



IN BRIEF

In order to preserve the efficacy of medically important antibiotics, SB 835 would put into California law the voluntary guidelines issued by the Food and Drug Administration (FDA) to phase out the use of medically important antibiotics as growth promoters in food animals and to require veterinary oversight for those drugs.

THE ISSUE

Current law does not prohibit the use of medically important antibiotics for growth promotion in food animals. Current law also does not require veterinary oversight or a prescription to administer medically important antibiotics to food animals.

On December 11, 2013, the FDA announced finalized guidelines to phase out the use of medically important antibiotics to promote growth in food animals and to require veterinarian oversight. However, the recommendations put forward in FDA Guidance for Industry document #213 are only voluntary – there is no obligation to comply.

BACKGROUND

The Centers for Disease Control and Prevention (CDC) estimates that each year at least 2 million people are infected with – and at least 23,000 people die from – antibiotic resistant infections. Each year, antibiotic resistant infections result in at least \$20 billion in direct health care costs and at least \$35 billion in lost productivity.¹

The CDC states, “antimicrobial resistance is one of our most serious health threats. Infections from resistant bacteria are now too common, and some pathogens have even become resistant to multiple types or classes of antibiotics (antimicrobials used to treat bacterial infections). The loss of effective antibiotics will undermine our ability to fight infectious diseases and manage the infectious complications common in vulnerable patients undergoing chemotherapy for cancer, dialysis for renal failure, and surgery, especially organ transplantation, for which the ability to treat secondary infections is crucial.”² **The CDC has deemed antibiotic resistance its top public health threat for 2014.**³

Antibiotic resistance means that bacterial infections can no longer be treated with antibiotics.⁴ Over what are often short periods of time, bacteria can evolve to resist antibiotics that would otherwise threaten their existence. As more antibiotics are used, resistance grows at a faster rate. The resistant bacteria can transfer from food animals to humans by entering the food supply or through the environment.

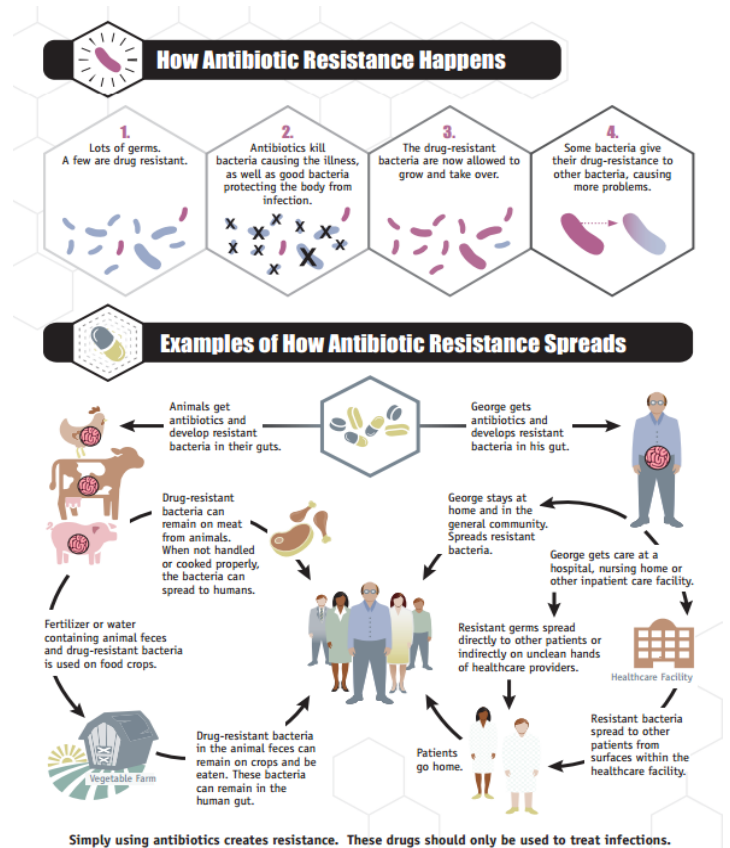


Image from the CDC’s report: *Antibiotic Resistance Threats in the United States, 2013.*

According to FDA data published in 2011, a substantial majority of medically important antibiotics are used not in humans, but are actually used in food animals.⁵ In fact, an independent analysis of the FDA data found that at least 70 percent of all medically important antibiotics are administered to food animals.⁶

Some of the most common medically important antibiotics given to food animals include tetracycline, macrolides and penicillin, all of which are used to treat common infections in humans.⁷

Medically important antibiotics do have legitimate uses in food animals – to treat and prevent disease. But medically important antibiotics are more often used in food animals for to promote growth. Veterinary oversight is not required when administering a medically important antibiotic to food animals and according to the FDA, it's poorly understood how these drugs promote growth.⁸ There is no scientific reason why medically important antibiotics should be used to promote growth in food animals.

In December 2013 the FDA released the finalized version of Guidance for Industry document #213, which asks industry to voluntarily phase out the use of medically important antibiotics to promote growth in food animals. According to the FDA press release, the agency is “*implementing a voluntary plan with the industry to phase out the use of certain antibiotics for enhanced food production*” because “*all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, [so] it is important to use these drugs only when necessary.*”⁹

The FDA guidance document is only voluntary – the industry does not have any obligation to comply. Some major drug companies, such as Zoetis (previously a part of Pfizer), have said they will comply. Some parts of the agricultural industry, such as the National Chicken Council, have also said they support the voluntary guidelines.

THE SOLUTION

SB 835 would put the FDA’s voluntary Guidance for Industry (GFI) document #213 into California law to phase out the use of medically important antibiotics as growth promoters and to require veterinarian oversight for the administration of those drugs. Specifically SB 835 would:

- Require the state Secretary of the Department of Food and Agriculture to refuse to register a medically important antibiotic for use in food animals unless it complies with FDA GFI #213. This means, that in order to be eligible to register a drug for use in California, the drug manufacturer must meet all of, but not limited to, the following:
 - The drug company must remove from the label of any medically important antimicrobial or animal combination drug, any mention or implication that growth

enhancement or feed efficacy are approved uses of the substance.

- The drug company must revise the conditions for using medically important animal drugs and combination drug products so that they are no longer available over the counter (OTC) and require a veterinary prescription (Rx) in order to be purchased and used. This means sale and use of medicated feed products also would require a veterinary feed directive and no longer be available OTC. Sale and use of medicated drinking water products would require an Rx as well.
- The drug company must ensure that medically important antimicrobials are used only to treat, prevent, or control disease under the supervision of or by prescription from a licensed veterinarian.
- SB 835 would define a veterinarian-client-patient relationship as a relationship meeting the requirements of Section 2032.1 of Title 16 of the California Code of Regulations.
- SB 835 would provide manufacturers three years to make the necessary changes and reregister their drugs with the state Secretary of the Department of Food and Agriculture.
- SB 835 would stipulate that medically important antibiotics are any antimicrobial drugs listed in Appendix A of Guidance for Industry document #152 or its most updated version, and include all three tiers of medically important antimicrobials: those that are critically important, highly important and important. This includes penicillin, tetracyclines, cephalosporins and many others.¹⁰

SUPPORT

California State Grange
Infectious Disease Association of California
Health Officers Association of California
California Veterinary Medical Association
The Pew Charitable Trusts (Pew)
California Cattlemen’s Association
Health Care Without Harm

FOR MORE INFORMATION

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¹ Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2013*, <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>, pg. 11

² Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2013*, <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>, pg. 5.

³ CDC Works for You 24/7 Blog, *CDC's Top Ten: 5 Health Achievements in 2013 and 5 Health Threats in 2014*, <http://blogs.cdc.gov/cdcworksforyou24-7/2013/12/cdc%E2%80%99s-top-ten-5-health-achievements-in-2013-and-5-health-threats-in-2014/>.

⁴ Antibiotics are a class of medicines used to treat bacterial infections and are part of the broader class of antimicrobials, which include other drugs, like antivirals and antifungals, which are also used to kill microbes.

⁵ Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf>, pg. 3.

⁶ PEW, *Human Health and Industrial Farming 101*, <http://www.pewhealth.org/reports-analysis/issue-briefs/human-health-and-industrial-farming-101-85899410551>.

⁷ Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf>, pg. 3.

Tetracycline is used to treat common infections, such as pneumonia and other respiratory infections, as well as urinary tract infections, acne and stomach ulcers. Over 12 million pounds were administered to food animals in 2011.

Macrolides are a family of broad spectrum antibiotics, such as erythromycin and azithromycin, used to treat staph infections, pneumonia and chlamydia. Over 1.2 million pounds were administered to food animals in 2011.

Penicillin is used to treat many different infections such as syphilis and staph. Over 1.9 million pounds were administered to food animals in 2011.

⁸ FDA Consumer Health Information, *Phasing Out Certain Antibiotic Use in Farm Animals*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm>.

FDA Consumer Health Information, *Phasing Out Certain Antibiotic Use in Farm Animals*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm>.

¹⁰ For the comprehensive list of medically important antibiotics, please see FDA Guidance for Industry document #152:

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>.