









The preservation of

Antibiotics for Medical Treatment Act

briefing book

CHRISTINE SEQUENZIA

Federal Policy Advisor Government and Legal Affairs

202.446.2140 Christine@awionline.org 900 Pennsylvania Avenue SE Washington, DC 20003

CHRIS HEYDE

Deputy Director Government and Legal Affairs

202.446.2142 Chris@awionline.org 900 Pennsylvania Avenue SE Washington, DC 20003







Preservation of Antibiotics for Medical Treatment Act

Protect Animal and Human Health by Ending the Misuse of Antibiotics in Agriculture

THE PROBLEM

1. Non-therapeutic use of antibiotics leads to resistance. The practice of feeding farm animals low doses of antibiotics in food and water originated in the 1950s and has since become standard practice, enabling confinement operations to suppress disease while rearing tens of thousands of animals in crowded and unhealthy environments. The development of antibiotic-resistant strains of bacteria is traceable to the excessive use of antibiotics in agriculture and presents one of today's most urgent public health threats.

Bacteria carried by animals can develop resistance when exposed to antibiotics at low levels. Antibiotics are administered at these low levels for two non-therapeutic purposes: 1) to increase feed efficiency and promote growth; and 2) to suppress disease in animals who are not yet sick. Most antibiotics used for growth promotion and all antibiotics used for prophylactic disease suppression are used or related to antimicrobials used in human medicine.

2. Antibiotic use is not subject to administrative record keeping. No government entity maintains data on which antibiotics are used in animal agriculture and in what quantities. The Union of Concerned Scientists estimates that non-therapeutic livestock use constitutes about 70 percent of antibiotics consumed in the U.S. Currently, the U.S. leads the world in the use of antibiotics in food animal production, yet there

- is no reporting system, antibiotics administrative oversight or veterinary supervision in place to document the full extent of such use.
- 3. Antibiotic resistance increases healthcare costs. Large confinement operations profit significantly from the misuse of antibiotics, but at the expense of our health. A 2005 study by Tufts University estimated that antibiotic-resistant infections increase healthcare costs by \$50 billion a year. Moreover, resistant strains of E. coli, Salmonella and Campylobacter infect farm animals as well, jeopardizing the economic stability and biological security of industrial farming.



Source: Kevin Moloney for The New York Times





THE SOLUTION

The Preservation of Antibiotics for Medical Treatment Act (PAMTA), H.R. 1549/S. 619

Introduced by Representative Louise Slaughter (D-NY), the late Senator Edward Kennedy (D-MA) and Senator Olympia Snowe (R-ME), PAMTA:

- would prohibit the non-therapeutic feeding of medically important antibiotics to livestock;
- would withdraw FDA approval of antibiotics for non-therapeutic use unless the drug manufacturer demonstrates a reasonable certainty that such use will not harm human health due to antibiotic resistance;
- would not restrict the use of antibiotics to treat sick animals. In addition, it would only reach classes of drugs used in human medicine, leaving other drug options available to producers.

Producers who employ appropriate management needn't excessively medicate their animals to keep them healthy. The Animal Welfare Institute's Animal Welfare Approved certification program prohibits the use of non-therapeutic antibiotics.

Farmers in the AWA program maintain herd health through vaccination, pasture management, exceptional hygiene and the reduction of stressors which weaken animal immune systems.

Animal Welfare Approved requires farmers to provide sick animals with appropriate medical treatment but promotes the use of antibiotics only for animals who have been diagnosed with a microbial disease.







animalwelfareapproved.org





Human Health Risk Defined

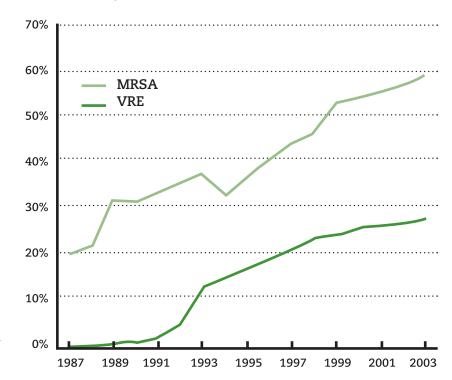
Protect Animal and Human Health by Ending the Misuse of Antibiotics in Agriculture

MRSA AND VRE CASES SHARPLY INCREASE

The proportion of methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant enterococcal infections has continually increased, as shown in the graph to the right compiled by the Center for Disease Dynamics, Economics and Policy.

MRSA infections are up more than 50 percent since 1987. Even more worrisome data is represented by the steady increase in the proportion of resistant isolates found in E. Coli and K. pneumonia, which has increased more than 20 percent in the past 20 years.

The Centers for Disease Control estimates 94,360 serious MRSA infections develop each year, of these 18,650 persons die during their associated hospital stay.

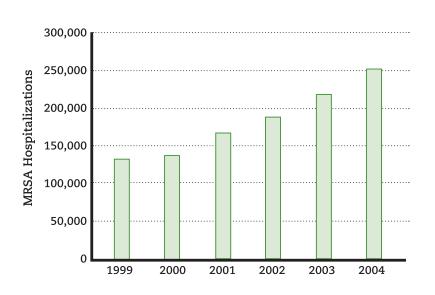


MRSA HOSPITALIZATIONS REACH 250,000

Growing resistance combined with an increasing number of Staphylococcus aureus infections has resulted in an increasing number of hospitalized patients who have MRSA infections

Also, the United States ranks 3rd in the proportion of MRSA infections compared to other high-income countries (2004). The U.S. in this case is preceded only by Japan and Korea.

The data presented here reveals our current public health threat is a direct result of prophylactic antibiotic use in animals being raised for food.



Laxminarayan, Ramanan. Center for Disease Dynamics, Economics and Policy (CDDEP). Resources for the Future. 2008.



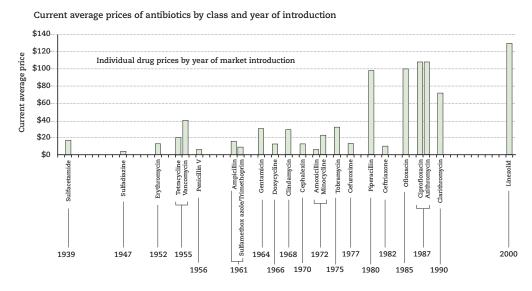


MORE POWERFUL AND EXPENSIVE DRUGS ARE BEING USED TO COMBAT RESISTANCE

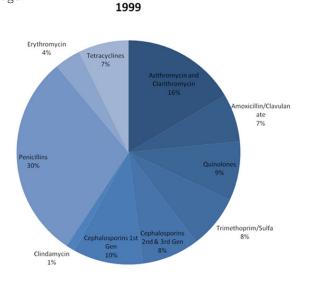
Antibiotics in use today are in grave danger of becoming inadequate to treat human illness. This is a direct result of resistant bacteria which is a response to the overuse of antimicrobials and bad management practices employed in today's intensive food animal production.

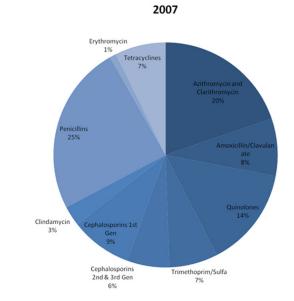
Emergency room doctors have been forced to treat these serious bacterial outbreaks with more costly and powerful drugs. The use of Azithromycin/Clarithromycin has increased over 5 percent in the past 10 years, while the use of Penicillin, a more common drug, has dropped by over 5 percent.

Penicillin's associated cost per treatment remains low at around \$3, while the cost associated with Azithromycin/Clarithromycin on the other hand has skyrocketed to over \$110 per treatment on average.



Laxminarayan, Ramanan. Center for Disease Dynamics, Economics and Policy (CDDEP). Resources for the Future. 2008.





5 Human Health Risk Defined





ANTIBIOTICS: USED AS A FEED ADDITIVE

Fifty-pound bags of antibiotics, like the one shown at right, may be purchased for around \$85 per bag. This drug, which requires a physician's prescription for use in human medicine, may be purchased by any livestock producer wishing to use it as a feed additive through any local sales representative or online.

This particular antibiotic contains Chlortetracycline HCI at 40 grams per pound, Sulfathiazole at 40 grams per pound and Penicillin at 20 grams per pound.

These drugs are given to livestock in the absence of disease. The producer's intent is to enhance weight gain and help prevent outbreak of disease on crowded, inhumane and unsanitary factory farms. However studies show animals can grow and thrive without these unprescribed medications.





ANTIBIOTICS: USED IN INJECTABLE FORM

The bottle shown at left is an injectable form of the feed additive above. This particular drug is only approved for treatment of a sick animal but may be purchased by any livestock producer, online or in a feed store, without a license or prescription. This drug, Noromycin 300LA, sells for around \$70 per bottle and contains 300mg of oxytetracycline.

VETERINARY OVERSIGHT

To prevent increased human health risk we must employ veterinary oversight of all antimicrobial use in animals, especially if the drug is used in human medicine. In the absence of proper reporting and supervision we have seen similar zoonotic bacteria and disease transfer to humans. Infectious diseases in humans originating in animals include HIV/AIDS, SARS, West Nile Virus, Avian Influenza and Swine Influenza.*

6 Human Health Risk Defined

^{*}Blackwell, DVM MPH, Michael. Assist. Surgeon General, USPHS (ret.) and College of Vet. Med., University of Tennessee, Dean (ret). PAMTA presentation to Congress. 2009.





Learn by Example: Benefit to Livestock Producers and Human Health

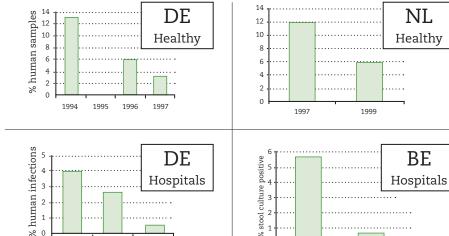
It is time for the United States to become a global leader in protecting human health by withdrawing prophylactic antibiotics

THE EU, DENMARK, SWEDEN AND QUEBEC HAVE TAKEN ACTION TO PROTECT HUMAN HEALTH

Currently, the U.S. is four years behind the European Union (EU), 14 years behind Denmark and 24 years behind Sweden in banning the non-therapeutic use of medically important antibiotics in farm animal production. These nations, along with Quebec's voluntary withdrawal, have taken action to protect the long-term viability of their citizens and the antibiotics that protect them against disease. The EU's last antibiotic phase out took effect January 1, 2006. Along with Denmark, Sweden and Quebec, the EU has already seen the benefit of its actions.

Effect on vancomycin resistance in humans

No Danish monitoring



Klare et al., 1997; van den Bogaard et al. 2000; Ieven et al. 2001, Witte, 2001 (personal comm.)

2001

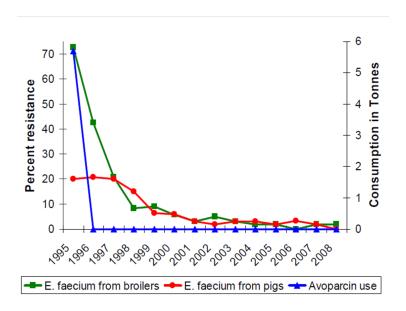
DENMARK: HUMAN HEALTH BENEFIT FOLLOWS THE SUBTHERAPEUTIC BAN

Denmark, which is significantly smaller than the U.S., witnessed a 51 percent reduction in antimicrobial consumption following the ban on subtherapeutic antibiotics. Danish scientists estimate a country the size of the U.S. would experience a 80 percent reduction because initial use is higher.

In a study monitoring the effect on vancomycin resistance in humans, Denmark also noticed a 3.5 percent drop in human-resistant bacterial infections three years after the withdrawal of nontherapeutic antibiotics and a 5 percent drop in resistant bacteria-positive stool cultures a mere four years following the national withdrawal.*

^{*}Aarestrup, Frank. Danish Technical Institute. Letter to Speaker of the House Nancy Pelosi. 2008.





DENMARK: IMPOSES A MANDATORY WITHDRAWAL IN 1996

Denmark also saw a drop in resistant stains of bacteria after they banned non-therapeutic antibiotics in 1996-7.

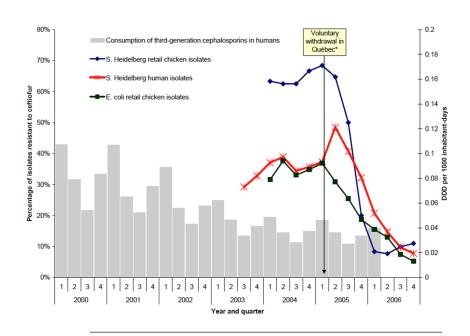
The graph to the left shows a dramatic decrease in the presence of E. faecium found in broiler chickens and pigs, which directly correlates with the halt in prophylactic use of Avoparcin, an antimicrobial, in food animal production.**

QUEBEC: SUGGESTS A VOLUNTARY WITHDRAWAL IN 2005

Food animals being raised without prophylactic antibiotics in their diet have shown a significant drop in the presence of resistant strains of bacteria.

The study to the right shows the presence of S. Heidelberg bacteria in retail chickens dropped from 70 percent in 2005 down to 8 percent in 2008 after Quebec initiated a voluntary withdrawal of non-therapeutic antimicrobials. E. Coli presence in the same batch showed a 30 percent drop.

All the while, human health in Quebec improved significantly. Resistent bacteria found in humans decreased by 40 percent less than one year after the voluntary ban.*



*Avery, Brent, Patrick Boerlin, Anne-Marie Bourgault, Linda Cole, Danielle Daignault, Walter Demczuk, Andrea Desruisseau, Lucie Dutil, Rita Finley, Linda Hoang, Greg B. Horsman, Rebecca Irwin, Johanne Ismail, Frances Jamieson, Anne Maki, Lai King Ng, Ana Pacagnella, and Dylan R. Pillai. Ceftiofur Resistance in Salmonella enterica Serovar Heidelberg from Chicken Meat and Humans, Canada. Emerging Infectious Diseases Vol. 16, No. 1. Centers for Disease Control and Prevention. Department of Health and Human Services. www.cdc.gov/eid. January 2010.

^{**}Aarestrup, Frank. Danish Technical Institute. Letter to Speaker of the House Nancy Pelosi. 2008.



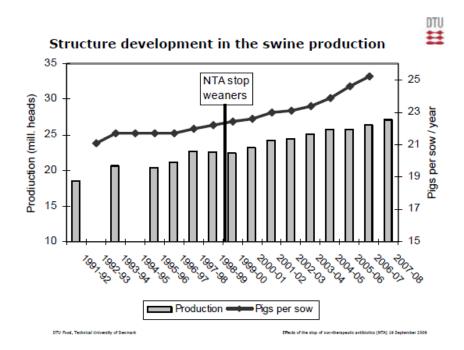


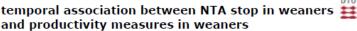
DENMARK: INCREASE IN PRODUCTION FOLLOWS THE SUBTHERAPEUTIC BAN

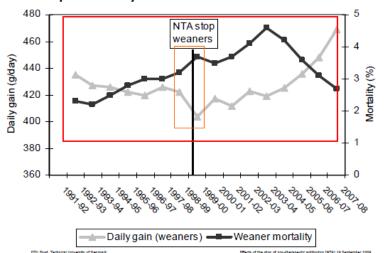
Agriculture industry interests in the U.S. have expressed their concern about possible loss in sales and production after a possible ban on antimicrobials.

The study to the right suggests a steady increase in the number of pigs per sow and a steady increase in production after the ban which demonstrates healthier animals reproduce more efficiently, which will lead to an overall increase in financial gain for industry.

This increase in production coupled with reduced overhead costs, associated with discontinuing mass prophylactic antibiotic treatment, can only work to increase financial gain to the producer. *







DENMARK: INCREASE IN DAILY WEIGHT GAIN FOLLOWS THE SUBTHERAPEUTIC BAN

Another concern expressed by some U.S. producers centers around possible short term loss while facilities wean animals and infrastructure off antimicrobials.

The graph to the left illustrates a short-lived spike in mortality rates following the national ban. Demark witnessed the return of pre-ban mortality rates 3-4 years after removing the medical crutch, which continues to jeopardize human health in the U.S.

Most importantly, Demark has experienced a steady increase in animal daily weight gain as animals have become healthier and facilities work to provide appropriate living conditions for their animals. This study suggests producers have nothing to lose and everything to gain by reforming their current standard.*

^{*}Ministry of Food, Agriculture and Fisheries. Danish Veterinary and Food Administration. Information note regarding the Danish and EU restrictions of nontherapeutical use of antibiotics for growth promotion, August 12, 2009.





JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

The concern some producers have about a possible increase in production cost following a ban on antibiotics has been trumped by several university studies on the issue.

Johns Hopkins Bloomberg School of Public Health released a study in 2008, which was the first of its kind utilizing large-scale empirical data collected by U.S. industry frontrunner, Perdue. At the time of study Perdue ranked as the fourth largest poultry producer in the United States.

Johns Hopkins researchers concluded the production changes associated with non-therapeutic antibiotic use were insufficient to offset the cost of using prophylactic antibiotics. The report showed the use of antibiotics in industrial farming actually devalued chickens at a loss of \$0.0093 per animal. The authors also found no basis for the claim that the use of prophylactic antibiotic use lowers the cost of production.

*Graham, Jay P., John J. Boland, PhD., and Ellen Silbergeld, PhD. Growth Promoting Antibiotics in Food Animal Production: An Economic Analysis, 2007.



USDA: ECONOMIC RESEARCH SERVICE

The United States Department of Agriculture (USDA) also published similar findings in their Economic Information Bulletin, printed in January 2009. USDA found little impact of prophylactic antibiotic use at the finishing stage—farms that used prophylactic antibiotics had costs of production that differed little from those that did not. The researchers also stated any productivity improvement from non-therapeutic antibiotic use was not large enough to offset the additional expense.

In this volume, USDA researchers pointed out these findings were consistent with the EU ban on non-therapeutic antibiotics.

Further, a separate USDA study found that prophylactic antibiotics boosted feed efficiency slightly, but not enough to offset the expense, so facilities not using non-therapeutic antibiotics preformed slightly better financially.

^{*}MacDonald, James M., and William D. McBride. Economic Research Service. Economic Information Bulletin Number 43. The United States Department of Agriculture. January 2009.





Medical Risk in the News

How many drugs and vaccines will we give food animals before the public demands cleaner food?

The New York Times

December 4, 2009 After Delays, Vaccine to Counter Bad Beef is Being Tested By WILLIAM NEUMAN

HOLYOKE, Colo.—Jason Timmerman coaxed a balky calf into a chute on his feedlot one recent afternoon and jabbed a needle into its neck. He was injecting the animal with a new vaccine to make it immune to a dangerous form of the E. coli bacteria. The calf and thousands of others are part of a large-scale test to see whether animal vaccines are an answer to one of the nation's most persistent food-safety problems. ... And now, even if the vaccines prove successful in the ambitious tests that are just getting under way, they face an uncertain future as farmers and feedlot owners worry about who will pick up the extra cost. While studies have shown varying degrees of effectiveness, many researchers believe E. coli vaccines can reduce the number of animals carrying the bacteria by 65 to 75 percent. That may be enough to prevent the surge of E. coli that typically occurs each summer, when the germ thrives and reports of illness increase. ...

Food poisoning from toxic strains of E. coli, mostly the O157:H7 variety, has become a recurring problem. The strain is responsible for an estimated 73,000 illnesses and 61 deaths across the country each year. ... Since January 2007, the industry has initiated 52 recalls of beef tainted with E. coli, compared with 20 in the three previous years. In one of the most recent cases, in October, a company in upstate New York recalled more than 500,000 pounds of ground beef after two people died and more than two dozen were sickened. ... Many E. coli strains live in a cow's digestive tract without making it sick. But several strains, notably O157:H7, can sicken people who eat it in ground beef or other foods. ... The Food and Drug Administration determined that it did not have jurisdiction, either. While it regulated many animal medicines as well as drugs aimed at human health, it was not responsible under federal law for animal vaccines. ... Officials determined that the vaccines must show at least a 90 percent reduction in the number of cattle carrying the bacteria. Farmers and feedlot owners fear that they will be stuck with the vaccine cost and that it will cut into already tight margins.



March 2, 2009 Antibiotic-Resistant Infections Among Children on the Rise By JUDY FORTIN

ATLANTA, Georgia (CNN)—It was 10 a.m. on a recent weekday and the emergency room at Scottish Rite Children's Hospital in Atlanta, Georgia, was quiet, except for a little boy crying in room 45. Two-year-old Talan Williamson was battling a painful staph infection. It's not just any infection, but the kind that most parents dread: methicillin-resistant Staphylococcus aureus or MRSA. "I'm scared," said his mother, Trisha Williamson, 24, of Cartersville, Georgia. "I'm scared and frustrated. I want answers to why we cannot get rid of it."

Doctors claim they are seeing more and more cases of MRSA in children. The bacteria are resistant to most common antibiotics, so they have to turn to a small handful of stronger ones. But doctors want to use the stronger antibiotics as a last resort, fearing that they, too, will become ineffective over time. According to the Centers for Disease Control and Prevention, an estimated 95,000 people in the United States developed serious MRSA infections in 2005 (the latest data available). While the CDC cannot say how many children were infected, the agency reported the greatest increase in hospital visits were among those under 18 during an eight-year period ending in 2005.

Dr. Martin Belson, a pediatric emergency room physician with Children's Healthcare of Atlanta, experienced the trend firsthand. "I can't think of a shift where I haven't had a case of an abscess from MRSA," he said. These days, Belson explained, everyone is at risk, but children are especially vulnerable because of their underdeveloped immune systems. "It used to be, decades ago, it was just people who were hospitalized or had surgical procedures that were at risk for MRSA. Now, it's becoming more community-acquired," Belson said. A study published in the January edition of the Archives of Otolaryngology-Head and Neck Surgery revealed a 16-percent increase in pediatric MRSA infections in the head and neck during a recent six-year period. Belson called the rise alarming. He blamed part of the problem on an increased resistance to the antibiotics used to treat MRSA. ... Trisha Williamson said she's tried everything including bleach baths and special cleansers for the shower. "I'm really at wits end," she lamented. "We keep getting it."

11 Medical Risk in the News