KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

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Frequently Asked Questions About Agricultural Use of Antibiotics

1) **Wouldn't the "Preservation of Antibiotics for Medical Treatment Act" (H.R. 2932/S. 1460) ban antibiotics that FDA has already approved as safe**?

The legislation would phase out the use of eight classes of medically important antibiotics as feed additives. FDA approved those drugs' use as antibiotic feed additives many years ago, at a time when resistance issues were far less well understood than they are at present. (Although FDA collected some additional antibiotic-resistance data on feed additives in the early 1980s[1], it did so using specific test methods that even the animal-drug industry now says "are not predictive" in assessing "the rate and extent of resistance development and the impact this might have on public health."[2] In other words, data from those tests were ineffectual in assessing whether the drugs are safe in terms of antibiotic resistance.) In contrast, the "Preservation of Antibiotics for Medical Treatment Act" provides that already-approved feed antibiotics can remain on the market *only if* FDA concludes that they are safe based on current scientific knowledge – the same standard that has been in the law all along. Significantly, the pending legislation does *not* limit use of any drugs to treat sick animals or to prevent outbreaks in herds and flocks when clinical disease is present.

2) **Why is there a need for legislation? Can't the FDA handle whatever concerns there are with antibiotic feed additives using its existing legal authorities?**

FDA's record indicates that it would likely take a half-century or more to address the eight classes of medically important antibiotics now used as feed additives. As FDA has itself noted, its existing procedures would require the agency to examine each drug or drug class separately, using a process that "can consume extensive periods of time and Agency resources."[3] For example, prior withdrawals took six years for diethylstilbestrol (DES) and 20 years for nitrofurans, while FDA's October 2000 proposal to withdraw approval for therapeutic use of Cipro-like drugs (fluoroquinolones) in poultry is still dragging on after three years. A half-century is simply too long to wait for bureaucratic business-as-usual; resistance is likely to render these drugs ineffective by that time.

3) **Won't animals get sick more without routine use of antibiotic feed additives? Don't the drugs keep animals healthier, so they get sick less and transmit fewer illnesses?**

Studies by the World Health Organization and others have shown that ending the routine use of antibiotic feed additives does *not* compromise food safety.[4] Studies also show that if animals are raised using good animal-husbandry practices, they do not need to be continually dosed with antibiotics to prevent disease. Such practices include proper diet, good hygiene, and avoiding overcrowding, excessive stress, or premature weaning.[5]

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[1] Section 558.15 studies, so called because they were required under Section 558 of the Code of Federal Regulations.

[2] Comments of the Animal Health Institute to FDA Docket No. 98D-0969, "FDA Workshop on Pre-Approval Studies in Antimicrobial Resistance and Pathogen Load," submitted May 3, 2000. www.fda.gov/cvm/index/vmac/VMACAHICOMMENTS1.pdf.

[3] Letter of February 28, 2001, from Stephen F. Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine, Food and Drug Administration, to Karen Florini, Senior Attorney, Environmental Defense, re: Docket 99P-0485/CP.

[4] World Health Organization (2003). *Impacts of antimicrobial growth promoter termination in Denmark.* Report number WHO/CDS/CPE/ZFK/2003.1. www.who.int/salmsurv/links/gssamrgrowthreportstory/en/.

[5] Dritz, Tokach, Goodband, and Nelssen (2002). Effects of administration of antimicrobials in feed on growth rate and feed efficiency of pigs in multisite production systems. *J. American Veterinary Medical Association,* 220: 1690-1695. www.avma.org/publications/javma/articles_public/020601_swine_dritz.pdf. Wierup (2000). The control of microbial diseases in animals: alternatives to the use of antibiotics. *International Journal of Antimicrobial Agents,* 14: 315-319.

4) **How much impact do resistant bacteria from animals have on human health?**
Organizations ranging from the American Medical Association to the National Academy of Sciences have concluded that agricultural use of antibiotics must be reduced in order to help combat the emerging public health crisis of antibiotic resistance. Similarly, an interdisciplinary panel of experts concluded after a two-year review of more than 500 scientific studies that "use of antimicrobials in food animals contributes to the growing problem of antimicrobial resistance in animal and human infections."[6] Public health experts and scientists, rather than pharmaceutical companies and agribusiness, should be the ones to make the determination regarding impact on human health. And they have spoken.

5) **Is there is evidence that banning agricultural antibiotics reduces resistance in people?**
Studies have shown a decline in certain vancomycin-resistant bacteria (specifically enterococci) isolated from humans after a ban on the agricultural use of avoparcin (which triggers cross-resistance to vancomycin) in European countries.[7] Additionally, the World Health Organization reports that levels of antibiotic-resistant bacteria in food animals have declined since Denmark ended routine use of antibiotic feed additives[8] (Denmark has the world's best data on agricultural antibiotic use and antibiotic resistance).

6) **Hasn't ending routine use of antibiotic feed additives in Denmark led to increased use of antibiotics that are of greater clinical importance?**
Comparing 1994 with 2001, use of medically important antibiotics has decreased significantly in Denmark.[9] Avoparcin was banned from agricultural use in 1995, with complete phase-out of antibiotic growth promoters by 1999. Overall antibiotic use decreased by 54% between 1994 and 2001, according to the World Health Organization (though there has been a modest increase in the number of piglets treated with therapeutic antibiotics for diarrhea at time of weaning). On average, use of antibiotics in pigs and broiler chickens has declined from essentially life-long, approximately 170 days and 42 days respectively, to less than eight days in pigs and 0.4 days in broilers.

7) **Don't antibiotic feed additives help maintain a safer meat supply?**
No. Since the continuous use of antibiotics creates antibiotic-resistant bacterial strains, the opposite is true; their routine use threatens human health. Experience bears this out: after Denmark ended routine use of antibiotic feed additives, levels of antibiotic-resistant bacteria in animals decreased significantly.[10]

8) **Wouldn't irradiating meat and poultry products solve the problem of antibiotic resistance?**
Irradiating meat (itself a controversial technique) could in theory reduce the number of resistant bacteria present on meat. But, even if irradiation could eliminate all bacteria on meat, this would not affect the public health threat from resistant bacteria spread directly from animals or farms to farm workers and their communities, or reduce environmental contamination by resistant bacteria from manure that leaches into ground and surface waters and is placed directly on soil.

9) **What about the cost to producers? Banning antibiotic feed additives is projected to cost the U.S. hog industry $700 million over 10 years, or an increase of $4.50 per pig.**
This estimate, from an industry-funded study, ignores real-life experience in countries where use of antibiotic feed additives has already ended. In Denmark, where the transition has already been made, the World Health Organization has documented that Denmark experienced *no* impact on poultry production costs, and only about a 1% increase in pork production costs (approximately $1.25 per pig). [11] The increase was so small that there was no detectable change in consumer prices. Moreover, the Danish phase-out covered some antibiotics that are not used in human medicine; by contrast, The "Preservation of Antibiotics for Medical Treatment Act" (H.R. 2932/S. 1460) expressly covers *only* antibiotic feed additives that are members of classes of drugs used in human medicine.

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[6] Barza M., S.L. Gorbach (2002). The need to improve antimicrobial use in agriculture – ecological and human health consequences. *Clinical Infectious Diseases*. 34 (suppl. 3). Report of the Facts about Antibiotics in Animals and Their Impact on Resistance) project of the Alliance for the Prudent Use of Antibiotics, www.journals.uchicago.edu/CID/journal/contents/v34nS3.html.

[7] Ieven, M. et al. (2001). Significant Decrease of GRE Colonization Rate in Hospitalized Patients after Avoparcin Ban in Animals? 41st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting, December 16-19, 2001. Chicago, Illinois.

[8] World Health Organization (2003). *Impacts of antimicrobial growth promoter termination in Denmark.* Report number WHO/CDS/CPE/ZFK/2003.1. www.who.int/salmsurv/links/gssamrgrowthreportstory/en/.

[9] Ibid.

[10] Ibid.

[11] Ibid.

10) **Won't ending the use of antibiotic feed additives increase animal weight variability at time of slaughter, resulting in lower prices (sort loss) for livestock producers?**
Variability in animal weights is dependent on a large number of factors independent of use of antibiotic feed additives. Livestock producers that want to maximize profits sort animals by weight before taking them to slaughter. Results of large-scale trials in the U.S. have found that ending the use of antibiotic feed additives in finishing swine does not affect average pig weight or result in greater pig weight variability. [12]

11) Won't restricting antibiotic use lead to greater consolidation as less well-managed farms find it harder to survive? Won't this disproportionately affect small farms?
There is no basis to believe that small farms are less well-managed than larger ones. Clearly, restricting the routine use of antibiotics will have a greater impact on farms with poor animal health and unsanitary conditions. But as the U.S. Department of Agriculture has documented, large farms are currently more likely to use antibiotics than small farms.[13] In fact, the majority of farms that use no antibiotics such as pasture-raised or organic pork are family-operated farms. Restrictions on antibiotic use will make these farms more competitive with large-scale "factory" farms.

12) Antibiotic use in animals primarily concerns resistance levels in bacteria that cause food-borne illness. Aren't those rates are already low?
Wrong on both counts. First, rates of food-borne illness are still unacceptably high. For example, the Centers for Disease Control and Prevention estimates that the two most common bacterial causes of serious food poisoning – Salmonella and Campylobacter – cause more than 3.8 million illnesses, 29,000 hospitalizations, and 700 deaths annually.[14] Second, some bacteria that reach humans via food, but that do not cause traditional food poisoning, can take up residence ("colonize") in the gastro-intestinal (G.I.) tract and remain for weeks or months. These include *E. coli*, the major cause of urinary tract infections, and enterococci, a type of bacteria that causes heart valve infections, gall bladder infections, and life-threatening bloodstream infections in patients with other medical conditions. Moreover, when bacteria like *E. coli* and enterococci colonize a person's G.I. tract, they come in contact with millions of other bacteria. Resistance genes are often carried on bits of genetic material, called plasmids, within bacteria. These plasmids can travel from *E. coli* and enterococci to other bacteria in the G.I. tract and cause them to be resistant to the same antibiotics. Focusing only on resistant pathogens directly known to be food-borne in origin ignores the scientific certainty of plasmid transfer of resistance genes.

13) Wasn't there a recent study, which found that data generated through the National Antimicrobial Resistance Monitoring System (NARMS) are too limited and flawed to be a sound decision-making tool?
Significantly, the study was funded by the Animal Health Institute, a trade association for producers of agricultural antibiotics that has long opposed restrictions on use of agricultural antibiotics. While NARMS is not perfect and could certainly benefit from additional resources, the study's wholesale rejection of the NARMS data is unfounded. In particular, there is no rationale for rejecting trend data from NARMS, as the methodologies used in the program have been consistent since its establishment in 1997. Thus, even if any of AHI's criticisms of NARMS' methodologies have merit, those criticisms would only impact the absolute figures, not trends over time. In many instances, the time-trend data are the most critical, including the 6% increase in fluoroquinolone-resistant Campylobacter from 1997 to 2001 (from 13% to 19%, respectively).[15]

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[12] Dritz, Tokach, Goodband, and Nelssen (2002). Effects of administration of antimicrobials in feed on growth rate and feed efficiency of pigs in multisite production systems. ***J. American Veterinary Medical Association,*** 220: 1690-1695. www.avma.org/publications/javma/articles_public/020601_swine_dritz.pdf.

[13] USDA (2002). National Health Monitoring System (NAHMS) Second Swine 2000 Report http://www.aphis.usda.gov/vs/ceah/cahm/Swine/Swine2000/swinepart2.pdf

[14] Mead, Slutsker, Dietz, et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases* 5(5): 607-625. www.cdc.gov/ncidod/EID/vol5no5/mead.htm.

[15] Centers for Disease Control and NARMS Working Group (2001). National Antimicrobial Resistance Monitoring System (NARMS) 2001 Annual Report. www.cdc.gov/narms/annual/2001/2001.pdf. Page 10.