

Regulation of medically-important antimicrobials in food-producing animals
to combat antibiotic resistance in the United States

A policy proposal for U.S. Representatives

by

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Abstract

The routine feeding of antimicrobials to healthy food-producing animals is contributing to a concerning rise in antibiotic-resistant infections among Americans. Antibiotic resistance poses a serious threat to the health of Americans and our animal food supply. Current federal initiatives to combat antibiotic resistance are unlikely to be effective because they do not regulate the use of antibiotics in food animals. U.S. Representatives need to strengthen current strategies by: (1) passing the Preservation of Antibiotics for Medical Treatment Act (PAMTA); (2) passing the Delivering Antimicrobial Transparency Act (DATA); and (3) authorizing President Obama's funding request to combat antibiotic resistance with adequate funds allocated to implementing and overseeing PAMTA and DATA. These actions would save eight (8) critical classes of antibiotics from being fed to healthy animals and collect essential information on how antimicrobials are used in food animals. There is widespread public support to reduce unnecessary use of antibiotics in food animals; this support must be heard and regulatory policy enacted if we are to stem the rise in antibiotic resistance.

Excessive use of antibiotics has led to a substantial increase in antibiotic-resistant bacteria, which now cause more than two million infections and 23,000 deaths in the U.S. each year.(1) When antibiotics are used, pressure is put on bacteria to develop drug resistance.(1) Antibiotic-resistant “superbugs” can then cause infections in humans and animals that are difficult or impossible to treat. Overuse of antibiotics in both humans and animals in the U.S. has contributed to the rise in antibiotic resistance.(1) However, the large majority—80%—of all antimicrobials* sold are used in food-producing animals.(2) These antimicrobials are available over-the-counter and are commonly fed to healthy animals to promote growth and prevent diseases in confined living conditions.(3) Superbugs can develop in food animals fed antimicrobials, and then spread to humans and other animals through manure run-off into water sources, manure spreading on crop fields, physical interactions with agricultural workers, and by remaining on meat that is eaten by consumers.(1) The routine feeding of antibiotics to healthy food-producing animals, therefore, is unnecessary and poses a serious threat to the health of Americans and our animal food supply.

Action is needed by the U.S. Congress to stem the rise in antibiotic resistance. The three (3) recommended actions are as follows:

1. Pass the Preservation of Antibiotics for Medical Treatment Act (PAMTA; H.R. 1552). This act was introduced by Representative Slaughter on March 23, 2015. If passed, the act would amend the Federal Food, Drug, and Cosmetic Act to save eight (8) critical classes of antibiotics from being routinely fed to healthy animals. These medically-important antibiotics would be reserved for use in sick humans and sick animals as deemed necessary by licensed physicians and veterinarians.

*Antibiotics comprise a class of antimicrobials. Both are substances that kill or inhibit the growth of bacteria.

2. Pass the Delivering Antimicrobial Transparency Act (DATA). This act is expected to be introduced by Representative Slaughter later this year. The act would require drug manufacturers and large-scale animal food producers to report to the Food and Drug Administration (FDA) on how their antimicrobials are used in food-producing animals.
3. Authorize President Obama's funding request for antibiotic resistance. In March 2015, President Obama requested that Congress approve increased funding for a five-year strategy to combat antibiotic resistance. This funding request should be approved, under the condition that a sufficient portion of the funds be allocated to federal agencies to support enactment and oversight of PAMTA and DATA.

The policy actions above complement existing policy initiatives that are unlikely to be effective on their own. The FDA has issued voluntary guidelines to aid drug companies and food producers in reducing overuse of antibiotics in food animals, primarily by having drug companies remove "growth promotion" as a labeled use on their products and requiring medically-important antibiotics to only be fed to sick animals under veterinarian orders (as they are currently available over-the-counter).(4) The FDA argues that its approach cultivates stakeholder buy-in and is faster and less expensive than regulation.(4) There is no reason, however, to believe that voluntary guidelines will be effective as long as feeding medically-important antibiotics to healthy food animals is legal and boosts profits. Major drug companies and food producers have agreed to the voluntary guidelines, but there is little evidence that they are actually being followed.(4,5) Additionally, the latest FDA report showed that the sales of medically-important antimicrobials for food animals continued to increase through 2013.(6)

Additionally, President Obama issued an Executive Order in 2014 to implement a five-year strategy to combat antibiotic resistance, and called on Congress in March 2015 to fund the

strategy.(7,8) The Obama administration strategy aims to avoid opposition from drug companies and large-scale food producers by putting the onus of the antibiotic resistance problem on overuse of antibiotics in humans.(7) Of the \$1,167,000,000 requested by the President, no money is allocated to the FDA or to curb antimicrobial use in animals.(7,9) Merely 6.6% of the funding would be allocated to the U.S. Department of Agriculture (USDA) to develop alternatives to antibiotics in food animals; the rest of the funding would focus on antibiotic misuse in humans and drug development.(9) Given that 80% of antimicrobials sold are for food-producing animals, the President's strategy misses a primary cause of antibiotic resistance.

The Congressional actions recommended above would strengthen the strategies of the FDA and Obama Administration. PAMTA would change the FDA's guidelines for veterinarian prescription of medically-important antibiotics to a regulation that could be overseen and enforced. DATA would enable the surveillance of antimicrobial use in food-producing animals so compliance with PAMTA could be assessed and antibiotic resistance could be better understood and monitored. Finally, a portion of funds requested by President Obama could adequately finance the implementation of PAMTA and DATA, making the President's five-year initiative more comprehensive and effective.

A number of stakeholders support the recommended actions, particularly scientific, environmental, and public health groups. (Bibliography of stakeholders attached.) The major leader of advocacy efforts for this stakeholder coalition is the National Resources Defense Council. In policy-making, the CDC and FDA represent the health interests of Americans, and thus would be expected to support PAMTA and DATA if adequate funding were also provided.

A small, but vocal, minority has stymied regulation of antimicrobials in food animals. This group is a coalition of drug companies and food producers, primarily led by the Animal

Health Institute, the trade group for companies that manufacture veterinary medicines.(10-12) In federal policy-making, food producer interests are represented by the USDA.(13) Firstly, this oppositional coalition takes the position that there is insufficient evidence to determine if antibiotic use in food animals affects human health.(3,13) Secondly, they argue that regulation will make it nearly impossible for animal farmers to make a living.(12,14) Thirdly, they state the health and well-being of food animals will suffer.(4,13,15) They do not argue that antibiotic resistance is a major health concern and—at least food producers—support increased regulation of antibiotic use in humans, as they argue there is definitive evidence that antibiotic use in humans leads to the spread of antibiotic resistant infections.(10-12)

Oppositional stakeholders are correct that there is not biological evidence that the use of a specific antibiotic in a food animal has caused a specific antibiotic-resistant infection in a human. However, the FDA, USDA, and CDC have all testified before Congress that there is a definitive link between routine use of antibiotics in food animals and antibiotic resistance in humans.(16) Furthermore, the pathway by which antibiotic-resistant bacteria develop and spread has not been sufficiently studied because drug companies and food producers refuse to disclose details about their use of antimicrobials beyond the total amount sold and distributed.(8,16) DATA would enable the collection of the information needed to fully understand how antimicrobial use and drug resistance are related.

It could also be true that agricultural profits would decrease if meat prices were unchanged after enactment of PAMTA. That is not necessarily true, however, as economic studies have estimated a price impact to be minimal (14) and a wide number of antibiotics that are not crucial for human health would still be available over-the-counter for use in healthy food animals. For the same reason, there is no reason to believe that animal health would suffer.

DATA would not be a large financial burden as drug companies and food producers would only be reporting to the FDA on information they already collect.

Drug manufacturers and large-scale food producers are powerful interests in shaping policy. However, they are a small group compared to the general public, which has become increasingly supportive of antibiotic regulation. It is practically impossible to find a news story that does not frame this issue as extremely important to the health of Americans. The decisions of a few major restaurants, including McDonald's and Chipotle, to reduce their meat supplies from sources that use medically-important antibiotics have been commended in the media.(7,17,18) Conservative news sources tend to give either neutral or supportive reports of antibiotic regulation in food animals.(7,21,22) Even Rush Limbaugh, a very conservative news commentator, stated on his show that a reason to eat organic foods is that they “may live up to their billing of lowering exposure to pesticide residue and antibiotic-resistant bacteria.”(23) The major failing of the media—including conservative, liberal, and neutral sources—has been the framing of antibiotic resistance as a problem caused by the overuse of antibiotics in humans without mention of antibiotic use in food animals.(19,20) Similarly, only one major newspaper, The Washington Post (9), included in its coverage that the President's recent funding request did not address misuse in agriculture despite most antibiotics being used in food animals.

Congress must act on the current momentum to curb antibiotic resistance by regulating the use of medically-important antibiotics in healthy food-producing animals. With a rising number of antibiotic-resistant infections and dwindling supply of last-line antibiotics, there is not time to wait and see if consumer preferences and federal voluntary guidelines will effect change on their own. Congressional approval of PAMTA, DATA, and adequate funding can build on current strategies to ensure that the antibiotics we need to protect health remain effective.

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Annotated Bibliography of Stakeholders in Support

This list is non-comprehensive, but represents most individual stakeholders.

1. American Academy of Pediatrics. The American professional society of pediatricians, which has released official statements calling on the FDA to regulate the inappropriate use of medically-important antibiotics in food-producing animals to protect children's health. <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/FDAGuidanceAntibioticsinAnimals.aspx>.
2. American Medical Association. The AMA is the largest association of physicians in the U.S. and openly calls for federal policy to ban antibiotic use in healthy food animals, including the adoption of a resolution at its annual meeting in 2014. <http://www.mag.org/sites/default/files/downloads/ama14-refcommE-report.pdf>.
3. American Nurses Association. The ANA is the American professional society for nurses and has openly endorsed PAMTA. <http://www.nursingworld.org/DocumentVault/GOVA/Letters-Handouts/AntibioticsLetter-Marc2011.pdf>.
4. American Public Health Association. APHA is the American professional society for public health professionals and has passed resolutions and advocated for regulation of misuse of antimicrobials in food-producing animals to protect public health. <http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/02/08/15/helping-preserve-antibiotic-effectiveness-by-demanding-meats-produced-without-excessive-antibiotics>.
5. American Society for Microbiology. The ASM is the American professional society for people working in microbiology and has endorsed PAMTA, President Obama's funding request, and openly advocates for a comprehensive plan to halt misuse of medically-

important antimicrobials in food animals.

http://www.asm.org/index.php?option=com_content&view=article&id=2637.

6. Centers for Disease Control and Prevention. The CDC is the national public health institute of the U.S. and advocates for increased understanding and regulation of antimicrobials in food-producing animals to protect human health.

<http://www.cdc.gov/narms/animals.html>.

7. Consumers Union. Consumers Union is a U.S.-based nonprofit organization that advocates on behalf of the consumer interest, and openly advocates for regulation of antimicrobial use in food-producing animals. *<https://consumersunion.org/news/the-overuse-of-antibiotics-in-food-animals-threatens-public-health-2/>*

8. Food and Drug Administration. The FDA is the national agency responsible for protecting and promoting public health through regulation and supervision, and thus supports and strategizes to promote judicious use of antimicrobials in food-producing animals. *<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/>*

9. Infectious Diseases Society of America. The IDSA represents physicians, scientists, and other health care professionals who specialize in infectious diseases and openly advocates for the enactment of PAMTA, DATA, and other regulatory measures.

http://www.idsociety.org/topic_antimicrobial_resistance/

10. National Resources Defense Council. The NRDC is a large U.S.-based environmental action group that actively advocates for regulation of antimicrobial use in food-producing animals, has sued the FDA on the issue, and leads a coalition of medical and scientific organizations on the issue. *<http://www.nrdc.org/food/saving-antibiotics.asp>*

11. Union of Concerned Scientists. The UCS is a U.S.-based nonprofit science advocacy organization that primarily supports this cause by funding and publicizing relevant scientific research. http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/food-safety-antibiotics.html#.VUa54_lVhBc
12. World Health Organization. The WHO is the United Nations agency concerned with international public health and calls for policy actions that regulate and promote appropriate uses of medicines in agriculture.
<http://www.who.int/mediacentre/factsheets/fs194/en/>

Annotated Bibliography of Stakeholders in Opposition

This list is non-comprehensive, but represents most individual stakeholders.

1. American Veterinary Medical Association. The AVMA is a professional society for veterinarians and lobbying organization for veterinarians and affiliated industries in animal commerce and agriculture that routinely lobbies against any regulation regarding food-producing animals, including antimicrobial use. <https://www.avma.org/KB/Resources/FAQs/Pages/Antimicrobial-Use-and-Antimicrobial-Resistance-FAQs.aspx>
2. Animal Health Institute. AHI is the trade organization for companies that manufacture veterinary medicines, and as such has been the main lobbying group against regulation of antibiotics in animals, which would decrease profits for its members. <http://www.ahi.org/issues-advocacy/animal-antibiotics/>
3. Department of Agriculture. The USDA is the federal department responsible for meeting the needs of farmers and ranchers, and as such generally does not support regulation that threatens the income of food producers, including regulation of antimicrobial use in animals. <http://www.usda.gov/documents/usda-antimicrobial-resistance-action-plan.pdf>
4. National Cattlemen's Beef Association. The NCBA is a lobbying group for beef producers in the U.S. that aims to increase profits for cattle and beef producers, and actively lobbies against regulation of antimicrobials used in food-producing animals. http://www.beefusa.org/uDocs/Antibiotics%20fact%20sheet%20FINAL_4%2026%2006.pdf
5. National Chicken Council. The NCC is the lobbying organization of the U.S. chicken industry and has been particularly active in opposition to regulation of antimicrobials in

food animals; the growth promoting effects of antimicrobials are most pronounced in chickens. http://www.nationalchickencouncil.org/?attachment_id=2226

6. National Pork Producers Council. The NPPC is the lobbying organization of pork producers and other pork industry stakeholders, which has also advocated against regulation of antimicrobial use in food-producing animals.

<http://www.nppc.org/issues/animal-health-safety/antimicrobials-antibiotics/>

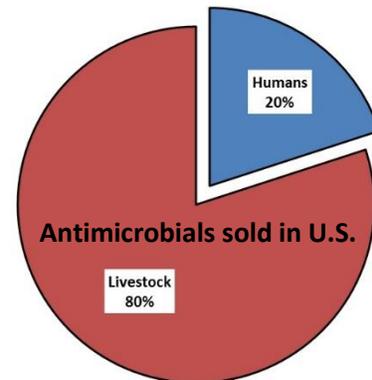
Support oversight of antibiotics to protect health

Background: Antibiotics in Food Animals & Antibiotic Resistance

Antibiotics are routinely bought over-the-counter and fed to healthy food-producing animals (livestock).

Antibiotic overuse contributes to bacteria becoming antibiotic resistant. Such bacteria can pass from food animals to humans by manure run-off, farmers, and meat.

Antibiotic resistance is increasing and poses a serious threat to the health of Americans and food animals.



Current Federal Initiatives are Ineffective

The Food and Drug Administration (FDA) issued guidelines to help drug companies and food producers reduce the use of the most medically-important antibiotics in healthy food animals, but these guidelines are *voluntary*.

President Obama issued an Executive Order in 2014 for a 5-year strategy to combat antibiotic resistance and called on Congress in March 2015 to increase funding for the initiative.

FDA's voluntary initiative does not require compliance and the latest FDA report found sales of medically-important antimicrobials for food animals continued to rise through 2013.

President Obama's strategy does not provide any funding to address overuse of antibiotics in food animals. It focuses on the development of new antibiotics and overuse in humans—a much smaller amount of antibiotics than used in food-producing animals.

Specific Actions Needed by Congress

1. **Pass the Preservation of Antibiotics for Medical Treatment Act (PAMTA; H.R. 1552)** introduced on March 23, 2015. If passed, it would amend the Federal Food, Drug, and Cosmetic Act to save 8 critical classes of antibiotics from being routinely fed to healthy animals, and reserve them only for sick humans and sick animals.
2. **Pass the Delivering Antimicrobial Transparency Act (DATA)**, to be introduced later this year by Rep. Slaughter. It would require drug manufacturers and large-scale animal food producers to report to the FDA on how their antimicrobials are used in food animals.
3. **Authorize the President's funding request for antibiotic resistance**, under the condition that sufficient funds be allocated to federal agencies to support enactment and oversight of PAMTA and DATA.

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