



Iowa Pork Producers Association  
 P.O. Box 71009  
 Clive, IA 50325-0009

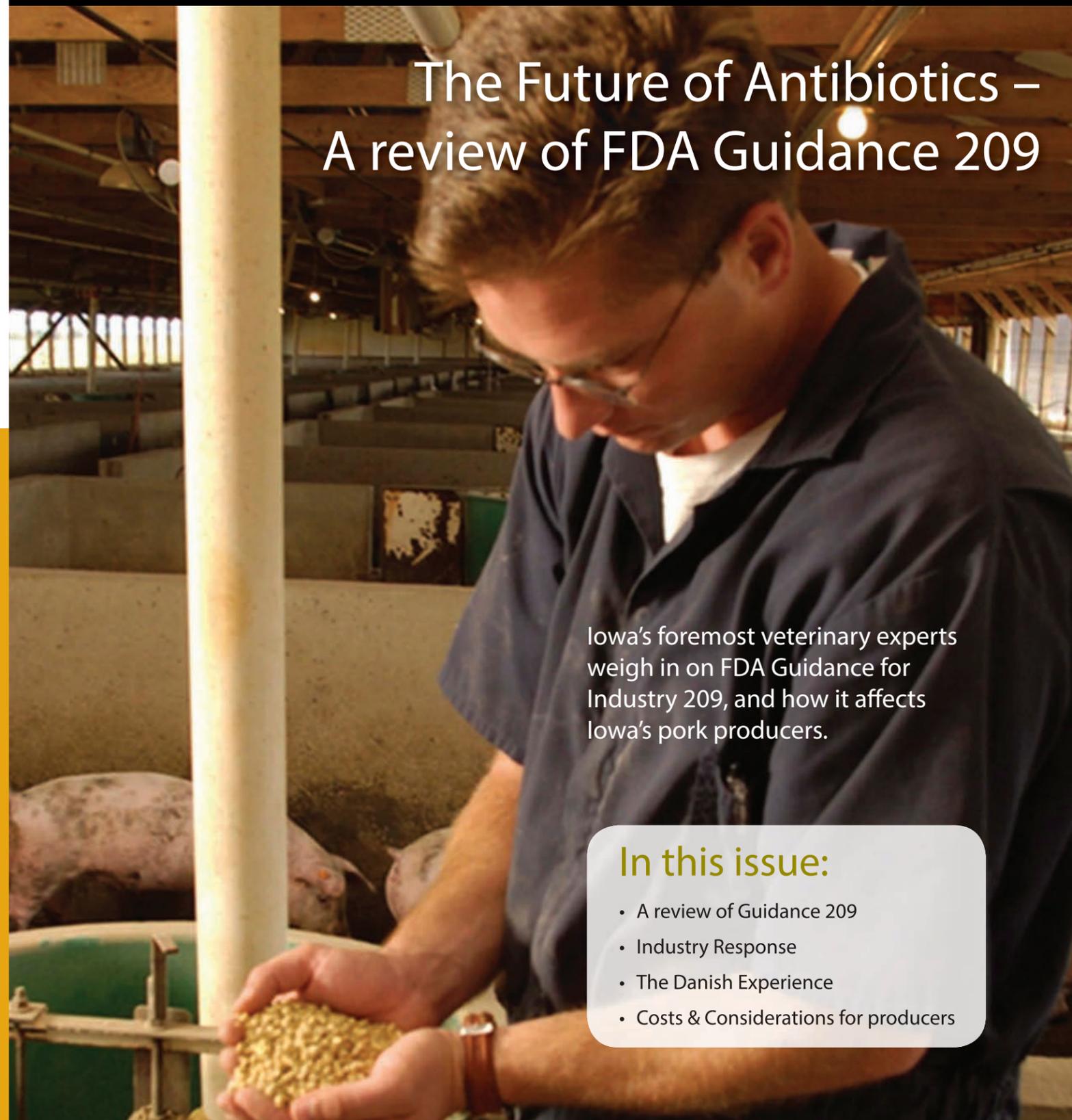
ADDRESS SERVICES REQUESTED

NON PROFIT  
 U.S. POSTAGE  
**PAID**  
 Des Moines, IA  
 Permit No. 1911




A PUBLICATION OF THE IOWA PORK PRODUCERS ASSOCIATION ••• Summer 2012, Vol. 11 No. 1

# The Future of Antibiotics – A review of FDA Guidance 209



Iowa's foremost veterinary experts weigh in on FDA Guidance for Industry 209, and how it affects Iowa's pork producers.

### In this issue:

- A review of Guidance 209
- Industry Response
- The Danish Experience
- Costs & Considerations for producers



## About the Author

This issue of *Headlines* was organized by Colton Jones, 2012 Pork Checkoff Intern. Colton is from Audubon in southwest Iowa. He will be a senior at Iowa State University with majors in agricultural business and economics. Colton plans on graduating in December of 2013 and pursuing a career in the pork industry.

The Iowa Pork Producer *Headlines* newsletter is an official publication of the Iowa Pork Producers Association. Editorial and advertising offices are located at the address listed below.

*Headlines* is published three times a year and mailed from Des Moines, Iowa. The publisher cannot guarantee the accuracy of all information or the absence of errors and omissions, nor be liable for content of any advertisements that may appear in the newsletter.

All *Headlines* inquiries should be directed to the editor at:

Iowa Pork Producers Association  
 1636 N.W. 114th Street  
 Clive, Iowa 50325-7071  
 Ph: (515) 225-7675  
 Fax: (515) 225-0563  
 www.iowapork.org  
 E-mail: info@iowapork.org

#### Mission Statement

The Iowa Pork Producers Association is an industry inclusive organization whose mission is to provide a unified voice to promote and educate for a sustainable, socially responsible, profitable and globally competitive pork industry.



## Reviewing FDA Guidance 209

According to Dr. Jim McKean, the Extension swine veterinarian for Iowa State University, "Guidance 209 demonstrates FDA thinking and expectations for feed additive uses in production and antimicrobial resistance development going forward." Guidance 209 is suggested to be a voluntary program, when, in fact, it is not. It will be adhered to similar to how we adhere to a law, but it is not a law and does not confer a legal standing for these policies. It does indicate FDA's future plans.

### Two guiding principles from Guidance 209 are,

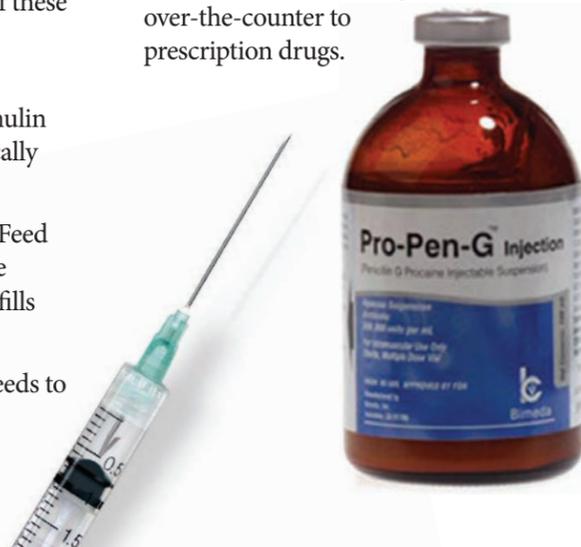
- 1) The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health; and
- 2) The use of medically important drugs in food-producing animals should be limited to those uses that include veterinary

oversight or consultation. The Guidance applies to all medically important drugs (those used in human medicine) used in feeds for food animals.

209

### Other points outlined by Dr. Howard Hill of Iowa Select Farms and the National Pork Producers Council include:

- Pharmaceutical companies have three years to eliminate label claims of "Growth Promotion" in medically important antibiotics.
- If companies can prove that antibiotics can fit a prevention, control or treatment label, the product can still be sold (all feed additives have one of these label claims.)
- Exceptions include bacitracin, carbadox, bambamycin and tiamulin as these are not considered medically important to human medicine.
- Producers will need a Veterinary Feed Directive (VFD) for all feed-grade antibiotics. Dose, duration and refills need to be recorded.
- The number of animals treated needs to be recorded (not weight of feed.)
- Keep a fax or e-mail (you won't need the original) from your veterinarian to show valid Veterinarian-Client-Patient Relationship.
- Keep treatment records for two years.
- Under Draft Guidance 213, water medication will be changed from over-the-counter to prescription drugs.



All uses for growth promotion and feed efficiency would be eliminated by sponsors. Under guidance 209 treatment, prevention and control claims would remain on the approved labels. For now, it is unclear what the pharmaceutical companies will do. Because some of these drugs are past their patent date, companies have little incentive to remove a label claim for growth promotion and feed efficiency. There is no extra-label usage allowed, so claim reduction would reduce use alternatives. Pork producers will more easily meet the second point about veterinary oversight since the Pork Quality Assurance Plus' Good Production Practices one and two deal with this subject already.

"The major impact will be the removal of low-level feed antimicrobials for pigs. Initially, the post-weaned pig to 30-40 lbs. will be the most likely to be clinically affected," said McKean. "Management changes and timely water medications may be required to control the diarrheas and respiratory infections that will become more common, which will raise the cost of production and increase post-weaning mortality until solutions are found and incorporated into daily management. It is likely that solutions will be specific for each site/flow of pigs and will be found by trial and error."

## The Real Facts About Antibiotics Use In Food Animals



- ✓ Antibiotics help animals grow healthier, improve animal well-being and help provide safe food.
- ✓ The U.S. Food and Drug Administration regulates antibiotic use in humans and animals. The FDA inspects the feed mills that produce medicated feed. The agency also evaluates the safety of antibiotics used in animals for human safety.
- ✓ Strategic use of antibiotics in animal agriculture prevents disease and produces safer food. A side benefit of this use is faster growth.
- ✓ Less than 1 percent of food-borne illnesses require antibiotic therapy. The human-health crisis with resistance is focused on pathogens that are often hospital-acquired.
- ✓ Since antibiotics have been used in humans for more than 60 years and in livestock for about 50 years, if there was going to be an epidemic of resistance related to antibiotic use in agriculture, it would have occurred by now. The fact that it has not means that antibiotic use in animals is not a major risk to human health.

*Dr. H. Scott Hurd, an associate professor at the Iowa State University College of Veterinary Medicine and a former U.S. Department of Agriculture deputy undersecretary for food safety.*



National Pork Producers Council | 122 C Street, N.W., Suite 875 | Washington, D.C. 20001 | www.nppc.org

In his blog, Dr. Hurd also stated, “Although no published scientific risk assessment has shown a direct human health impact of on-farm antibiotic use, the concern is that farmers are creating a “super bug.” This, combined with the anti-big agriculture sentiment of many consumer groups, has led FDA to determine growth promotion use to be “injudicious” (i.e., not in their best judgment). The word injudicious represents an artful move by the politicians (recall, I was one) and shifts the argument from science (risk assessment) to precautionary politics.”

Activities more likely to happen than acquiring a resistant strain of bacteria.

Being Injured at work: 1 in 49.

Dying from heart disease: 1 in 384.

Illness or death from pneumonia: 1 in 4,300.

Illness or death from the flu: 1 in 130,000.

Dying from choking: 1 in 200,000.

Acquiring a foodborne infection from fruit or vegetables: 1 in 375,000.

Being struck by lightning: 1 in 550,000.

Illness or death from chicken pox: 1 in 4.4 million

Dying from a bee sting: 1 in 6 million.

Dying from a dog bite: 1 in 18 million.

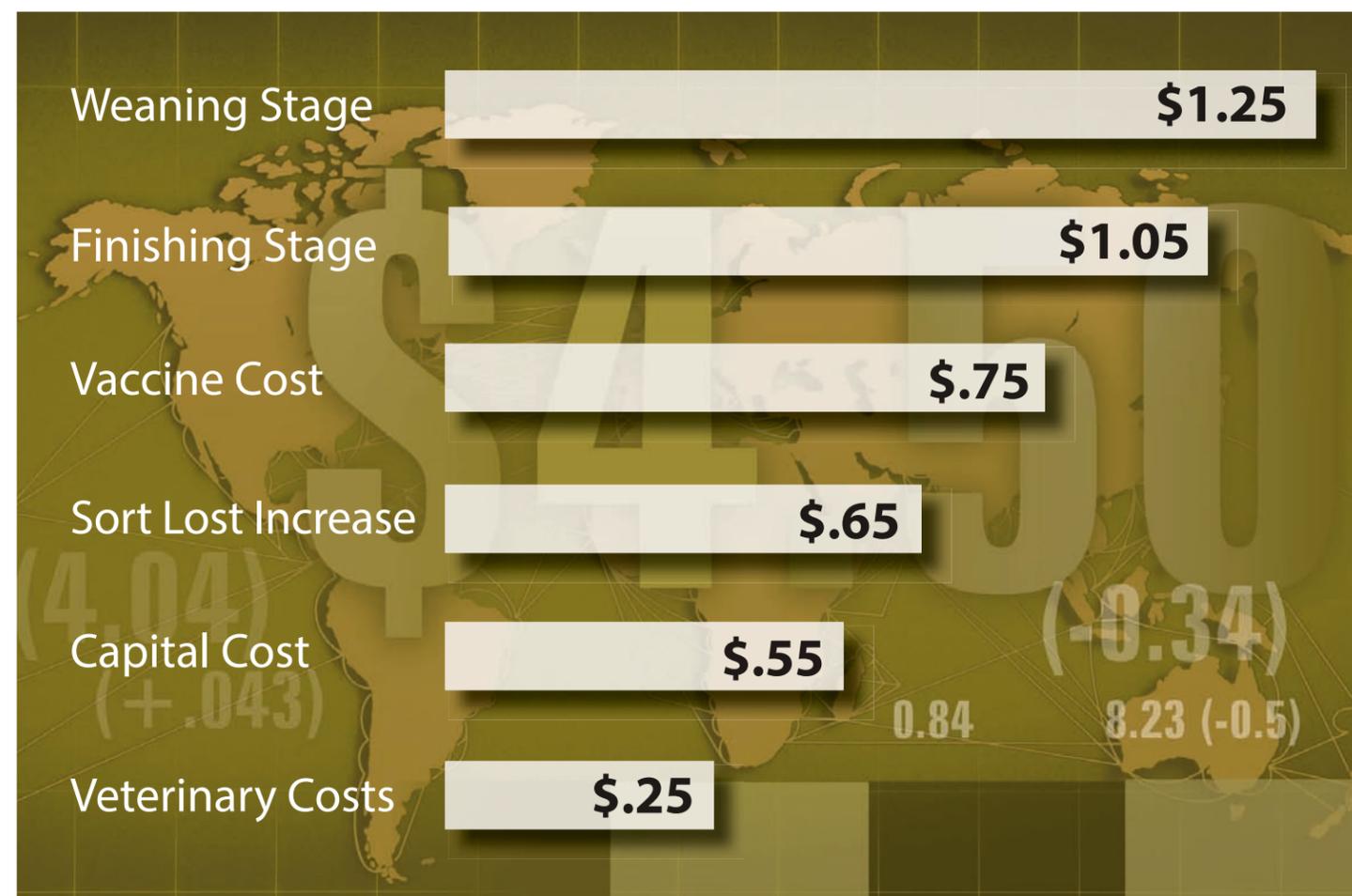
Acquiring resistant E. faecium from macrolid-treated swine which results in treatment failure: <1 in 21 Million

Information courtesy of positiveaction.info



## Costs & Considerations for producers

An Iowa State University economist estimates that costs of production could increase by \$4.50 per animal in the first year.



Graphic courtesy of National Pork Board

With this guidance now in place, producers will want to make sure that their herd stays healthy. If something similar to what happened in Denmark happens here, the nursery-age pigs will be most affected. According to Dr. Jim McKean, there are several things that producers can do to help their pigs.

- Inventory health status of herd with a veterinarian to determine cost-effective strategies for disease control.
- Always be mindful of your farm’s biosecurity plan.
- Follow the All-In All-Out principle.
- Separate nursery pigs from sows in order to prevent disease transmission.
- Make sure that all buildings are clean, dry and draft free.
- Wean at a later date so nursery pigs guts are better adapted to solid feed.
- Change antibiotics to a non-medically important one (carbadox, bambarmycin, tiamulin).
- Be on the lookout for pigs that need treatment and treat them quickly and according to the veterinary instructions.
- Utilize sick pens to isolate pigs that need treatment so they can receive individual attention.
- As always, before making any changes to the nutritional content or production practices, make sure you research the product yourself and consult with a veterinarian that has a valid veterinarian-client-patient-relationship with your herd.

# Potential Challenges: The Danish Experience to Guidance 209

According to the National Pork Board's brochure regarding a ban comparable to Guidance 209, the Danish government enacted similar legislation in 2000. They banned all antibiotics claiming growth promotion on the label.

In 1998, Denmark outlawed all antibiotics used in finishing pigs that claimed growth promotion. Some farmers noticed slower weight gain and more of a difference in weight between pigs of the same age.

In 1999, Denmark passed another similar law for all ages of pigs. This time,

however, the health of the weaned piglets declined more noticeably. The mortality rate increased, diarrhea increased and other noticeable problems in the finishing animals increased.

While the amount of sub-therapeutic antibiotics decreased, veterinarians had to resort to using more therapeutic doses of antibiotics in order to offset the declining health. Total usage has decreased, but therapeutic doses in 2005 were greater than the growth promoting levels in 1996 before the ban went into effect.

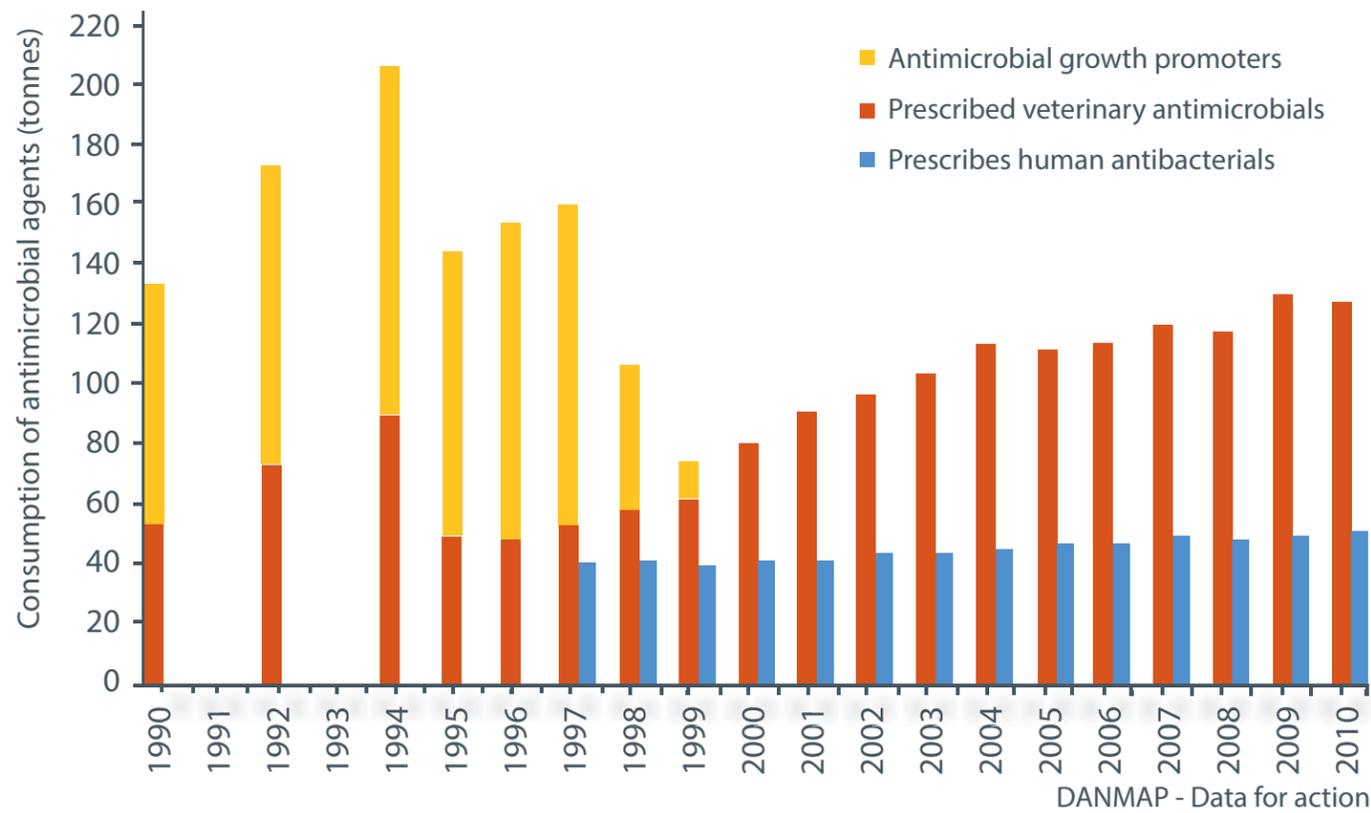
Also according to Pork Board, there have been no positive human health

benefits to banning these antibiotics in animals. There may be one negative one. Salmonella that is tetracycline-resistant has been infecting humans more frequently since the ban.

What is important to notice about the following graph is that since 2000, when Denmark's ban went into effect, prescribed veterinary antimicrobial use has risen steadily. While these numbers are similar to a single year (1994), Denmark has not seen a significant decrease in this type of antimicrobial use since the ban took effect in 2000.



Consumption of antimicrobial agents in animals and humans



## Industry Response

According to former USDA Undersecretary of Food Safety Dr. H. Scott Hurd, now a professor at Iowa State University, there's more to resistance than just "Using antibiotics in livestock leads to resistance in humans." There's an entire chain of events that needs to happen to lend credence to that claim. There are eight steps that the bacteria needs to go through for this claim to be viable, not just the two that some might have you believe.

1. Antibiotic is used in animal
2. Development of resistant strain
3. Strain remains on meat through packing plant
4. Strain remains on meat through transport and to the retail counter
5. Consumer buys meat and strain remains viable through preparation (most likely through cross contamination) and is transferred to food to be eaten
6. Strain is transmitted to human
7. Human goes to the doctor and is prescribed an antimicrobial treatment
8. Human does not recover

Dr. Hurd also theorized through a risk assessment that you are more likely to die from a bee sting than to have a few extra days of diarrhea due to a resistant infection acquired from on-farm-antibiotic use.

