

Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture

Statement of

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Antimicrobial drugs are used to treat infections caused by microorganisms. The term “antimicrobial” are drugs that have activity against a variety of microorganisms, including bacteria, viruses, fungi, and parasites (such as malaria). The term “antibacterial” refers to drugs with activity against bacteria in particular. An “antibiotic” is a natural compound produced by a fungus or another microorganism that kills bacteria that cause disease in humans or animals (example penicillin). Some antibacterial drugs are synthetic compounds; i.e., they are not produced by microorganisms; they are referred to as antibiotics in common usage. Antimicrobial agents have been used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. Many infections that were fatal, or left individuals with severe disabilities, are now treatable or preventable. However, because resistance to antimicrobial drugs is expected to occur with their use, it is essential that such drugs be regulated and used judiciously to delay the development of resistance. Misuse and overuse of these drugs contribute to an even more rapid development of resistance. Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to cure or prevent infections. A 2004 report from the Infectious Diseases Society of America (IDSA) noted that “About two million people acquire bacterial infections in U.S. hospitals each year, and 90,000 die as a result. About 70 percent of those infections are resistant to at least one drug. Many factors contribute to the spread of antimicrobial resistance. In some cases, doctors prescribe antimicrobials too frequently or inappropriately. Sometimes patients do not complete the prescribed course of an antimicrobial, making it more likely that surviving microbes will develop resistance. Antimicrobial use in animals contributes to the emergence of resistant microorganisms that can infect people. Through international trade and travel, resistant microbes can spread quickly worldwide.

Dr. Joshua M. Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), which is an agency of the Department of Health and Human Services (HHS) testified July 14, 2010 to the Subcommittee on Health of the US House of Representatives. He discussed the FDA's role with regard to antimicrobial resistance.

Preserving the effectiveness of current antimicrobials and encouraging the continued development of new ones are vital to protecting human and animal health against infectious microbial pathogens. A 2004 report from the Infectious Diseases Society of America (IDSA) noted that "About two million people acquire bacterial infections in U.S. hospitals each year, and 90,000 die as a result. About 70 percent of those infections are resistant to at least one drug." Resistant pathogens lead to higher health care costs because they often require more expensive drugs and extended hospital stays. The problem is not limited to hospitals. Clinicians practicing in every field of medicine, including my own field of pediatrics, encounter resistant infections frequently. So, too, do veterinarians. Community-acquired infections are frequently resistant to multiple antimicrobial drugs, such as community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA), common respiratory pathogens, including *Streptococcus pneumoniae*, and gram-negative bacilli, which can infect humans through contaminated food.

In my testimony, I will provide background information on antimicrobial resistance, describe FDA's actions to combat resistance and promote product development, and discuss the newly released draft guidance entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals."

As I will discuss in more detail later, in the draft guidance, FDA concludes that the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health. Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health.

BACKGROUND

Antimicrobial drugs are used to treat infections caused by microorganisms. The term "antimicrobial" refers broadly to drugs with activity against a variety of microorganisms, including bacteria, viruses, fungi, and parasites (such as malaria). The term "antibacterial" refers to drugs with activity against bacteria in particular. Another term commonly used to describe an antibacterial drug is "antibiotic." This term refers to a natural compound produced by a fungus or another microorganism that kills bacteria that cause disease in humans or animals. Some antibacterial drugs are synthetic compounds; i.e., they are not produced by microorganisms. Though these do not meet the technical definition of antibiotics, they are referred to as antibiotics in common usage.

Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance occurs when bacteria change in some way that reduces or

eliminates the effectiveness of drugs, chemicals, or other agents designed to cure or prevent infections.

Many factors contribute to the spread of antimicrobial resistance. In some cases, doctors prescribe antimicrobials too frequently or inappropriately. Sometimes patients do not complete the prescribed course of an antimicrobial, making it more likely that surviving microbes will develop resistance. Antimicrobial use in animals contributes to the emergence of resistant microorganisms that can infect people. Through international trade and travel, resistant microbes can spread quickly worldwide.

Antimicrobial agents have been used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. Many infections that were fatal, or left individuals with severe disabilities, are now treatable or preventable. However, because resistance to antimicrobial drugs is expected to occur with their use, it is essential that such drugs be regulated and used judiciously to delay the development of resistance. Misuse and overuse of these drugs contribute to an even more rapid development of resistance. After several decades of successful antimicrobial use, we have seen and continue to see the emergence of multi-resistant bacterial pathogens, which are less responsive to therapy. Antimicrobial resistant bacterial populations are emerging because of the combined impact of the various uses of antimicrobial drugs, including their use in humans and animals.

New classes or modifications of older classes of antimicrobials over the past six decades have been matched slowly but surely by the development of new bacterial resistance mechanisms. As of today, antimicrobial resistance mechanisms have been reported in the scientific literature for all known antibacterial drugs that are currently available for clinical use in human and veterinary medicine. In some cases, strains have been isolated that are resistant to multiple antibacterial agents.

U.S. INTERAGENCY TASK FORCE ON ANTIMICROBIAL RESISTANCE

The U.S. Interagency Task Force on Antimicrobial Resistance (Task Force) was created in 1999 to develop a national plan to combat antimicrobial resistance. FDA co-chairs the Task Force, along with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health.

The Task Force also includes the Agency for Healthcare Research and Quality, Centers for Medicare and Medicaid Services, Health Resources and Services Administration, United States Department of Agriculture (USDA), Department of Defense, Department of Veterans Affairs, and the Environmental Protection Agency. In 2001, the U.S. Agency for International Development joined the Task Force to help address global antimicrobial resistance issues.

In 2001, the Task Force published the “Public Health Action Plan to Combat Antimicrobial Resistance” (Action Plan). The Action Plan has four major components: surveillance, prevention and control, research, and product development. The Interagency Task Force has been working on a revised Action Plan. The revised Action Plan, which is currently undergoing

interagency review, will provide more specific action items than the 2001 Action Plan and will include goal dates for completing many of the action items.

ANTIBIOTIC REDUCTION IN HUMAN MEDICINE

The issue of antimicrobial resistance is being addressed on a number of fronts. My colleague from CDC will discuss the data associated with human resistance as it relates to antimicrobial use in food-producing animals and on his agency's leadership in efforts to fight resistance in human medicine. As a pediatrician, I remember when CDC and the American Academy of Pediatrics published principles in 1998 (Dowell SF, Marcy SM, Phillips WR, Gerber MA, Schwartz, B. Pediatrics. 1998;101:163-165) for the judicious use of antibiotics in common pediatric infections: the common cold, otitis media, acute sinusitis, and pharyngitis. Children often have a high number (3-8) of viral upper respiratory infections each year, and it is important to not be using antibiotics for viral infections that will not respond to them but will increase the child's probability of having a resistant organism when they do have an infection due to a bacteria. Otitis media, or ear infections, are one of the most common infections of childhood where an antibiotic may be needed. By 3 years of age, greater than 80 percent of children have had at least one episode of acute otitis media and 46 percent have had three or more episodes of ear infections. Judicious use of antibiotics helps decrease the probability that this common infection will be caused by an organism that is resistant to the more commonly used antibiotics (Feigin & Cherry: 1998). This initiative has been successful in reducing antibiotic prescription rates. Pediatricians are now using more discretion when administering antibiotics to their patients. A recent study in the Journal of the American Medical Association, which utilized national databases, reported that antibiotic prescription rates for children under 5 years of age with respiratory tract infections (including infections such as the common cold) decreased by 41 percent between 1995-1996 and 2005-2006 (JAMA 2009;302:758-66).

FDA'S ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE

Many Centers at FDA are addressing the public health concern about antimicrobial resistance. For example, research and regulatory efforts at the Center for Biologics Evaluation and Research (CBER) have contributed to the development and continued availability of effective vaccines, which have eliminated or markedly decreased antimicrobial resistance by reducing or nearly eliminating some types of infections. Additionally, the Center for Devices and Radiological Health (CDRH) leads several efforts to clarify regulatory requirements for both industry and the scientific community on clearance of diagnostic tests for use in antimicrobial resistance initiatives.

Since today's hearing focuses specifically on the use of antimicrobials in animal agriculture, my testimony will highlight the efforts at the Center for Veterinary Medicine (CVM). I will also provide a brief update to Dr. Janet Woodcock's recent testimony before this Subcommittee about the initiatives at the Center for Drug Evaluation and Research (CDER).

CVM (Center for Veterinary Medicine) is working with the FDA to address the antimicrobial resistance issue.

FDA's strategy for addressing the antimicrobial resistance issue starts with surveillance through the National Antimicrobial Resistance Monitoring System (NARMS). NARMS is a multi-faceted system that monitors trends in the prevalence of antimicrobial-resistance among bacteria isolated from humans, retail meats, and food animals. CVM is the lead coordinator of NARMS and collaborates with CDC, USDA's Agricultural Research Service and State public health laboratories. NARMS data are critical for monitoring antimicrobial drug resistance among Salmonella and other enteric bacterial organisms from human and animal populations, as well as retail meats. Such data provide important information to regulatory officials, physicians, and veterinarians for assessing trends and identifying appropriate risk mitigating measures. Additionally, NARMS provides a national source of enteric bacterial isolates that are invaluable for conducting antimicrobial resistance research.

As part of the new animal drug approval process, CVM developed and implemented an approach for assessing antimicrobial resistance concerns associated with the use of antimicrobial drugs intended for use in food-producing animals. This approach uses risk assessment methodologies to assess the potential human health impact from the proposed antimicrobial use in animals and outlines risk management strategies that may be applied. In 2003, FDA published Guidance for Industry #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." (To view FDA guidance documents, please visit <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm>¹). Guidance #152 provides recommendations to drug sponsors on the use of a qualitative risk assessment approach for evaluating the likelihood that an antimicrobial drug used to treat a food-producing animal may cause an antimicrobial resistance problem in humans. The risk assessment approach recommended in the guidance considers a broad set of information, including the importance of the drug in question to human medicine. This information is collectively considered in determining whether the proposed antimicrobial product will pose a risk to public health.

FDA believes the approach outlined in Guidance #152 for evaluating the safety of antimicrobial drugs as part of the drug approval process is scientifically sound and is protective of the public health. However, many antimicrobial drug products, approved prior to the implementation of Guidance #152 in 2003, have not been evaluated under the current processes for assessing safety, with respect to antimicrobial resistance. Of particular concern are those antimicrobials that are considered medically important drugs (i.e., those drugs or classes of drugs that are important in human medicine) and are approved for use in food-producing animals for production or growth-enhancing purposes.

Judicious-Use Guidance for Antimicrobials in Food-Producing Animals

To address this concern, CVM released a draft guidance on June 28, 2010, entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>²). This draft guidance is intended to inform the public of FDA's current thinking on the use of medically important antimicrobial drugs in food-producing animals. It is intended to help minimize antimicrobial resistance by outlining several broad

principles for ensuring that medically important antimicrobial drugs are used judiciously in animal agriculture.

The draft guidance reviews the major public health reports on this topic, including reports by the Institute of Medicine, the Government Accountability Office, and the World Health Organization. FDA believes the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health.

In the draft guidance, FDA recommends phasing in measures that would (1) limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health and (2) include veterinary oversight or consultation. These steps would help reduce overall use of medically important antimicrobial drugs, thereby reducing the selection pressure that generates antimicrobial resistance. Prior to issuing the draft guidance, FDA consulted with USDA to seek their input on the recommendations. FDA and USDA are committed to working collaboratively to address this important public health issue.

FDA is seeking public comment on the draft guidance through August 30, 2010. FDA is committed to working with USDA, animal drug sponsors, the veterinary and public health communities, the animal agriculture community, and all other interested stakeholders in developing a strategy to address antimicrobial resistance concerns in a manner that is protective of both human and animal health. For example, FDA intends to work closely with USDA, producers, and veterinarians on strategies for increasing veterinary involvement in the use of antimicrobial drugs and for assuring that specific animal health needs are met as the measures outlined in the guidance are implemented.

CDER

FDA's efforts to address antimicrobial resistance are not limited to uses of antibiotics in food-producing animals. It is important that (1) our existing antibacterial drugs for humans be used prudently to preserve their effectiveness and (2) that new antibacterial drugs for humans be developed as we expect that resistance will develop to existing therapies over time. In her recent testimony, Dr. Woodcock described several initiatives under way to address challenges in human medicine at CDER, which include gathering scientific data to inform the development of recommendations on designing informative, ethical, and feasible clinical trials; issuing draft guidance documents concerning clinical trial designs for studying antibacterial drugs; and working towards publishing additional draft guidance documents in the coming months to address the development of antimicrobial drugs intended for use in treating skin infections and hospital-acquired/ventilator-associated bacterial pneumonia. In addition, FDA recently announced a public workshop to be held August 2-3, 2010, regarding issues in the design and conduct of clinical trials for antibacterial drug development. The public workshop is intended to provide information for and gain perspectives from health care professionals, researchers, academia, industry, and regulators on various aspects of design and conduct of clinical trials for antibacterial drugs.

CONCLUSION

Addressing antimicrobial resistance is a challenging task that requires the expertise and efforts of many entities. FDA will continue to work with federal, state, local, and foreign government officials, medical professionals, including the veterinary community, the regulated industry, and all of FDA's stakeholders, in developing sound strategies to address and advance both human and animal health.

Thank you for the opportunity to discuss FDA's activities with regard to antimicrobial resistance. I would be happy to answer any questions.

The Risk to Human Health

It is estimated that over one-half of the antibiotics in the U.S. are used in food animal production. The overuse of antimicrobials in food animal production is an under-appreciated problem. In both human and veterinary medicine, the risk of developing resistance rises each time bacteria are exposed to antimicrobials. Resistance opens the door to treatment failure for even the most common pathogens and leads to an increasing number of infections. The mounting evidence of the relationship between antimicrobial use in animal husbandry and the increase in bacterial resistance in humans has prompted several reviews of agricultural practices by scientific authorities in a number of countries, including the US.

Overview of the Relationship Between Antimicrobial Use in Food Animal Production and Antibiotic Resistance

- Exposure to antimicrobials fundamentally alters microbial ecosystems of humans, animals and the environment, which may lead to the development of antimicrobial resistance.
- Increasing antimicrobial resistance limits treatment options, raises health care costs, and increases the number, severity and duration of infections.
- Antimicrobial use is a major cause of antimicrobial resistance.
- It is estimated that, in the United States, the amount of antimicrobials administered to food animals is comparable to that used in humans. These antimicrobials are utilized largely to promote growth and prevent disease, thereby reducing production costs. A substantial amount of them are sold over-the-counter and do not require a veterinarian's prescription.
- Most food animals in the US are exposed to antimicrobials in feed, water, or by injection at some point during their lives.
- Fecal waste from food animals treated with antimicrobials, which is often composted and spread as fertilizer, is implicated in environmental contamination with resistant bacteria.
- Several lines of evidence may link antimicrobial use in food animal production to resistant infections in humans. These include: (i) direct studies tracing resistant infections in humans to specific meat and poultry operations; (ii) temporal evidence (i.e. the emergence of resistance in animal-associated bacteria prior to its emergence in human pathogens); (iii) circumstantial evidence linking human disease to trends in resistance among common bacterial pathogens such as *Salmonella*, *Campylobacter* and *E. coli*; (iv)

studies suggesting that farmers and family members may be more likely than the general public to harbor antimicrobial-resistant intestinal bacteria; and (v) studies of the transfer of resistance in commensal bacteria.

- Most antimicrobials used in food animal production are the same as, or closely related to, drugs used in human medicine.
- Current antimicrobial use policy for animals in the US differs from policy enacted in the European Union, which has banned the use of some antimicrobials for growth promotion on the farm.
- Also of concern is the farm use of antimicrobials of critical importance in human medicine, such as fluoroquinolones and third (or higher) generation cephalosporins
- Once the prevalence of antimicrobial resistance in a population reaches a certain level, reversal of the problem becomes extremely difficult.
- The study entitled "[Changes in the use of antimicrobials and the effects on productivity of swine farms in Denmark](#)" identifies positive results from the enactment of policies in Denmark that regulate antimicrobial use in agriculture. Trends showed a decrease in antimicrobial consumption per kilogram of pig produced from 1992-2008 along with an improvement in overall swine productivity. These findings provide the best evidence supporting a ban on the use of antimicrobial growth promoters.
- For more information please see the APUA [FAAIR](#) (Facts about Antibiotics in Animals and Their Impact on Resistance) report sponsored by the Joyce Foundation. The report entitled The Need to Improve Antimicrobial Use in Agriculture: Ecological and Human Health Effects contains scientific evidence meant to inform the policy debate surrounding the use of antibiotics in food animal production. Please also see the [2005 FAAIR II report](#) focused on obtaining improved antibiotic usage estimates in US food animal production to guide regulatory decision-making.

• **THE NEED TO IMPROVE ANTIBIOTIC USE IN FOOD ANIMALS**

- There is significant evidence and consensus among major scientific and medical groups (AMA, APHA, IDSA) linking antimicrobial use in food animal production to resistant infection in humans. Antimicrobial resistance **limits treatment options, raises healthcare costs, and increases the number, severity, and duration of infections** ⁽¹⁾.
- In the United States, it is estimated that the amount of antimicrobials used in food animal production is greater than the amount used in humans. The FDA has communicated that about 28.8 million pounds of antibiotics were sold and distributed for use in food animals in 2009 ^{(2), (3)}.
- Antibiotic growth promotion in food animals utilizes **sub-therapeutic doses of an antibiotic for extended periods of time**. This selects for resistant strains, and amplifies their persistence and dissemination in the environment where they can be transferred to humans ⁽⁴⁾.
- **Concentrated animal feeding operations (CAFOs)** and the improper composting of fecal waste contribute to antibiotic resistance emergence and spread of infectious disease ⁽⁵⁾. **Improved husbandry practices** would reduce overuse of antibiotics in food animals ⁽⁶⁾.
- Many AGP's (antibiotic growth promoters) used in food animal production are the same antimicrobial treatments used in human medicine. Antibiotics **classified as critically important to human health** (such as penicillin, cephalosporins, tetracycline, and the fluoroquinolones) should be regulated in food animal production ⁽⁷⁾.

- **Guidance #152, passed in 2003**, was the first FDA recommendation that drug sponsors use a qualitative risk assessment approach to evaluate the likelihood that use of an antimicrobial in food animals could cause antimicrobial resistance in humans⁽⁸⁾. Many antimicrobials used in food animals were **approved decades before this recommendation** ⁽⁹⁾.
- Drug resistant organisms take a staggering toll in the US and worldwide: just one organism, **methicillin-resistant *Staphylococcus aureus* (MRSA) kills more Americans every year than emphysema, HIV/AIDS, Parkinson's disease, and homicide combined** ⁽¹⁰⁾. In 2005, about **94,000 persons** developed their first invasive (i.e., serious) MRSA infection, of which **approximately 19,000 died** ⁽¹¹⁾.
- A study conducted by APUA and John H. Stroger, Jr. Hospital of Cook County in 2009 found that antimicrobial-resistant infections **add 6.4-12.7 hospital days per patient and \$26 billion to \$35 billion total in healthcare costs** ⁽¹²⁾.
- Current antimicrobial use policy for animals in the United States differs from **policy enacted in the European Union**, which in **2006 banned the use of all antimicrobials for food animal growth promotion** in deference to public health concerns ⁽¹³⁾.
- Studies found that regulation of antimicrobial use in agriculture in Denmark between 1992 and 2008 resulted in **improvement of overall swine productivity by 47%** ⁽¹⁴⁾.
- **RECOMMENDATION: To slow the pace of antibiotic resistance, emergence, and spread, the use of antimicrobials for animal growth promotion should be terminated. In addition, nationwide antibiotic use data should be made available to enable health impact assessment and to guide policy changes** ⁽¹⁵⁾.

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- (1) B. Marshall and S. Levy. "Food Animals and Antimicrobials: Impacts on Human Health"(2011) *Clinical Microbiology Review* 24,4: 718-733
- (2) "2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals" (2009) Food and Drug Administration
- (3) Personal communication, FDA to Ralph Loggisci, Center for a Livable Future (2010) www.livablefutureblog.com/2010/12/new-fda-numbers-reveal-food-animals-consume-lion%E2%80%99s-share-of-antibiotics
- (4) FAAIR Scientific Advisory Panel (2002) "Select Findings and Conclusions." *Clinical Infectious Diseases* 34:S73-75.
- (5) Pew Trusts. "Putting Meat on the Table: Industrial Farm Animal Production in America" (2009) A Report of the Pew Commission on Industrial Farm Animal Production. Pp. 1-108: 6.
- (6) Ibid, 35.
- (7) J Sharfstein, "Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture." (2010). FDA Commissioner Testimony.<http://www.fda.gov/NewsEvents/Testimony/ucm219015.htm>
- (8) Pew Trusts. "Putting Meat on the Table: Industrial Farm Animal Production in America" (2009) A Report of the Pew Commission on Industrial Farm Animal Production. Pp. 1-108: 31.
- (9) Alliance for the Prudent Use of Antibiotics. Executive summary: select findings, conclusions, and policy recommendations. *Clin Infect Dis.* 41, 4: S224-S227. (2005).
- (10) Infectious Disease Society of America (2011). "Facts About Antibiotic Resistance" http://www.idsociety.org/AR_Facts/
- (11) Klevens et al. *Journal of the American Medical Association* 2007;298(15):1763-1771.
- (12) Roberts RR, Hota B, Ahmad I, et al. Hospital and societal costs of antimicrobial-resistant infections in a Chicago teaching hospital: implications for antibiotic stewardship. *Clin Infect Dis* 2009; 49:1175-84
- (13) C. Coglian, H. Goossens, C. Greko. Restricting antimicrobial use in food animals: lessons from Europe. *Microbe* 6, 6: 274-279. (2011).
- (14) Ibid.
- (15) Alliance for the Prudent Use of Antibiotics. Executive summary: select findings, conclusions, and policy recommendations. *Clin Infect Dis.* 41, 4: S224-S227. (2005).
- The Alliance for the Prudent Use of Antibiotics (APUA) has been the leading global non-governmental organization working to preserve the effectiveness of antimicrobial drugs since 1981. For more information, please visit: <http://www.tufts.edu/med/apua/>.
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<http://www.serconline.org/antibiotics/fact.html>

Fact Pack

Agricultural Use of Antibiotics

- The Union of Concerned Scientists (UCS) estimates that 70% of all antibiotics used in the United States – more than 24 million pounds per year – are routinely put in the food and water of healthy livestock. More than half of these drugs are identical or nearly identical to the antibiotics doctors rely upon to treat human illnesses. They are given to animals to make them grow faster on less feed and compensate for the crowded, unhygienic conditions typically found on today's industrialized livestock "farms."
- Of the over 24 million pounds of antibiotics used per year for subtherapeutic uses in agriculture, approximately 10.3 million pounds are used for hogs, 10.5 million pounds are given to poultry, and 3.7 million pounds are fed to cattle.
- Antibiotics are used in 90% of starter feeds, 75% of grower feeds, and more than half of finishing feeds for pigs in the U.S.
- The Union of Concerned Scientists estimates that nearly 5 million pounds of two tetracycline antibiotics are given to healthy swine each year in the U.S. The volume of these two medicines given to healthy pigs alone, according to UCS estimates, is sixty percent greater than the volume of all antibiotics given to sick humans.
- Agricultural use, much of it for growth promotion, accounts for 40 percent of the antibiotics sold in the United States.

Consequences of the Agricultural Use of Antibiotics

- The United States Department of Agriculture estimates that 70% of all food-borne illnesses in the United States can be traced to meat.
- According to the Federal Drug Administration (FDA), 5000 deaths and 76 million cases of food-borne illness occur annually.
- Overuse of antibiotics in animals is causing more strains of drug-resistant bacteria, which is affecting the treatment of various life-threatening diseases in humans. The Institute of Medicine at the National Academy of Sciences has estimated that the annual cost of treating antibiotic-resistant infections in the United States is \$30 billion.
- The Centers for Disease Control and Prevention (CDC) estimate that there are two to four million *Campylobacter* infections per year, resulting in as many as 250 deaths each year in the United States. Furthermore, about one in a thousand *Campylobacter* infections leads to Guillan-Barre syndrome, a disease that can cause paralysis. There is evidence that *Campylobacter* is becoming resistant to fluoroquinolones due to their use in poultry which the FDA approved for poultry use only a few years ago.
- Every year, approximately 40,000 cases of *Salmonella* are reported in the United States. *Salmonella* is also showing high rates of antibiotic resistance.
- Each year in the United States an estimated 73,000 people suffer from *E. coli* O157:H7 infections. Antibiotic-resistant strains of *E. coli* O157:H7 in humans are

correlated with antibiotic use in cattle.

Subtherapeutic Use vs. Therapeutic Use of Antibiotics

- The subtherapeutic use of antibiotics as growth promoters (low level doses of antibiotics – less than 50 milligrams per ton of animal) can enhance the productive efficiency of animals. This type of use has also been shown to:
 - Increase the daily body weight gain;
 - Improve the food-to-weight gain ratio;
 - Increase the voluntary intake of food; and
 - Decrease both illness and morbidity.

The therapeutic use of antibiotics is solely to treat the bacterial infections an animal or group of animals may have. Doses are typically larger and are administered for a specific portion of time.

Many popular fast food chains have issued statements that they will not purchase meat from suppliers who engage in the subtherapeutic use of antibiotics. Here are a few of the letters:

Hardee's, Carl's Jr., La Salsa Fresh Mexican Grills and Green Burrito Restaurants

The suppliers to CKE Restaurants, Inc., the parent company of Hardee's, Carl's Jr., La Salsa Fresh Mexican Grills and Green Burrito Restaurants, do not use any antibiotics for growth promotion or prophylactic purposes. All of our poultry suppliers have totally eliminated the use of fluoroquinolones. Our policy is to only purchase from suppliers who guarantee they produce chicken without the nontherapeutic use of medically important antibiotics. Additionally, we purchase poultry only from companies who guarantee they produce without the use of fluoroquinolones... CKE Restaurants, Inc. has always been a leader in food safety and we are committed to protecting the public's health. – *Letter to "Keep Antibiotics Working," July 19, 2002*

KFC

“KFC does not purchase poultry treated nontherapeutically with medically important antibiotics.” – *Letter to "Keep Antibiotics Working," August 28, 2002*

McDonald's

‘We’ve listened to the concerns, studied the issue, and the bottom line was we thought it was the right thing to do to discontinue the use of [fluoroquinolone

antibiotics] in poultry,' said Walt Riker, spokesman for Oak Brook-based McDonald's. – *Walt Riker, McDonald's, "Chickens Fed With Antibiotics McGone," Chicago Sun-Times, February 12, 2002*

Subway

We feel this is an important issue and will not knowingly buy chicken that has been treated with fluoroquinolones... Subway Restaurants has received statements from its chicken vendors who verify that they are not using fluoroquinolones antibiotics, nor are they using medically important antibiotics in healthy animals. Thank you for contacting us and letting us communicate our position. Good luck in your work to reduce antibiotic use! – *Letter to "Keep Antibiotics Working," April 24, 2002*

Wendy's

"McDonald's, Wendy's and Popeye's are now refusing to buy chicken that has been treated with [fluoroquinolones]." – *"Poultry Industry Quietly Cuts Back on Antibiotic Use," New York Times, February 10, 2002*