeholders, many of them are here actually today in the audience. We have a number of other activist groups, i.e., that are helping us across the board with anything on medicine, consumers, academics, association groups that you will see here trying again to see how can we work together to address whatever these challenging issues are. Working with other agencies as well brings us forward. The public at large. We often have calls, letters from the public with their issues and their concerns all the way from whatever it is with companion animal medicine to the issues du jour of how we can be more judicious in the use and protection of antimicrobials. I know we don't do the biologics, that is done with USDA, but together those will help ad-

dress the health concerns that we face and the venues of how we can all come together.

And what that also does is it brings some of the best scientists and the issues du jour and how fast science is advancing. And so there have been opportunities to further collaborate with groups. They have come in and suggested different things that we can do with them. The sharing of information has been absolutely fabulous on that end.

Mr. GARDNER. Thank you, Dr. Dunham. I yield back my time.

Mr. PITTS. The chair thanks the gentleman. That concludes our first panel.

Thank you very much, Dr. Dunham, for coming, for all the good information and testimony you presented. The members may have additional questions. They will forward those to you if they do.

We will now call the second panel to the witness stand and I will introduce them as they come. Dr. Richard Carnevale, Vice President of Regulatory, Scientific and International Affairs, Animal Health Institute. Secondly, we have Dr. Mike Apley, Professor and Section Head of Production Medicine and Clinical Pharmacology, College of Veterinary Medicine, Kansas State University. Thirdly, Dr. Lance Price, Professor in the Department of Occupational and Environmental Health, George Washington University. And that concludes the second panel.

Thank you all for coming. You will each have 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Dr. Carnevale, we will start with you. You are recognized for 5 minutes.

STATEMENTS OF DR. RICHARD A. CARNEVALE, VICE PRESIDENT, REGULATORY, SCIENTIFIC AND INTERNATIONAL AFFAIRS, ANIMAL HEALTH INSTITUTE; DR. MIKE APLEY, PROFESSOR AND SECTION HEAD, PRODUCTION MEDICINE AND CLINICAL PHARMACOLOGY, COLLEGE OF VETERINARY MEDICINE, KANSAS STATE UNIVERSITY; AND DR. LANCE B. PRICE, PROFESSOR, DEPARTMENT OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH, GEORGE WASHINGTON UNIVERSITY

STATEMENT OF RICHARD A. CARNEVALE

Dr. CARNEVALE. Thank you, Mr. Chairman and members of the subcommittee. Thank you very much for holding this hearing on this important piece of legislation, as you have aptly described today, and for the opportunity to speak to you today about an important human and animal health benefit that results from using medicines to keep animals healthy.

I am Dr. Richard Carnevale. I am a veterinarian by training with a degree from the University of Pennsylvania School of Veterinary Medicine, and I am here today on behalf of the Animal Health Institute, a trade association that represents companies that make medicines for animals.

Our companies share a common mission. We contribute to public health by protecting animal health. Animal health products also give veterinarians and livestock and poultry producers the nec-

essary tools to protect the health and well-being of food-producing animals. Veterinarians work hard to prevent disease in animals, and it is important for them to have the medicines available when needed to treat a disease or disease threat.

Mr. Chairman, the Center for Veterinary Medicine has a rigorous science-based approval process that provides to the American public the products necessary to protect public health by protecting animal health. Every year scientists uncover new diseases in animals, some of which pose a threat to human health. As more animals are raised to feed the planet and as animals are reared closer to people, we will continue to need new medicines to protect animal and human health.

The reauthorization of ADUFA will continue to provide the agency the resources necessary to maintain and improve this approval process, provide new and innovative products to allow our pets to live longer and healthier lives, and contribute to food safety by keeping food animals healthy.

The FDA animal drug approval process looks much like the human drug approval process. Animal drug companies submit data packages that demonstrate safety, efficacy, and the ability to meet the same stringent FDA manufacturing standards as human medicines. It is a costly process, requiring as much as $100 million and 7 to 10 years to bring an animal drug to market.

The market for animal drugs, however, is nothing like the market for human drugs. Our products are used to treat seven different major species of animals and many more minor species. A blockbuster animal drug will have sales of around $100 million, but the vast majority of animal health products have market sizes of around $1 million or less. There is no Medicare or Medicaid—excuse me. I am missing a page. Sorry. I will move right on.

The reauthorization of ADUFA will continue to provide the agency the resources necessary to maintain and improve this approval process, provide new and innovative products to allow our pets to live longer and healthier lives, and contribute to food safety. Passage of this important legislation will have several benefits. FDA/CVM benefits by having additional resources to meet its mission of protecting public health. Animal health sponsors benefit from a stable and predictable review process, allowing them to make informed decisions about the investment risks of research and development dollars. Veterinarians benefit from having new and innovative medical advances available to treat, control, and prevent diseases in their patients. Livestock and poultry producers and the veterinarians on whose advice they rely also have the tools to keep food animals healthy. Pet owners benefit by having their animals live longer and healthier lives, increasing their enjoyment of these companions. And consumers reap the food safety benefits that come as a result of the availability of additional tools to keep food animals healthy.

AHI believes that the funding agreed to by the industry over the next 5 years is based on an objective assessment of agency resource needs and will allow the agency to maintain all current standards and also improve performance in key areas. The agreement calls for approximately $118 million in funding over the 5 years and uses a variable rather than fixed inflation factor, as was mentioned

today. The financial agreement seeks to reduce the impact that fees may have on small businesses and small product markets by reducing the total percentage of fees coming from new animal drug applications and supplemental applications from 25 percent to 20 percent. The agreement also includes a provision for FDA to make up potential fee shortfalls that may be experienced by allowing for adjustments to levied fees in the outyears of the program.

FDA has consistently met timeframes for all sentinel submissions identified in the goals letter, as Dr. Dunham explained, and we are confident the agency will continue to do so over the next 5 fiscal years. The new agreement continues all current submission review timeframes mandated in ADUFA II; however, the new agreement adds important enhancements to the review process.

Animal drugs generally go through a phased review process, whereas each specific area, called technical sections, of the new animal drug application is submitted and reviewed independently. Once the technical sections for safety, efficacy, manufacturing, and environmental impact are completed, an administrative NADA is filed referencing those sections, and approval of the product occurs within 60 days. If technical sections can be completed more rapidly, it will lead to earlier filing of the administrative NADA and, therefore, reduce overall time to market of safe and effective animal medicines.

Mr. PITTS. Could you wrap up, please?

Dr. CARNEVALE. Yes. And that will be accomplished by significantly shortening the review times of the second pass submissions.

There are other agreements that we have talked about today, and I will sum by saying that the new agreement commits the agency to work with the industry to examine some longer-term goals. First, AHI will enter into discussions about how to extend conditional approval process and also will take a look at how current animal drug combinations are approved. This could have significant future import with the advent of the FDA proposal to move more antimicrobials used in feed to the veterinary feed directive program, as was discussed.

Mr. Chairman, I ask you to pass this legislation in a timely manner and reject any changes that would jeopardize this bill so this program can continue without interruption. Thank you very much.

Mr. PITTS. Thank the gentlemen.

[The prepared statement of Mr. Carnevale follows:]

Testimony of Dr. Richard Carnevale
Vice President, Scientific, Regulatory and International Affairs
Animal Health Institute

House Energy and Commerce Committee
Subcommitee on Health

April 9, 2013

Mr. Chairman and members of the Subcommittee:

Thank you for holding this hearing on this important piece of legislation, and for the opportunity to speak to you today about the important human and animal health benefits that result from using medicines to keep animals healthy.

I am Dr. Richard Carnevale. I am a veterinarian by training with a degree from the University of Pennsylvania and I am here today on behalf of the Animal Health Institute (AHI), a trade association that represents companies that make medicines for animals. Our companies share a common mission: we contribute to public health by protecting animal health. With food animals in more demand from our growing global population, the importance of the nexus between animal health and human health has never been greater, and is one of the driving forces behind the Center for Disease Control's "One Health" initiative. As companion animals have become a more important part of our everyday lives they have moved from the backyard into our living rooms and bedrooms, increasing their importance to humans and requiring greater attention to their health needs. As medical breakthroughs from human medicine are adapted to animal medicine, our pets are living longer and healthier lives.

Animal health products also give veterinarians, and livestock and poultry producers, the necessary tools to protect the health and well-being of food producing animals. More and more evidence demonstrates that a vital first step in producing safe meat, milk and eggs is keeping animals healthy. Veterinarians work hard to prevent disease in animals, but it is important for them to have medicines available when needed to treat a disease or disease threat.

The statutory standard for FDA approval of animal drugs under the Federal Food, Drug and Cosmetic Act is the same as that for human drugs: they must be proven to be safe and effective. As a result, the animal drug approval process looks much like the human drug approval process: animal drug companies submit data packages to demonstrate safety, efficacy, and the ability to meet the same stringent FDA manufacturing standards. It is a costly process, requiring as much as $100 million and 7-10 years to bring an animal drug to market. In the case of food animals, the standard to ensure that meat, milk, and eggs are safe for human consumption adds an additional set of requirements that increases the cost and time to market.

The market for animal drugs, however, is nothing like the market for human drugs. Our products are used to treat seven different major species of animals and many more minor species. A blockbuster animal drug will have sales of $100 million, and the vast majority of animal health products have a market size of around $1 million. There is no Medicare or Medicaid and, except in rare cases, no employer supported health insurance -- the cost of animal drugs is borne in full by the animal owner.

One significant challenge we face in animal health is the declining number of new animal drug approvals. The data we collected in preparation for ADUFA III clearly showed that while we significantly increased the amount of user fees going to the agency in ADUFA II, the workload has substantially declined. There are likely many reasons for this, but a big reason is the ever-increasing regulatory cost and burden. In a market as fractured as the animal health market, this increased regulatory burden results in fewer live-saving and extending drugs being brought to market. We hope Congress will in the future consider ways to incentivize animal health research and provide for a regulatory environment that increases the availability of animal health products.

Animal health companies rely on a rigorous, efficient, predictable and science-based review process at the Food and Drug Administration's Center for Veterinary Medicine (CVM) to provide these products. That's why our companies supported the first authorization of the Animal Drug User Fee Act ten years ago. The Animal Drug User Fee Act of 2003 (ADUFA I) made it possible for our companies to bolster funding at CVM so that they could meet performance standards to improve the efficiency and predictability of the animal drug approval process and ADUFA II, passed in2008, continued that progress.

Passage of this important legislation will have several benefits:

1. FDA/CVM benefits by having additional resources to meet its mission of protecting public health.
2. Animal health sponsors benefit from a stable and predictable review process, allowing them to make informed decisions about the investment risks of research and development dollars.
3. Veterinarians benefit from having new and innovative medical advances available to treat, control and prevent diseases in their patients.
4. Livestock and poultry producers, and the veterinarians on whose advice they rely, also have the tools needed to keep food animals healthy.
5. Pet owners benefit by having their animals live longer and healthier lives, increasing their enjoyment of these companions.
6. Consumers reap the food safety benefits that come as a result of the availability of additional tools to keep food animals healthy.

AHI believes that the funding agreed to by the industry over the next five years is based on an objective assessment of agency resource needs and will allow the agency to maintain all current standards and also improve performance in key areas. The agreement calls for approximately $118 million in funding

over the five years, depending on inflation. The funding agreement going forward differs from the funding provided over the last five years. AHI has agreed to an annual fee level adjusted by a variable rather than the fixed annual inflation factor utilized in ADUFA II. The variable rate will be more closely aligned with actual cost increases that FDA might realize from year to year.

The financial agreement seeks to reduce the impact that fees may have on small businesses and smaller product markets by reducing the total percentage of fees coming from new animal drug applications and supplements from 25% to 20%. This should result in a substantial reduction in an individual application fee in FY 2014 and beyond. The 5% reduction is then distributed among the three remaining fee areas – sponsor, product and establishment. Since smaller companies have fewer products and facilities, they are hit hardest by the application fee. The agreement also includes a provision for FDA to make up potential fee shortfalls that may be experienced by allowing for adjustments to levied fees in the out years of the program.

FDA has consistently met timeframes for all sentinel submissions identified in the goals letter submitted to Congress and we are confident that the agency will continue to do so over the next five fiscal years. The new agreement continues all current submission review timeframes mandated in ADUFA II. However, the new agreement adds important enhancements to the review process.

The process for reviewing and approving animal drugs has evolved over the years and is somewhat different than that for human medicines. Animal drugs generally go through a phased review process whereby each specific area called technical sections of the new animal drug application is submitted and reviewed independently. Once the technical sections for safety, efficacy, manufacturing, and environmental impact are complete an administrative NADA is filed referencing those sections and approval of the product occurs within 60 days.

If technical sections can be completed more rapidly it will lead to earlier filing of the administrative NADA and, therefore, reduce overall time to market of safe and effective animal medicines. This will be accomplished under the new agreement by FDA agreeing to significantly shorten the review times of the second pass submissions that ordinarily are reviewed in the same time frame as the original or first pass submissions, when certain criteria in the goals letter are met. Depending on the type of submission this can result in up to a four month (120 day) decreased review time and could be critical in moving an important animal medicine to the market sooner.

The new agreement also commits the agency to work with industry to examine longer term goals:

AHI and FDA will enter into discussions on how to more broadly extend the conditional approval process currently available only to minor species to major species applications. The Minor Use/ Minor Species Act of 2004 provided a new mechanism for the approval of animal drugs. For minor species or minor uses, a sponsor can submit an application to FDA allowing the firm to market the product while continuing to collect effectiveness data to satisfy the "substantial evidence" requirement under the FD&C Act, as long as enough data has been submitted to allow the agency to determine there is a "reasonable expectation" of efficacy before it goes on the market. Of course, the application must still meet all requirements for animal, human, and environmental safety, manufacturing quality, and be

properly labeled prior to marketing. The conditional approval lasts for five years after which time the product is fully approved or withdrawn from the market if the sponsor fails to demonstrate substantial evidence.

AHI believes that a strong case can be made to extend this provision to certain drugs proposed for major species other than those specifically for minor use. This allows earlier marketing of important products that can be studied and thoroughly tested for effectiveness because the sponsor is adding revenue to fund such studies. The data gathered under a conditional approval will be much more robust and allow the agency to have better confidence in the safety and effectiveness of the product before it issues final approval. The advantage to FDA is that it can easily terminate the marketing of a product if the sponsor fails to complete the data commitment. There is no increased risk to animal for public health since safety will be assured prior to marketing. Additionally, conditional approvals are currently in place at USDA, which regulates animal vaccines and at EPA, which regulates flea and tick products for animals. Conditional approvals could be one mechanism to address the current decline in animal drug submissions and bring much needed new product development to the market for major species.

The other policy issue that will be discussed under the new agreement will be the issue of combination medicated feed new animal drug approvals. It is common practice in the field to combine two or more drugs in a medicated feed being given to cattle, pigs, or poultry. For the past 40 plus years FDA has required that two or more approved drugs added to an animal feed must first also be approved by the agency before they can be mixed concurrently. There is a long history of FDA requiring this and dates back to a policy first established in the 1960's that considered animal feeds containing an animal drug to be a finished drug formulation. A producer or feed manufacturer can only combine approved animal drugs in feed if an application for that combination has been approved by FDA. Therefore, an animal drug sponsor obtaining an approval for a drug to be added to animal feed is responsible for filing additional new animal drug applications providing for the concurrent mixing in the feed of the newly approved drug with other approved drugs. These are essentially administrative NADA's that simply reference the approvals of the other products but still require submission of some limited data and new labeling.

This has been an onerous requirement since it can significantly delay the ability of a sponsor to market a new product because the sponsor may not submit these other application for review and approval by FDA until the new drug is first approved. Some relief was realized in 1996 at the passage of the Animal Drug Availability Act, which lessened the requirements for the approval of these combination applications, but did not eliminate the need to submit an NADA for these combinations. Experience has shown since the ADAA that few problems can be identified by the mixing of two or more approved drugs concurrently in the feed in the way of interference with the active ingredients or with changes to animal safety or human food residues.

FDA has agreed to enter into discussion with the animal drug and animal feed industry and state regulatory authorities overseeing animal feed manufacturers over the next 3 years to determine how these requirements might be modified. This could have significant future importance with the advent of the FDA proposal to move more antimicrobials used in feed to a Veterinary Feed Directive program by

allowing for veterinarians to more efficiently write VFD orders for antibiotics to be mixed into feed with other non-VFD drugs. Eliminating the requirement for combination feed approvals could pave the way for a smoother implementation of the VFD program and ensure that antimicrobials added to feed are being use for therapeutic purposes only under the order of a veterinarian.

Mr. Chairman, CVM has a rigorous, science-based approval process that provides to the American public the products necessary to protect public health by protecting animal health. Every year scientists uncover new diseases in animals, some of which potentially pose a threat to human health. As more animals are raised to feed the planet and as animals are reared closer to people, we will continue to need new medicines to protect animal and human health.

The reauthorization of ADUFA will continue to provide the agency the resources necessary to maintain and improve this approval process, provide new and innovative products to allow our pets to live longer and healthier lives and contribute to food safety by keeping food animals healthy. I urge you to pass this bill in a timely manner and reject any changes that would jeopardize this bill so this program can continue without interruption.

Again, thank you for holding this hearing and I would be happy to answer any questions.

Mr. PITTS. Recognize Dr. Apley, 5 minutes for opening statement.

STATEMENT OF MIKE APLEY

Dr. APLEY. Mr. Chairman and members of the committee, good afternoon, I am Mike Apley. I am a veterinarian——

Mr. PITTS. Is your mike on? Yes.

Dr. APLEY. Got it. Thank you.

I am Mike Apley. I am a veterinarian and a clinical pharmacologist at Kansas State University College of Veterinary Medicine, with friends at North Carolina and Colorado.

Mr. SHIMKUS. What about Illinois?

Dr. APLEY. Some up there, too.

My specialty areas are food animal production and the use of drugs in these animals. Today I wanted to share with you a little bit about how drugs are used in food animals.

The first thing I wanted to emphasize is that this use revolves around the relationship of veterinarians to food animal producers. Veterinarians are a vital part of the drug use decisions by food animal producers, especially for antibiotics. This relationship is described and promoted in programs such as beef quality assurance and pork quality assurance. The combination of close monitoring and knowledge of the animals by the producer with the training and experience of the veterinarian is the best possible approach to animal health.

Antibiotics may receive approval by the FDA Center for Veterinarian for five indications: treatment of disease, prevention of disease, control of disease, improved feed efficiency, and improved rate of gain. Those last two indications are production uses, which may also be referred to as growth promotion claims. These claims are specifically referred to in FDA Guidance for Industry 209, which Dr. Dunham referred to, in which FDA/CVM refers to these indications as injudicious uses and asks for voluntary withdrawal of these indications.

While the FDA has not released official definitions for indications 2 and 3, which were prevention and control, that I am aware of as yet, as a clinical pharmacologist I wanted to share my working definitions of these applications. Prevention is the use of an antibiotic to prevent disease occurrence in a population of animals when experience suggests that this particular time in a production cycle is very likely to result in a disease outbreak in this population of animals. The need for prevention varies according to the current disease pressure and may change over time. Control, on the other hand, is use of an antibiotic to reduce the number of additional clinical cases in a population where clinical observation or recent stressors and exposure indicate that the disease process is clinically apparent or in development.

The overarching goal of veterinarians and producers is to replace the need for prevention or control uses of antibiotics through practices such as biosecurity and vaccinations. The use of antibiotics for therapy and control are considered a therapeutic use by the American Veterinary Medical Association, the FDA Center for Veterinary Medicine, the World Organization for Animal Health, and Codex Alimentarius.

In my submitted testimony, I have included tables of labels for cattle and swine. My first table summarizes uses that are labeled for improvement of rate of gain or feed efficiency, with the emphasis on ones that would be affected by Guidance 209. For antibiotics in cattle with labels strictly for improvement of rate of gain or feed efficiency, there are four which are not classified as human medically important and five which are. There are some labels which have a rate of gain or feed efficiency claim and a prevention or control claim. In that category, there is one which is not medically important and three that are. These claims are examples of ones that would be affected by the removal of growth promotion claims. When we move to prevention or control of disease only, there are only three out of eight which are medically important.

I would also like to emphasize the findings of a study in which I was lead author, which addressed the use of antibiotics in the feed for swine. In this study, it was found that approximately 15 percent of the medically important antibiotic use in feed for swine was for growth promotion. The greatest use on a kilogram basis of the medically important antibiotics in swine was attributable to the tetracyclines, which are chlortetracycline and oxytetracycline in these cases.

As for cattle, there are other antibiotics, which have an injectable or in-water route of application on the label. These include ceftiofur, ampicillin trihydrate, tulathromycin, penicillin G. This illustrates the complexity of this issue and the need to evaluate our discussion based on these different antibiotics and pathogens of interest.

Lastly, if they are to be used other than according to the label, there must be a veterinarian involved, and this would include any changes in dose, duration, or disease indications. Provisions are available to allow some extralabel use in feed and minor food animal species, but for major food animal species, any extralabel use in the feed is illegal.

Thank you for the opportunity to be here today, and I will answer questions as they come.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Mr. Apley follows:]

Testimony to the House Energy and Commerce Committee

Subcommittee on Health

"Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA"

April 9, 2013

Michael D. Apley, DVM, PhD

Professor, Kansas State University College of Veterinary Medicine

Note: In this testimony, the common term antibiotic is used to represent both antibiotics and antimicrobials.

Summary:

Uses of antibiotics in food animals are highly regulated, starting with specific indications on the label. Currently, the indications may include treatment, prevention, or control of disease, improved feed efficiency, and improved rate of gain. The FDA/CVM has indicated through Guidance for Industry #209 that indications on labels for medically important antibiotics which include feed efficiency and rate of gain are to be removed from the labels. This guidance also indicates the intention to require veterinary authorization for all feed and water uses of antibiotics in food producing animals. The remaining label indications (treatment, prevention, and control) are therapeutic uses.

Antibiotics labeled for administration in the feed must be used only for label directions, any other use is illegal. Any extralabel use of other food animal antibiotics must meet the strict requirements of the Animal Medicinal Drug Use Clarification Act regulations, including strict oversight requirements for veterinary involvement as well as standards for rationale for this use.

Examples of antibiotic approvals for cattle and swine indicate that there is a wide variety of antibiotics approved for use with varying indications. A 2012 estimate of 2006 swine in-feed antibiotic use indicates that approximately 20% of in-feed antibiotic use of classes medically important in human therapy was attributable to growth promotion uses.

The Relationship of Veterinarians to Food Animal Producers

Veterinarians are a vital part of the drug-use decisions by food animal producers, especially for antibiotics. This relationship is described and promoted in programs such as beef quality assurance and pork quality assurance.

Label Indications for Uses of Antibiotics in Food Animals

Antibiotics may receive approval by the FDA Center for Veterinary Medicine for these indications

1. Treatment of disease
2. Prevention of disease
3. Control of disease
4. Improved feed efficiency
5. Improved rate of gain

Indications 4 and 5 are production uses, also referred to as growth promotion claims. These claims are specifically referred to in FDA Guidance for Industry #209, in which the FDA/CVM refers to these indications as injudicious uses and asks for voluntary withdrawal of these label approvals by the sponsors (GFI #209, 2012). The initial time frame for withdrawal of these indications is 3 years after the mechanisms for label revision are established in the form of FDA Guidance for Industry #213 (GFI #213, 2012). Guidance for Industry #213 is intended to provide streamlined methods for removing these claims and adding veterinary oversight to all feed and water uses of antibiotics in food animals (which are also specified as an intended change in Guidance for Industry #209). The FDA/CVM has indicated that they may alter this time frame if necessary, but will take regulatory action to remove these label claims if voluntary removal does not occur.

While the FDA/CVM has not released official definitions for indications 2 and 3, as a clinical pharmacologist, my working definitions in the field are as follows.

- Prevention: Use of an antibiotic to prevent disease occurrence in a population of animals when experience suggests that this particular time in the production cycle is very likely to result in a disease outbreak in a population of animals. The need for prevention varies according to the current disease pressure in the population, therefore the need for this preventive practice may vary over time.
- Control: Use of an antibiotic to reduce the number of additional clinical cases in a population where clinical observation or recent stressors and exposure indicate that the disease process is clinically apparent or in developmental stages in some of the animals. Treatment at this time will interfere with advancement from the incubatory stage to the clinical stage of disease.

The overarching goal of veterinarians and producers is to replace the need for prevention or control uses of antibiotics through practices such as biosecurity and vaccination. Uses of antibiotics for therapy and control are considered a therapeutic use by the American Veterinary Medical Association, the FDA Center for Veterinary Medicine, the OIE (World Organization for Animal Health), and Codex Alimentarius (International Food Standards).

Cattle antibiotic labels include a wide variety of indications. Table 1 summarizes in-feed labels by type of indication. These indications are for different diseases and represent different dosing regimens intended for different ages use classes of cattle. This table is for summary purposes only. Summaries of label inclusions for FDA/CVM-approved drugs for all veterinary species may be accessed through a search engine on the FDA/CVM website (Animal Drugs @ FDA, 2013).

Table 1. Examples of in-feed approvals for antibiotics in cattle. These approvals are not ranked by frequency or amount of use. Shaded drugs indicate individual antibiotics or antibiotic combinations which contain a medically important antibiotic as defined in Food and Drug Administration Guidance for Industry #152, Appendix A (GFI #152, 2003) for which the rate of gain and/or feed efficiency label indication will be affected by FDA/CVM GFI #209.

Improvement in rate of gain or feed efficiency only
Bacitracin Zinc
Bambermycins
Chlortetracycline
Laidlomycin
Lasalocid
Neomycin / oxytetracycline
Oxytetracycline
Sulfamethazine / Chlortetracycline
Virginiamycin

Rate of gain or feed efficiency and a prevention/ control claim
Monensin
Chlortetracycline
Neomycin / oxytetracycline
Oxytetracycline

Prevention or control of disease only
Amprolium
Bacitracin methylene disalicylate
Chlortetracycline
Decoquinate
Lasalocid
Monensin
Tylosin
Virginiamycin

Table 1 (continued):

Treatment of disease and prevention or control
Neomycin
Neomycin / oxytetracycline
Oxytetracycline
Sulfaquinoxaline
Tetracycline

Treatment of disease only
Amprolium
Chlortetracycline
Oxytetracycline
Sulfachlorpyridazine
Sulfamethazine
Sulfadimethoxine

Table 2 gives examples of antibiotics labeled for cattle which may be administered by the water (individually or to a group) or which are administered individually to cattle either by injection or by administration in the mammary gland for mastitis (IMM). As for Table 1, the list does not imply extent or amount of use.

Table 2: Injectable, intramammary, and water antibiotics for cattle. The vast majority of these require a veterinary prescription.

Class	Antimicrobial	Route
Thiamine analog	Amprolium	Oral in water or as a drench
Penicillins	Amoxicillin	IMM
	Ampicillin trihydrate	Injectable
	Cloxacillin	IMM
	Hetacillin	IMM
	Penicillin G procaine	Injectable, IMM
	Penicillin G procaine / Benzathine	Injectable
Cephalosporins	Ceftiofur	Injectable and IMM
	Cephapirin	IMM
Tetracyclines	Oxytetracycline	Injectable and in water
	Chlortetracycline	Oral as bolus
Fluoroquinolones	Danofloxacin	Injectable
	Enrofloxacin	Injectable
Phenicols	Florfenicol	Injectable
Aminoglycosides	Dihydrostreptomycin	IMM
	Gentamicin	Ocular spray
	Neomycin	Oral In water/milk
Sulfas (all non-potentiated)	Sulfachlorpyridazine	Injectable
	Sulfamethazine	Oral as bolus
	Sulfamethazine	Injectable
	Sulfadimethoxine	Injectable, oral as drench, in water, or bolus
Macrolides	Gamithromycin	Injectable
	Tildipirosin	Injectable
	Tilmicosin	Injectable
	Tulathromycin	Injectable
	Tylosin	Injectable
Aminocoumarin	Novobiocin	IMM
Lincosamides	Pirlimycin	IMM

An estimate of in-feed use of antibiotics in swine was recently published, in which I served as lead author (Apley, et al., 2012). This estimate utilized the USDA National Animal Health Monitoring System's Swine 2006 Survey data in conjunction with a veterinary swine practitioner survey to estimate the amount of antibiotics use in swine feed for the year 2006. The following table is reproduced from this publication.

TABLE 5. NATIONAL ESTIMATE OF TOTAL KILOGRAMS OF SWINE IN-FEED ANTIMICROBIALS FOR ALL PRODUCTION CYCLES IN A YEAR BY ANTIMICROBIAL AND REASON

	Antimicrobial	*Growth promotion*	*Prevention*	*Therapy*	*Any reason 'yearly basis'*
Antimicrobials **not listed** in FDA/CVM Guidance 152 Appendix A	Arsanilic acid	0	10,494	0	10,494
	Bacitracin	72,760	11,032	24,914	108,707
	Bacitracin zinc	4,844	0	0	4,844
	Bambermycins	543	0	0	543
	Carbadox	3,787	7,409	12,923	24,119
	Roxarsone	461	51	4,456	4,967
	Sulfamethazine[a]				
	as Chlortetracycline/Sulfamethazine/ Penicillin G (ASP)	2,735	3,663	1,148	7,546
	as Tylosin/Sulfamethazine	7,500	149	3,460	11,109
	Sulfathiazole[a]				
	as Chlortetracycline/Sulfathiazole/ Penicillin G (CSP)	942	14,673	3,784	19,398
	Tiamulin	2,393	6,770	3,571	12,734
Antimicrobials or classes **listed as Highly Important** in Guidance 152 Appendix A	Chlortetracycline[b]				
	as Chlortetracycline alone	83,331	206,076	217,622	507,029
	as Chlortetracycline/Sulfathiazole/ Penicillin G (CSP)	942	14,673	3,784	19,398
	as Chlortetracycline/Sulfamethazine/ Penicillin G (ASP)	2,735	3,663	1,148	7,546
	Lincomycin[c]	356	4,246	20,844	25,446
	Neomycin				
	as Neomycin/Oxytetracycline	4,068	2,632	16,394	23,094
	Oxytetracycline[b]				
	as Oxytetracycline alone	2,615	31,699	97,547	131,862
	as Neomycin/Oxytetracycline	4,068	2,632	16,394	23,094
	Penicillin				
	as Chlortetracycline/Sulfathiazole/ Penicillin G (CSP)	471	7,336	1,892	9,699
	as Chlortetracycline/Sulfamethazine/ Penicillin G (ASP)	1,367	1,832	574	3,773
	Virginiamycin[d]	26,108	54,858	493	81,459
Antimicrobials or classes **listed as Critically Important** in Guidance 152	Tilmicosin[e]	1,068	46,906	22,786	70,761
	Tylosin[f]				
	as Tylosin alone	25,641	37,893	91,160	154,694
	as Tylosin/Sulfamethazine	7,500	149	3,460	11,109

[a]Only potentiated sulfonamides are listed in Guidance 152, Appendix A.
[b]The tetracycline class representative in Guidance 152, Appendix A is tetracycline.
[c]The lincosamide class representative listed in Guidance 152, Appendix A is clindamycin.
[d]The streptogramin class representative in Guidance 152, Appendix A is dalfopristin/quinupristin.
[e]The macrolide class representatives listed in Guidance 152, Appendix A are erythromycin, azithromycin, and clarithromycin.
Antimicrobials are grouped according to classification or lack of classification in Appendix A of FDA/CVM guidance 152.

From this table it is evident that of the antibiotics listed as either highly important or critically important in FDA/CVM GFI #152, Appendix A, the estimate indicates that 15% was used for growth promotion purposes. The greatest use, on a kg basis, was attributable to the tetracyclines (chlortetracycline and oxytetracycline).

As for cattle, there are other antibiotics which have an injectable or in-water route of application on the label. These include ceftiofur, ampicillin trihydrate, tulathromycin, Procaine penicillin G, oxytetracycline, chlortetracycline (water only), tetracycline (water only), and enrofloxacin.

Use Other than According to the Label

Use of antibiotics in the feed for major food animal species in any manner other than specified on the label is illegal. This would include any changes in dose, duration, or disease indication. Provisions are available to allow some extralabel use in minor food animal species (e.g., sheep and goats) (FDA, 2007).

Any other extralabel use of antibiotics in food animals must be done in compliance with the Animal Medicinal Drug Use Clarification Act regulations (AMDUCA, 1994). These regulations require that a veterinarian prescribes the use within the confines of a valid veterinarian-client-patient relationship and that an extended withdrawal time be used as specified by the veterinarian.

Extralabel use of fluoroquinolones in food animals is prohibited by the FDA/CVM, along with other drugs on a list which is a standard knowledge base for all veterinarians (CFR 530.41, 2012). This extralabel use prohibition includes cephalosporins, with the exception of cephapirin, which may be used in an extralabel manner only for disease indication, with no allowable alteration of the dosing regimen (dose and route, duration, or frequency of administration).

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Mr. PITTS. And now recognizes Dr. Price 5 minutes for an opening statement.

STATEMENT OF LANCE B. PRICE

Dr. PRICE. Chairman Pitts, Ranking Member Pallone, and the members of the Health Committee, thank you for this opportunity. My name is Lance Price. I am a professor of occupational and environmental health at George Washington University here in D.C., where I study the connection between antibiotic use in food animal production and antibiotic-resistant infections in people. As such, I am here to testify that we need to know more about the antibiotics that we are using in food animal production.

First, let me thank you for giving us the 2008 ADUFA amendments that have shed some light on the gross quantity of antibiotics being sold through food animal producers. However, today's antibiotic resistance crisis forces me to ask you for even more detailed information in the 2013 reauthorization.

Antibiotic resistance is one of the greatest threats that we face as a Nation. Tens of thousands of Americans' lives are lost each year due to antibiotic-resistant infections, and we have no choice but to act swiftly and aggressively to meet this enormous public health challenge. The victims of this crisis have names, like Carlos Don, a boy who died 2 weeks before his 13th birthday of a drug-resistant infection. The victims are also the parents who pace helplessly in hospital rooms while doctors struggle and eventually fail to find an antibiotic to treat their sick children.

Sadly, we fail these victims even now, because we know how to control resistance, but we have taken insufficient action to do so. We control resistance by reducing antibiotics in hospitals and in clinics, but also, and importantly, we control resistance by reducing antibiotic use on our industrial farms. For as long as we have known about antibiotics, we have known that the more we use them, the more likely we are to have resistance, but despite this knowledge, we continue to use antibiotics as cheap production tools on our industrial farms. And I would like to be clear: We do need antibiotics to treat sick animals, but using them routinely for non-therapeutic purposes threatens animal and human health alike.

Our own FDA, the agency that is charged with protecting human health and charged with regulating antibiotics in food animals production, tells us that our food supply is riddled with antibiotic-resistant bacteria. Let me show you what the FDA tells us about drug-resistant bacteria in our food supply. These are the ADUFA reports since 2009. And what they tell us is that our food supply is full of drug-resistant bacteria. They show that half of the ground turkey products on our grocery store shelves are contaminated with multidrug-resistant E. coli, including some strains that are resistant to our most important antibiotics, such as cephalosporin. In the 2010 report, they showed a strain of salmonella that was resistant to all the antibiotics that they tested.

Now let me show you what we know about antibiotic use in food animal production. Here are the ADUFA reports. So here are the drug-resistant bacteria in our food supply, here are the ADUFA reports reporting on the drugs that are used in food animal production. The ADUFA reports tell us that 30 million pounds of anti-

biotics are being used in food animal production each year, but they tell us little else. They don't tell us how antibiotics are being divided up among the major animal species, whether they are sold over the counter or under veterinary order, or the proportion of antibiotics sold for nontherapeutic purposes. We need this information and we need our FDA to give us more.

The FDA has offered only voluntary guidelines to eliminate the most egregious use of antibiotics: growth promotion in food animal production. In response to criticisms that these voluntary guidelines are weak, the FDA Deputy Commissioner, Mike Taylor, said that the FDA would trust, but verify compliance. Unfortunately, without more detailed data collection, the FDA will lack the information it needs to verify, leaving them only to trust. The time to verify is now and the time for more detailed data collection is now.

ADUFA is the perfect bill for requiring additional data collection for three reasons: ADUFA is now, ADUFA is about drugs used in food animal production, and ADUFA already authorizes the FDA to collect some high level data via Section 105. With these data, we can assess the impact of FDA's voluntary guidelines, we can identify places where improvements can be made, and hopefully we can confirm industry claims that antibiotics are being used more sparingly.

This is an issue about transparency, it is about accountability, but most of all it is about public health. We need to act now to protect American lives. So as a public health researcher, a microbiologist, and a citizen of this country, I implore you to require more detailed data collection and reporting from the FDA, including how the antibiotics are being used divided up among those major animal species, whether they are sold over the counter or under veterinary control, and the proportion of antibiotics sold for growth promotion, disease prevention, control and treatment, such as the provisions included in the DATA Act, H.R. 820, sponsored by Ranking Member Waxman and Congresswoman Slaughter.

In closing, I would like to thank you for your time and for giving me the opportunity to testify on such a critical issue.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Mr. Price follows:]

Testimony before the

House Committee on Energy and Commerce, Subcommittee on Health

United States House of Representatives

April 9, 2013

Lance B. Price, Professor, Department of Environmental and Occupational Health,

The George Washington University

Chairman Pitts, Ranking Member Pallone and members of the Health Subcommittee, thank you for the opportunity to give testimony about the steps Congress must take to shine a light on antibiotic use.

I am grateful that today's hearing on the Animal Drug User Fee Act (ADUFA) will include a discussion of the issue of antibiotic resistance and, more specifically, Section 105 of the 2008 ADUFA amendments, which requires the Food and Drug Administration (FDA) to collect and report data from animal-drug manufacturers on the sale of antibiotics intended for use in food animal production. As a public health researcher with years of experience examining the relationship between antibiotic use in food animals and antibiotic-resistant infections in people, I strongly believe the public needs to know more about how and why antibiotics are used on food animals to produce meat and poultry. For this reason, I support the Delivering Antimicrobial Transparency in Animals (DATA) Act (H.R. 820), introduced by Representatives Waxman and Slaughter, to broaden and deepen understanding regarding this public health threat, and to inform the policymaking process at FDA and in Congress.

As a microbiologist, I have dedicated my career to studying bacteria. I'm fortunate to be doing so during a golden age of DNA sequencing technology. Quickly and cheaply, we can now map the entire

genomes of bacteria that infect people and use that information to determine where they are coming from. And the results tell us conclusively that using antibiotics on industrial farms is a danger to human health. My colleagues and I have published numerous journal articles showing that exposing bacteria to antibiotics breeds drug-resistant superbugs, that these bacteria are prevalent on our meat and poultry, and that the germs do in fact spread from animals to people where they cause infection.

It is undisputed that using antibiotics—appropriately or inappropriately—is the single most powerful force leading to the development of antibiotic-resistant bacteria that poses an immediate threat to the public's health. We cannot stop using antibiotics altogether because we need them to treat infections. What we can do, however, is reduce inappropriate use and slow the evolution of resistant bacteria. Hospitals across the country are implementing stewardship programs with the goal of reducing antibiotic use and curbing resistance. For years, the Centers for Disease Control and Prevention (CDC) has been undertaking a campaign called Get Smart About Antibiotics to promote more responsible prescribing and use among people. A key component of these programs is data collection. Doctors, pharmacists and hospital administrators are tracking antibiotic use prescription by prescription, noting when, where and for what diseases these drugs are being used. Because there is good data in human medicine, they know how antibiotic use is changing, how use contributes to resistance, where problems persist, and what targeted interventions will work best to address remaining issues. According to the CDC National Center for Emerging and Zoonotic Infectious Diseases, in 2011, there was a 25 percent reduction in the number of people developing healthcare-associated invasive MRSA infections[i]. And the American Academy of Pediatrics recently reported on a 40 percent reduction in cephalosporin-resistant *Klebsiella* infection and a 70 percent reduction in intensive care units.

But even if every hospital and every doctor participated in a stewardship program and tracked the use of all human antibiotics, we still would fail to understand the vast majority of antibiotic use taking place in this country—that is, the use of these drugs on industrial farms.

About two months ago, the Food and Drug Administration reported that, in 2011, drug companies sold nearly 30 million pounds of antibiotics for use in food animal production—the highest amount the agency has reported. The agency broke down these sales into eight drug classes and an "other" category aggregating the sales of several additional classes. While this information is helpful in illustrating the overall scope of antibiotic sales for meat and poultry production, it does not provide enough detail. In order to protect public health and animal well-being, we must also know why, how and in what animals these vital drugs are used.

First, we need to know to which animals antibiotics are being administered. Each year, the FDA measures the prevalence of superbugs on retail meat and poultry and finds considerable differences between what's on ground turkey, retail chicken, pork chops and ground beef. Bacteria on some products exhibit much higher rates of resistance than the same kinds of bacteria on other products. Understanding how antibiotics are intended to be used in each species can shed light on the superbugs that vary so significantly by product.

Second, we need to know why antibiotics are being used—that is, how often they are sold for non-therapeutic production purposes like growth promotion and disease prevention or for therapeutic purposes like disease control and treatment. Last April, the Food and Drug Administration issued a draft set of voluntary guidelines designed to eliminate the use of antibiotics to accelerate the growth of healthy animals. The agency's deputy commissioner for food, Mike Taylor, said in a *USA Today* op-ed to critics who thought this voluntary approach had no teeth that the FDA would "trust, but verify" that these policies are working. But if the FDA does not know how often antibiotics are being used to promote growth or compensate for overcrowded and unsanitary living conditions, it cannot verify progress. Complicating matters, the animal-drug industry has stated explicitly that it would seek replacement indications for product labels, essentially swapping "growth promotion" indications for "disease prevention," which could be virtually identical in practice. These practices pose a particular threat to human health because they involve low-dose antibiotics, which can do more harm than therapeutic doses.

They create an environment for bacteria that is just hostile enough to prompt them to develop resistance but not so harsh that they are killed off. Only with more data can the FDA truly verify that its policies are having a real effect on actual usage and not just on labeling.

Drug manufacturers should have some estimates of this species and intended use information. But the best information might come from feed mills, which are responsible for mixing antibiotics into animal feed for various purposes, either by order of a veterinarian, or per the request of producers or large-scale meat production companies. Congress should explicitly authorize FDA to require uniform annual reporting of these data from the largest feed mills or, if easier, from top meat production companies who are purchasing the antibiotics to be distributed to their growers in feed.

Third, we need more precise data that provides details on antibiotics important in human medicine. In the FDA's reports, it includes an "other" category that aggregates sales of antibiotic classes in which there are fewer than three companies selling products. This is intended to protect proprietary data, but it is unnecessarily broad. The FDA should divide this category into two components—one tallying sales of antibiotics used only in animals and another for sales of drugs used in humans and animals.

Fourth, the FDA should report how antibiotics are intended to be administered—such as, in feed, in water or by injection—both in total and by drug class. The FDA provided this information at the request of Representative Slaughter after the agency released its 2009 sales report and it should become a standard element of the agency's annual sales summary. It was from this information that we learned that 74 percent of antibiotics are administered in feed and 16 percent in the water. Route of administration does not definitively indicate why drugs are used, but the widespread administration of antibiotics in feed suggests that large groups of animals are routinely and indiscriminately being fed antibiotics they may not need, which may indicate that there are deeper, underlying production problems needing to be addressed.

As a microbiologist who is committed to public health, I must express deep frustration with the Food and Drug Administration. The agency's core mission is to protect the public's health, yet it is not doing nearly enough to monitor antibiotic practices that it knows are dangerous and injudicious. It negotiated an agreement to collect fees from drug makers in exchange for expediting drug approvals, while missing a prime opportunity to seek some common-sense provisions to simply measure—not restrict, just measure—the use of antibiotics. The agency has been in possession of data that would shed more light on how antibiotics are being used on industrial farms, but it has declined to share it in 2010 and 2011. FDA notes that it has the authority to collect more data but has not exercised it. Instead, the agency has initiated a years-long potential rulemaking process to further explore the question of data collection, a process that, unfortunately, will keep the public in the dark for at least a few more years, with no clear light at the end of the tunnel. Congress has the opportunity to direct FDA to do a better job, and to prioritize data collection and stewardship of antibiotics the agency approves.

I am grateful to this committee for considering the issue and I ask you to hold the FDA accountable. As this committee did five years ago, please seize this opportunity and allow the public to know more about how our food is produced and how antibiotics needed to safeguard human and animal health are being used on industrial farms. Please include additional antibiotics data collection provisions in the Animal Drug User Fee Act.

Thank you.

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[i] http://www.cdc.gov/ncezid/pdf/annual-report.pdf; accessed 3/3/13.

Mr. PITTS. That concludes the opening statements of the panelists. I will begin the questioning and recognize myself 5 minutes for that purpose.

Dr. Carnevale, what are some of the benefits of ADUFA and AGDUFA to livestock, poultry producers, veterinarians, pet owners, consumers? And why have ADUFA and AGDUFA been so successful?

Dr. CARNEVALE. Well, as you heard today, there is a really great need for new products for both livestock and pets and horses and other species as well. Getting a drug approved is a very expensive process, as I mentioned in my testimony. What ADUFA and AGDUFA does is allows the company to have more certainty with the agency about how the product will be reviewed and the timeframes for that approval.

It doesn't give any certainty that the product will be approved. All the standards for safety and efficacy are still maintained. It simply gives the manufacturer a better idea of, if they invest the amount of money it takes to get a product approved, they will have the FDA do an efficient job of reviewing that product, and if the data supports it, it will be approved.

So it helps to have these drugs out there faster for the livestock owner that needs those treatments. ADUFA will help get those products to market faster. It will help the pet owner as well to get products in the hands of his small animal veterinarian faster so that these products can be used. And it just enhances the whole efficiency of getting these products on the market.

Mr. PITTS. What are, in your opinion, the most important improvements in the user fee agreements that we are talking about today?

Dr. CARNEVALE. I think the important improvement is that we have maintained a reasonable cost basis. I think one of the things that we were concerned about going into ADUFA III was the cost of the program, the escalating cost of the user fee program, in addition to the cost of development.

We were able to do a very good objective assessment of what the costs should be, and I think we are compensating FDA for the needed costs that they have in running the program, but not overpaying. So I think that is one of the benefits that came out of the negotiation.

Also, we were able to get them to enhance the process. I mentioned second pass reviews. It will allow those second pass, the second time the submission comes into the agency to maybe have a shorter timeframe, to speed that administrative approval process. So there are some significant benefits. We also got the agency to agree to look at some long-term changes in the process that might help to get products to the market sooner.

Mr. PITTS. Do you feel, in light of the testimony we have heard today, that the FDA review process as it exists today protects animal and public health?

Dr. CARNEVALE. There is no question it does. It is a very rigorous process. I used to work at the agency a number of years ago. I know how rigorous the process is that takes place at the Food and Drug Administration. As I mentioned, the data requirements are as great, if not more, for animal drugs, particularly food animal drugs,

than they are for human medicine. FDA protects animal health to the utmost extent.

Mr. PITTS. Thank you.

Doctor——

Dr. CARNEVALE. Human health as well.

Mr. PITTS. Dr. Apley, can you please elaborate on the role of veterinarians in animal drug development and drug use decisions?

Dr. APLEY. In animal drug development, as a practicing veterinarian, previously I had the opportunity to interact with companies and interact on needs that drove research and development, which was very valuable for all of us.

As a veterinarian that guides use, one of our most important things we do is work with producers to develop protocols and establish those protocols. And to show you how far that goes, in my days as a feedlot consulting veterinarian, we actually had computerized records, and each animal that was treated was individually identified. And one of the first things I did each time I visited, twice a month, to train and monitor records was to go through the individual animal treatment records and determine what our treatment response was, if we were doing things appropriately. And we had a protocol that could change, but the only way it could change was if we all agreed on it.

Mr. PITTS. In your opinion, does the FDA have the authority to appropriately address antibiotic issues?

Dr. APLEY. In my opinion, they do. I have worked with them as a veterinarian and as a member of both producer and veterinary organizations. They are very good, in my opinion, about seeking our input and also evaluating what is going on out in the field.

Mr. PITTS. And do you think the reauthorization of these user fee programs will foster animal drug development?

Dr. APLEY. I do, yes.

Mr. PITTS. My time has expired. Thank you very much. Recognize the ranking member of the subcommittee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Dr. Price about your testimony regarding antibiotic resistance. Although this committee has looked at this issue repeatedly in the past, we do have some new members who did not get to participate in our prior hearings, and for those of us who were around, it might help to get a refresher. First of all, can you describe how resistance develops for us?

Dr. PRICE. Sure. So what we are talking about are bacteria that are resistant to the effects of antibiotics, right, and those bacteria can cause infections in people and those infections are harder to treat.

The way bacteria become resistant to antibiotics are through mutations in the DNA, but also by picking up genes from other bacteria. And these things are promiscuous, you know, the Berlusconis of the biological world, and they pass these genes around. And when you use an antibiotic, you select for those resistant ones, those that have picked up these resistance genes, to proliferate, and they grow and they multiply.

And bacteria multiply. I mean, you can go from, seriously, one bacterium to billions in 24 hours. These are fast growing bacteria.

And so wherever you are using antibiotics, you are selecting for these drug-resistant bacteria, whether it be in a hospital or on a farm where you have thousands of animals crammed together and, you know, among each others' feces and sharing bacteria constantly. And so when you add in these antibiotics, that is the magic ingredient for creating drug-resistant pathogens.

And then when you butcher those animals, you almost inevitably contaminate the carcass with the bacteria from those animals, and now you have meat products that are contaminated with drug-resistant bacteria that then are distributed to every grocery store in the country. And the NARMS reports tell us that the drug-resistant bacteria are there, that our food supply is riddled with drug-resistant bacteria.

And then there are the food animal producers, the people working in the industry that can pick up these resistant bacteria, bring them to their homes, bring them into our hospitals.

Mr. PALLONE. And then what is the harm to humans at that point? Because now they become resistant as well? What is the harm to humans?

Dr. PRICE. So the harm to humans is that we get infected with these drug-resistant bacteria, and the best defense against a bacterial infection is an antibiotic. So if you go into a doctor with a bacterial infection, they are going to try to treat you with an antibiotic, but if that bacteria is resistant to antibiotics, you could die of that infection, that treatment is going to fail.

And so every time we use antibiotics, every drug that we waste for nontherapeutic purposes in food animal production is creating resistance to those drugs, so those are taken off the shelf for therapy. So the physician has to reach higher and higher on that shelf for those last drugs.

Mr. PALLONE. And what you are saying is that the very nature of farm production with this bacteria causes that environment where the resistant bacteria thrive, essentially?

Dr. PRICE. Exactly. So when I look at a modern food animal production setting, I see the perfect setting for disease proliferation, for bacteria to spread among animal hosts, right. So we know if we cram people together in unsanitary conditions, they are going to spread bacteria among one another. And then we add the magic ingredient, which is antibiotics, which is going to force those bacteria to become resistant to those antibiotics. You know, people call these factory farms, but I don't see factories making meat, I see factories making drug-resistant bacteria.

Mr. PALLONE. All right. Thank you very much.

Mr. PITTS. The chair thanks the gentlemen. Now recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

And, Dr. Carnevale, you have heard Dr. Price and some of his answers. Can you explain to us why there are logistical difficulties and expenses for your members in reporting sales by animal species, dose, intent of use, and for the growth promotion, disease control, or treatment?

Dr. CARNEVALE. Yes. Well, as you know, since 2008, our companies have been providing sales data. Sales data is not an indicator of use. The problem with our companies trying to refine exactly

how those products are being used in the field is because when our companies sell their product, particularly feed use products, they will sell them to a distributor, to a veterinarian, to other sources. They may get used at that level or they may be sold to other distributors.

So once the product is out in the field and being used our companies don't know what the product was sold for, because many of these products have multiple species on the label and multiple indications. So they are frequently fairly long labels for many of these products. And once the product is sold in the marketplace our companies simply don't know exactly what species it has been used in or what is the purpose it was used for.

Mr. SHIMKUS. Thank you.

Dr. Apley, what is the relationship, if any, between the most serious human antibiotic-resistant concerns and antibiotic use and resistance in food animals?

Dr. APLEY. I think that relationship is discussed on the basis of specific organisms of concern. One of the things I want to make clear is that I think engaging in this conversation is critical and support that. I think if we start to assume that all resistance is due to this, we go down a road where we are going to end up with consequences that aren't appropriate. If you look at organisms such as salmonella, it is quite appropriate to have these discussions. There are others for which I think the evidence is much less apparent, at least in my evaluation of it.

Mr. SHIMKUS. So, I mean, you mean consequences that are not appropriate. What do you mean by that statement?

Dr. APLEY. We do good in animals with antibiotics when we apply them judiciously. We can have benefits for their health. And, you know, we talk about in the environments they are in. Well, if you take modern swine production, you know, you shower in, you shower out. They take a group of animals completely out, it is steam cleaned, it is sanitized, they come back in, and still——

Mr. SHIMKUS. So versus this walking around in each others' feces and——

Dr. APLEY. At times during the production period, like with a slatted floor, they will have some there, they track it through, so there is some present, but it isn't like they are wallowing in a cesspool. It is designed so that it is tracked through, goes into a pit and then is removed.

Mr. SHIMKUS. And you have operated major feed operations, or you have observed all this process——

Dr. APLEY. Yes.

Mr. SHIMKUS [continuing]. In the field?

Dr. APLEY. Yes. But we do have beneficial effects on creating healthy animals. And I am a believer that healthy animals create healthy food.

Mr. SHIMKUS. And that was my follow-up, too. It would be better to have a healthy animal that goes through the food process than an unhealthy animal for human consumption?

Dr. APLEY. Correct. And I want to emphasize that our goal in the food animal industries is to prevent disease. Sometimes we get the impression that we are throwing these things around and just flying them in. They are an expense to us, and when we have to use

them, we have an animal that is ill or on the verge of being ill, and it is in everyone's best interest, the animal, the producer, the consumer, that we do everything we can, vaccines, animal flow, to produce that. So it is important we realize that we don't use antibiotics because we are lazy and don't want to try to prevent disease, we use them as a tool.

Mr. SHIMKUS. Let's follow up on the collection of data and the responses that you have heard here. Will use data provide us the information we need to understand the epidemiology or the risk of antibiotic resistance? It is hard for me to say; easy for you all.

Dr. APLEY. I think we have to carefully define between use date and sales data. There is a recent paper by Jensen that was conducted in Denmark, in the Netherlands, that showed very clearly that sales data does not correlate well with use data.

And then the other important thing we ask is how are we going to use these data. It is very important that when we have these data we actually apply them to something that is related. If we collect use data over here and have resistance data over here and marry them together, we will get lines on a graph which we may try to interpret, but they may be, in fact, not be related.

I am not saying we shouldn't look, but we need to put very careful thought into how we are going to collect and interpret the data first.

Mr. SHIMKUS. Thank you very much.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentlemen. And now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for questions.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Dr. Price, thank you very much for being here today. Some in the animal production industry have recognized the overwhelming scientific evidence and acknowledge that routinely giving antibiotics to animals in their feed or water can lead to the growth of resistant bugs. However, they claim there are too many steps between raising those animals on the farm and buying their meat at the grocery store, and that the risks of a consumer contracting an antibiotic-resistant pathogen from that meat is remote.

Could you describe the steps by which the uses of antibiotics on the farm lead to these human illnesses?

Dr. PRICE. Well, I think it is very clear with the classic food-borne pathogens, like salmonella, for instance, that when we use antibiotics in food animal production, there is a direct line. We create the drug-resistant strains of salmonella in food animals that then make a direct line to humans through the food supply.

But the research that we have been doing in my lab and around the world now is looking beyond those classic food-borne pathogens, and now we are looking at the two biggest killers: we are looking at staph aureus and we are looking at E. coli. And every time we look now we are seeing more and more evidence that those bacteria, some burden of those—let me give you a case of the burden.

Mr. WAXMAN. Well, let me interrupt you, because I only have 5 minutes. In other words, isn't it a mistake to say that you give an antibiotic to an animal for whatever reason and the consumer that eats the meat from that animal is not exposed? Isn't it that by

using antibiotics for whatever purpose we are engendering the development of bacteria that are resistant to the antibiotics that we have now available?

Dr. PRICE. Exactly. Whenever we use antibiotics on the farm, we are creating drug-resistant bacteria that could possibly cause——

Mr. WAXMAN. And obviously antibiotics are appropriate under some circumstances, but there is such a large use of antibiotics for animals that we don't know if they are being used for therapeutic purposes or just being used to generally keep the animal healthy and in better commercial shape. Isn't that what the problem is?

Dr. PRICE. It is.

Mr. WAXMAN. Now, Dr. Apley seemed to talk about healthy animals are better, so that means we want to keep animals healthy. But is there a problem in trying to keep animals healthy if they don't have a disease, if we are just giving them antibiotics as a preventative for a disease?

Dr. PRICE. I see a major problem with using antibiotics to try to keep animals healthy as a preventative tool. If we have created a food animal system that makes animals sick routinely, then we have created a faulty system, we need to change the system. We need to prevent infections other ways than using antibiotics. That only invites resistance. And so I will say again, I think we should treat sick animals, but if we see that animals are getting sick all the time, we should change the way we are doing it.

Mr. WAXMAN. Now, we don't have the data, and I have introduced a bill called the DATA Act to require industries to provide FDA with more detailed information on which drugs are sold and in what quantities for which animals and report to FDA to provide more detailed public reports on that information.

Now, Dr. Carnevale said they don't keep track of this information. Of course they can make some estimates about it. They can know details. But they certainly have a lot more information than anybody else about the use of their antibiotics.

How would public health researchers such as yourself make use of this information and why is getting this information so important?

Dr. PRICE. Well, we need to look at the relationship between antibiotic use and antibiotic resistance, especially for the newer drugs. You know, the emergence of cephalosporin-resistant E. colis. You know, ask an infectious disease doc what they would use if they got a cephalosporin-resistant E. coli, and many would probably tell you they would use a carbapenem. And carbapenem-resistant E. colis are the CREs, the nightmare super bugs that the CDC hasbeen talking about.

So we need to understand how these antibiotics are being used, but also, as I said before, I think we need to be able to celebrate the food animal producers who are using them less.

Mr. WAXMAN. If we don't have every bit of information to show the link between the sale of an antibiotic and the use of the antibiotics, aren't estimates important rather than just say, we don't know, and therefore we don't want to know? I mean, if we recognize, for example, that drug companies don't have firsthand knowledge of how the drugs are actually used, if we ask them to give an estimate of which animals they are sold for, if they have good sales

departments, they should have at least a basis for these estimates. Isn't that important and helpful information?

Dr. PRICE. It is certainly important. And I hear people say that it is hard to get those data, it is so hard, it is going to be hard to do this. But I say what is hard is trying to treat a kid with a multidrug-resistant infection, watching them die of these drug-resistant infections, or trying to find new antibiotics to replace the ones that we have blown out through growth promotion and routine disease prevention.

Mr. WAXMAN. And if you will permit, Mr. Chairman. And the bill does ask for requirements by people who use the antibiotics, so we can get a pretty good picture overall even if the drug companies don't have detailed information about how their drug is being used after they sold it. But they don't know who the customers are and what it is used for. Thank you.

Dr. PRICE. That is why I am supportive of your bill.

Mr. WAXMAN. Thank you.

Mr. PITTS. The chair thanks the gentleman. And now recognize the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman.

And thank you to our panelists for being here today.

Dr. Apley, we are talking about tools and we are talking about antibiotics being used by veterinarians and farmers for their livestock to keep animals healthy. What other tools are there besides antibiotics that can be used if we are trying to get away from the use of antibiotics?

Dr. APLEY. Sure. And I mentioned pig flow strategies, for example, for the swine industry, which involves very precise control of where the pig is produced, where they move next, and monitoring disease upstream, if you will, say, in the actual pig production facility or in the farrowing facilities so that they can nip it in the bud before it goes further. An example in cattle is preconditioning, where instead of shipping them straight to the feedlot, as in the past, we give them an intermediate stage maybe closer to where they originally were, of altering weaning ages. One of the things we have discovered in cattle is called the Sandhills calving system, where we move them to fresh pastures; fence line weaning of calves, genetic selection. The list goes on and on, and there is a real, real huge focus on that type of disease prevention.

Mrs. ELLMERS. So it is more the process of the livestock farmer really taking care of the animals and making changes necessary.

I also want to ask you, and just in some of the other testimony and questioning that you had, to my understanding just listening to you, you feel that the data collection as far as antibiotic usage is adequate? Is that a correct assumption on my part?

Dr. APLEY. If I could really know a few more things, I would like to know out of interest. I think the question becomes, how would we work it so that it is practical and doable? And then as a scientist, I always want to know that the data I have collected here, how it is confounded, what differs in how it was collected to something I am going to compare it to.

So data estimates are good, but if we are going to make real conclusions as X is causing Y——

Mrs. ELLMERS. Right.

Dr. APLEY [continuing]. Then we have to be incredibly careful on how we interpret that. What I am waiting to hear is, as we move forward on methods for collecting the data, is how do we anticipate interpreting it and then moving from interpretation to regulatory or other uses.

Mrs. ELLMERS. Perfect. Thank you. I appreciate your approach. I think that is very effective.

Dr. Price, I have got some questions. I was just going over some of your testimony here. You are critical, I think that is an accurate assessment, of the FDA on the use of antibiotics and the treatment of use of antibiotics. And one of the quotes that I am just going to point out here, it says, the FDA, I am paraphrasing there, negotiated an agreement to collect fees from drug makers in exchange for expediting drug approval, while missing a prime opportunity to seek some commonsense provisions to simply measure, not restrict, just measure the use of antibiotics.

But in all honesty, isn't that really what you are looking for? I mean, you really are looking to restrict. And you have pointed out a number of situations. And, look, I am a nurse, I totally understand the idea and concept, and I think we are all well aware of overuse of antibiotics, but I am not necessarily sure that the farming community is where we need be focusing and not on just the over-prescription made on antibiotics, you know, out there in the medical world.

You named a few forms of bacteria—staph aureus, MRSA—you also mentioned cephalosporin-resistant E. coli. Now, E. coli I know are being found on farms, obviously. But are those found on farms? Are these particular bacteria strains there and something that we should be issuing?

And I would further that, and we have only got 30 seconds, so I apologize, my time will be running out, but we do cook food, I mean, and so the assumption that food is being eaten that is, you know, filled with bacteria, it does get cooked. So I would like you to comment on that as well.

Dr. PRICE. OK. I will go quickly. We see the same E. coli that cause urinary tract infections, kidney infections, blood infections on the farm, we see them in the animals, we see them in the meat. We see staph aureus, we see multidrug-resistant staph aureus, and we see MRSA on the farms. And there is a difference on the farms that use antibiotics and those that don't. We see more antibiotics on the conventional farms than those antibiotic-free farms. That is very clear.

You said we should cook the meat. It is true. We should cook the meat. I don't want anybody to think we shouldn't. But do you cook chicken? When you open that package, you know that liquid that is in there? Think about drug-resistant bacteria on your hands. So you open that up. Now your hands are contaminated. But we have spoken, so you are going to be really careful. And you are going to put that chicken right in the hot frying oil, right? And then you are going to take that package and you are going to open up the cabinet and you are going to throw it away. You have just contaminated your cabinet. You are going to go wash your hands. You are going to contaminate your faucet, you are going to pump the soap

and contaminate that. And you are going wash your hands and you are going to sing "happy birthday" and get them really clean, and you are going to rinse them off and you are going to recontaminate and you are going to make a salad, and that salad can get drug-resistant bacteria in it. And that is how those things can spread. And you still have them on your cutting board, on your countertop. These things spread around. We don't think it is that people are eating chicken sushi. That is gross, right? It is cross-contamination and that happens.

Mrs. ELLMERS. OK. And I appreciate that. And I realize I have run out of time, so I appreciate the indulgence. But I would say there again, it is an issue of process and efficiency. So thank you.

Mr. PITTS. The chair thanks the gentlelady. And now recognize the gentlelady from Virgin Islands, Dr. Christensen, 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. And good afternoon to the panel.

Dr. Price, it is nice to welcome a fellow Colonial here today. And my first question, you may have already answered, because the first question I had was, is there more that the FDA and industry should be doing to address the problem of antibiotic resistance stemming from the use of these drugs on the farm? And you have about four or five recommendations regarding reporting and data. Is there anything further that you would add?

Dr. PRICE. Well, I just want to emphasize that prudent use goes beyond just growth promotion. So that is, as I said, the most egregious use. But I think routine disease prevention. So I am not talking about, you know, for a short period of time you see that there is a problem and you have to use preventative antibiotics, but I am saying when you time it for a flock cycle or a herd cycle and you are going to say every time we are going to give antibiotics at this time, that is a problem and that is going to select for drug-resistant bacteria, and it does select for drug-resistant bacteria, and we have to get past that. You know, control I am OK with, therapy I am definitely OK with, but this routine disease prevention is, I think, insane.

Mrs. CHRISTENSEN. I am sure you are just passionate about the overuse of antibiotics in human beings.

Dr. PRICE. I am. I am. And they work hand in hand, and I wanted to say that earlier. It is not just antibiotic use in food animal production. I don't want anybody to walk away from here thinking that. You know, we have abused antibiotics in the hospitals and we have abused them on the farms. And the thing is, as I think about this environmental health paradigm where they say, with cancer, they say, you know, the genes load the gun and the environment pulls the trigger. So you are born with this propensity for cancer and then you get exposed to a carcinogen, and that can pull the trigger. But I think about the food loading the gun. So you are ingesting drug-resistant bacteria that is loading your system.

Most of us probably have some of these drug-resistant bacteria in our guts. Most of the time it is no problem. But then we get sick, we go into the hospital, we get treated with antibiotics, and then those bacteria have a selective advantage, and they proliferate and

they get disseminated, and then they get disseminated into the hospital.

Mrs. CHRISTENSEN. Thank you. And I had asked Dr. Dunham a question I wanted to ask you also. As we finalize the guidance that recommends the phasing out of animal production uses like growth promotion and feed efficiency, do you think it is possible for industry to essentially switch a growth promotion claim to a disease prevention claim with just some data showing that the same dose of a drug that promotes growth would also prevent disease?

Dr. PRICE. I am very concerned about this. I am very concerned that if we don't collect very detailed data, that if we don't get the data that I am asking for, that Congressman Waxman's bill would collect, that people are just going to change what they are doing. We need to be collecting data on how much are being used so we can see hopefully that they come down. But if they just switch the names of it, the bacteria don't care. The bacteria don't think about names of antibiotic use.

Mrs. CHRISTENSEN. Thank you. I yield back the balance of my time. Thank you.

Mr. PITTS. The chair thanks the gentlelady. And now recognize the gentlemen from Colorado, Mr. Gardner, 5 minutes for questions.

Mr. GARDNER. Thank you, Mr. Chairman. And thank you to the witnesses today for joining this hearing.

And, Dr. Price, you mentioned factory farmers earlier. What is your definition of a factory farm?

Dr. PRICE. Well, as I said, other people use this term. I rarely use that term. I think when I see these farms, I see factories making drug-resistant bacteria. I see an industry——

Mr. GARDNER. Just to be clear——

Mr. PRICE [continuing]. That is breaking all the rules.

Mr. GARDNER. Just to be clear, you are not talking about a feedlot in and of itself being a factory farm?

Dr. PRICE. No. I am talking about any kind of CAFO where you have animals packed together that are part of an industrial system where you are bringing the animals all in, you are cramming them together, and you are feeding them feed that is laced with antibiotics.

Mr. GARDNER. And I want to be very clear here. I am not trying to put words in your mouth.

Dr. PRICE. Please.

Mr. GARDNER. You don't like feedlots?

Dr. PRICE. I don't like putting thousands of animals together under unsanitary conditions and giving them antibiotics. I do not like this.

Mr. GARDNER. OK. So just the way we keep feedlots, you don't like that?

Dr. PRICE. I do not like situations where we feed animals crammed together antibiotics, because I know what it does. It creates antibiotic-resistant bacteria.

Mr. GARDNER. Right.

Dr. PRICE. My family owns a cattle ranch in Texas. I was raised working work on a cattle ranch. I am not against meat production.

There is not a person in this room that loves a hamburger more than me, I can tell you that.

Mr. GARDNER. Thank you.

Dr. Apley, it is not often that I get somebody from Kansas before this committee, so I thought we would spend the rest of the time talking about water. Just kidding, just kidding.

Dr. Apley, as a veterinarian you are obviously trained in a different way than a doctor is in how to assess—than an M.D., a medical doctor that treats humans, is trained to communicate with something that can't talk back to you to tell you where it hurts, to tell you what is wrong. And because of that you have a different relationship with the people that you see, the herd that you oversee, your—the people, the ranchers that you are dealing with.

Can you tell me a little bit about how you interact with the people who are managing a herd, because you have a relationship with them, right? It is not just, you know, distributing a drug, here it is, and you don't see them again, and they walk away, and they are gone.

Dr. APLEY. Well, probably the best way to describe a day, show up, look at the records, see the manager, and then the rest of my day was spent with the people that took care of the animals. The hardest thing as a veterinarian is to just stand back and not do, but to watch and observe. So we observed what they were doing, and we used protocols and standard operating procedures as the basis for our training.

Mr. GARDNER. And what would happen—if we talked about some of the preventative efforts to make sure that our herds are healthy, what would happen? What would the economic impact be on our food supply if we did not prevent disease in our herds?

Dr. APLEY. Well, it would be dramatic and catastrophic if we weren't able to prevent disease, and that goes back to all the different ways we are summing together to try to prevent that disease.

Mr. GARDNER. Would it impact the supply available to consumers around the world?

Dr. APLEY. It would definitely have a negative impact on what we are able to produce, yes.

Mr. GARDNER. Could you talk a little bit about some of the—and you mentioned it before, but go over again some of the key points of public and animal health safeguards that are in place from a regulatory standpoint and industry standpoint.

Dr. APLEY. Well, for example, in feed use we are not able to use that off label at all. That is strictly by the label. For injectable uses, uses we can use on individual animals like that, there is the ability to use that off label, but only under very strict Animal Medicinal Drug Use Clarification Act regulations, which require veterinarians involved, has a valid rationale, assigns an extended withdrawal period to make sure the animals are properly identified.

Mr. GARDNER. And is there anything the FDA could be doing more to establish appropriate guidelines, regulations regarding the administration of animal drugs?

Dr. APLEY. I think one of the biggest things, and Dr. Dunham mentioned this, is there are listening sessions out there as we look

at moving towards all of the feed and water uses being under veterinary control, that we come up with a system with limited veterinary availability in some areas that makes that workable for all parties. We appreciate them have those listening sessions, and I think right now that is one our biggest goals to get that done correctly.

Mr. GARDNER. Thank you. And just appreciate your work with us today and look forward to working with you through the process.

Yield back my time.

Mr. PITTS. The chair thanks the gentlemen.

We have a UC request.

Mr. PALLONE. Mr. Chairman, I would ask on behalf of Mr. Waxman unanimous consent to enter into the record some letters that were sent to him and you with regard to the DATA Act.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. I want to thank the witnesses for your testimony. It has been a very important hearing; excellent, excellent testimony. Members may have questions that they will send to you. I remind Members they have 10 business days to submit additional questions for the record, and I ask the witnesses to respond to the questions promptly. And Members should submit their questions by the close of business on Tuesday, April 23rd.

Without objection, the subcommittee is adjourned.

[Whereupon, at 6:05 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Center for Science in the Public Interest • Food Animal Concerns Trust • Health Care Without Harm
Keep Antibiotics Working • Natural Resources Defense Council • Union of Concerned Scientists

April 5, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn Building
Washington, D.C. 20515

The Honorable Joe Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn Building
Washington, D.C. 20515

Re: Public Health Enhancements to the Animal Drug User Fee Act

Dear Chairmen Upton and Pitts and Ranking Members Waxman and Pallone:

We write on behalf of a broad coalition of medical, public health, scientific, consumer, and environmental organizations, to urge that the reauthorization of the Animal Drug User Fee Act (ADUFA) include provisions to help preserve the efficacy of antibiotics vital to protecting public health. Specifically, we urge you to enact the data collection and reporting requirements in the Delivering Antimicrobial Transparency in Animals (DATA) Act (H.R. 820), introduced by Representatives Waxman and Louise Slaughter, as part of the Animal Drug User Fee Act (ADUFA).

Antibiotics, the miracle drugs of the last century, are losing their effectiveness as a result of misuse and overuse in human medicine and food animal production. We must continue to pursue efforts to address resistance related to human use of antibiotics, but antibiotic use in animal agriculture constitutes the overwhelming majority of antibiotic use (accounting for over 70% of total sales of medically important antibiotics in the United States) and must also be addressed. A focus on human use alone cannot address the problem.

Antibiotic resistance is an expensive and critical public health threat – one of the Centers for Disease Control and Prevention's "top concerns." Each year an estimated 900,000 cases of antibiotic-resistant infection cost society up to $26 billion in additional healthcare costs, and lead to tens of thousands of deaths as well. The Director General of the World Health Organization has warned that we face a "post-antibiotic era . . . in effect, an end to modern medicine as we know it" and that "'[t]hings as common as strep throat or a child's scratched knee could once again kill."

As the CDC and others note, strong science – more than 147 studies to date – links antibiotic use in animals to antibiotic resistance and risks to human health. Leading medical, public health, and scientific organizations have called for an end to the unnecessary use of antibiotics in animals that are not sick—a key contributor to the rising tide of antibiotic resistance—and for better tracking and reporting of data on antibiotic sales and use to address the threat.

We need action to curb the overuse of antibiotics in food producing animals. We also need the Food and Drug Administration (FDA) to better track and publicly report data that can be used to track trends in antibiotic resistance, design appropriate interventions, and fine-tune those efforts if they have not been effective.

In 2008, Congress through ADUFA reauthorization required drug manufacturers to report antimicrobial sales to FDA and directed FDA to release a summary of these data to the public. The FDA's Summary Reports for 2009, 2010 and 2011 report only total antimicrobial sales volumes by drug class, aggregated to the national level, without any information on animal species in which antibiotics are used or the nature and purpose of their use. Scientists need this data to better understand geographic and temporal trends in antibiotic resistance. Unfortunately, standalone summary sales data, without more detail, are insufficient to track these trends and develop appropriate interventions. To effectively control the antibiotic resistance epidemic, both governmental and non-governmental animal health and infectious disease experts need ongoing access to reliable data on the scope of antibiotic consumption in animals, by species, and in a unit of measure that can be compared across species and localities.

Therefore, during the current reauthorization, we ask the committee to enhance ADUFA further with the DATA Act's provisions to:

- Require large-scale live poultry dealers, swine contractors, and feed lot operators to report to the FDA information on the amount of antibiotics used by animal species and require drug sponsors to report antibiotic sales broken down by animal species
- Require FDA to include in its public summaries information on amounts of antibiotics sold (including for feed sold pursuant to a Veterinary Feed Directive)
    - by different dosage forms (i.e. in feed, in water, or by injection),
    - by different marketing status (e.g. over-the-counter or prescription),
    - by percentages sold for different approved purposes (i.e. growth promotion, disease prevention, disease control, and treatment),
    - by differing medical importance, and
    - by each food-producing animal species
- Require FDA to include in its public summaries information on quantities of antibiotic sold and distributed by state.

Again, we urge you to support stronger data collection and reporting for agricultural antibiotic sales and distribution by amending ADUFA to include these requirements. These provisions will help scientists better understand and track current use patterns, explain resistance trends, and monitor progress in reducing antibiotic use and resistance. This information can help ensure that these essential medicines continue to be effective and to protect children and families well into the future.

Thank you for considering our views.

Sincerely,

Center for Science in the Public Interest
Food Animal Concerns Trust
Health Care Without Harm
Keep Antibiotics Working
Natural Resources Defense Council
Union of Concerned Scientists

April 5, 2013

The Honorable Fred Upton
Chairman
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Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn Building
Washington, D.C. 20515

Dear Chairmen Upton and Pitts and Ranking Members Waxman and Pallone:

On behalf of the undersigned organizations representing medical, public health, scientific, agricultural, environmental, animal protection, and other organizations, we urge you to include H.R. 820, the Delivering Antimicrobial Transparency in Animals (DATA) Act, as part of the final Animal Drug User Fee Act (ADUFA). This legislation provides a reasonable, common-sense approach to better understanding antibiotic use in agriculture.

There is substantial scientific evidence supporting the claim that non-judicious use of antimicrobials in both humans and food animals leads to development of antimicrobial resistance in human pathogens. Given the increasing proportion of highly-resistant pathogens that are causing human disease today, improved antimicrobial stewardship will have a significant positive impact on human health. Unless we are able to significantly change the way we use antimicrobials in both clinical medicine and in agriculture, we risk entering a "post-antibiotic" era, where people die of common infections that previously had been treatable.

The DATA Act would provide the Food and Drug Administration (FDA) and the public with better information on the use of antimicrobial drugs in food animals. Such data will enable public health officials and scientists to better understand and interpret trends and variations in antimicrobial resistance, to improve the understanding of the relationship between animal uses of these drugs and antimicrobial resistance in animals and humans, and to identify interventions to prevent and control resistance.

FDA's current data collection efforts are insufficient to detect correlations between antibiotic use and the development of resistance.

The Animal Drug User Fee Act of 2008 (ADUFA) authorized FDA to collect and publish data from pharmaceutical companies on antibiotics sold for use in food animals, but unfortunately it stops short of requiring public reporting of critical details that would be needed to effectively interpret trends in resistance. ADUFA requires drug sponsors to report to the FDA basic

information about their antimicrobial products, including 1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; 2) quantities distributed domestically and outside the United States; and 3) dosage form, including a listing of the target animals, indications, and approved production classes. Despite being collected by the FDA, data publicly reported under ADUFA have been substantially limited. The Summary Reports for 2009, 2010 and 2011 report only total antimicrobial sales volumes by drug class, aggregated to the national level, without any information on animal species in which antibiotics are used or the purpose of their use. Unfortunately, standalone summary sales data, without additional granularity, is insufficient to effectively study and understand the relationship between antibiotic use and the development of resistance and to consider appropriate interventions.

In September 2011, the Government Accountability Office (GAO) published a report titled *Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*[1], which highlighted shortcomings in the current FDA regulations on antimicrobial animal drug sales and distribution reporting. Indeed, the current lack of adequate U.S. antibiotic consumption data impedes our understanding of geographic and temporal trends in antibiotic resistance. In the agricultural context, a more complete and accurate dataset on antibiotic consumption will make information currently collected under the National Antimicrobial Resistance Monitoring System (NARMS) more effective, because it could be used to show possible correlations between antibiotic use and the development of resistance.

The DATA Act will ensure that U.S. experts have access to reliable, standardized data on the scope of antibiotic consumption in animals by species.

To effectively control the antibiotic resistance epidemic, both governmental and non-governmental animal health and infectious disease experts need ongoing access to reliable data on the scope of antibiotic consumption in animals, by species, and in a unit of measure that can be compared across species and localities. The DATA Act accomplishes this goal by requiring:

- drug sponsors to include in their annual FDA reports the dosage form and the known or estimated amounts of the antimicrobial ingredients in new animal drugs sold or distributed for use in each food-producing animal species for which the new animal drug is approved.

- large-scale live poultry dealers, swine contractors, and feed lot operators to submit annual reports to FDA on the antimicrobials used in their animal feed. For antimicrobials in feed under a Veterinary Feed Directive (VFD), the reports would be required to include information on quantities, dosages, and duration of time that the feed may have been provided to the animals.

- FDA to report data on the percentage of antimicrobials sold for growth promotion/feed efficiency, disease prevention, disease control, and disease treatment.

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[1] U.S. Government Accountability Office, *Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*, GAO-11-801, September 7, 2011.

- FDA to provide the quantity of drugs sold or distributed state-by-state, as well as the quantity of drugs sold or distributed for each type of animal.

- for feed sold pursuant to a VFD, FDA to provide data on the indication for which the feed was sold or distributed, the quantities of feed sold or distributed for each such indication, the number of individual animals to which the feed was intended to be given, and the dosage and length of time for which such feed was intended to be given.

Again, we urge you to support stronger reporting requirements for agricultural antibiotic sales and distribution by amending ADUFA to include the DATA Act. This important legislation will help illustrate current use patterns, explain resistance trends, and monitor progress in assuring responsible animal antibiotic use. The American public needs assurance that these essential medicines will be effective in protecting children and families well into the future. Should you have any questions, please contact Amanda Jezek at 703-740-4790 or ajezek@idsociety.org.

Signed,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Public Health Association
Association for Politics and the Life Sciences
Food & Water Watch
Humane Society Veterinary Medical Association
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Johns Hopkins Center for a Livable Future
Pediatric Infectious Diseases Society
School Food FOCUS National Office
Society of Infectious Diseases Pharmacists
The Humane Society of the United States
Trust for America's Health
The Pew Charitable Trusts

cc: Members of the Committee on Energy and Commerce
Rep. Louise Slaughter


April 2, 2013

The Honorable Henry A. Waxman, Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
2204 Rayburn
Washington, DC 20515

Dear Ranking Member Waxman,

The Patient, Consumer, and Public Health Coalition strongly supports H.R. 820, the Delivering Antimicrobial Transparency in Animals (DATA) Act. Thank you for introducing this legislation, which would enhance the reporting requirements for antimicrobial drugs used in food animals.

The growing risk of drug-resistant bacteria infections will only be solved by responsible use of currently available therapeutics. With approximately 80% of antibiotics sold in the United States being used in food animals, we need to better understand how antibiotic use in food animals is contributing to the increase in drug resistant microbes that affect both animals and humans.

The DATA Act would make it easier for public health officials to track how antibiotics administered to food animals contribute to the development of microbial resistance to specific drugs. It would also provide much needed information for drug manufacturers, food-animal producers, and medical providers to design adequate strategies for responsibly using antibiotics.

H.R. 820 would standardize reporting of how antibiotics are used in food animals and require this information to be distributed in a timely manner. The Act would foster

interagency efforts at the Food and Drug Administration and the Department of Agriculture in tackling the growing problem of antibiotic resistance. The FDA's Draft Guidance 213 should help in reducing antibiotic use, and the DATA Act requires that the Final Guidance be published no later than six months after the enactment of the Act.

Reporting requirements in H.R. 820 would still permit poultry dealers, swine contractors, and feed lot operators to maintain healthy animals. At the same time, your bill would help to ensure that antibiotics continue to be life-saving therapeutics for humans, companion animals, and all other animals. We thank you for your leadership in addressing this growing public health problem.

Annie Appleseed Project
Connecticut Center for Patient Safety
Consumers Union
Jacobs Institute of Women's Health
National Consumers League
National Physicians Alliance
National Research Center for Women & Families
National Women's Health Network
U.S. PIRG
WoodyMatters

For more information, contact Jennifer Yttri at jy@center4research.org or Paul Brown at pb@center4research.org or (202) 223-4000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

APR 24 2013

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the April 9, 2013, hearing entitled "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA." This letter provides the response to Representative Frank Pallone's request at the hearing for information about when a proposed rule entitled "Electronic Distribution of Prescribing Information for Human Drugs Including Biological Products" will be issued. The current Unified Agenda notes that the Food and Drug Administration's (FDA or the Agency) target date for issuing the proposed rule is June 2013. Mr. Pallone also asked for an update on the process moving forward.

While we can not provide a specific timeline or details of the proposed rule's contents prior to the issuance of the proposed rule, this is an issue of importance, and FDA continues to move forward on this proposed rule. Once the proposed rule is published, there will be a public comment period, during which time all interested stakeholders and the public will have the opportunity to provide FDA with their views on the substance of the proposed rule. Public comments are carefully reviewed by FDA and taken into account when drafting a final rule.

FDA agrees that electronic distribution of professional prescribing information will allow for more rapid distribution to health care professionals of the most up-to-date information about a prescription drug, including new warnings, contraindications, and directions for use, which would contribute to better care for patients, reduction in medication errors, and improved public health. Currently, the professional prescribing information containing the information for the safe and effective use of the product is distributed in the form of paper leaflets. Although the information in the professional prescribing information is a valuable resource, it may not contain the most current information because the paper leaflets accompanying a drug during distribution may have been printed and distributed prior to more recent labeling changes. The most common reasons for the printed professional prescribing information that is in the package on pharmacy shelves to be out of date are changes related to new approved uses for a drug already on

the market and new safety information detected from post-market use of the drug or from ongoing clinical trials.

FDA seeks to establish a modern and efficient process to distribute professional prescribing information to health care professionals. Because it takes time to prepare revised paper professional prescribing information, include it in the drug packages, and get those packages into distribution, the electronic distribution of professional prescribing information would help ensure that health care professionals have more rapid access to the most up-to-date information about the safety of marketed drugs.

Please let us know if you have any further questions.

Sincerely,

Michele Mital

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

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