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H.R. 1549, PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT (PAMTA)

HEARING

BEFORE THE

COMMITTEE ON RULES
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

MONDAY, JULY 13, 2009

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ORIGINAL JURISDICTION HEARING ON H.R. 1549, PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT OF 2009

MONDAY, JULY 13, 2009

HOUSE OF REPRESENTATIVES,
COMMITTEE ON RULES,
Washington, DC.

The committee met, pursuant to call, at 2:28 p.m. in Room H–313, The Capitol, Hon. Louise M. Slaughter [chairwoman of the committee] presiding.

Present: Representatives Slaughter, Matsui, Cardoza, Pingree and Polis.

OPENING STATEMENTS

The CHAIRWOMAN. I am required to wait for a third Member, so we will be starting in a few minutes. They are on their way. [2:34 p.m.]

The Rules Committee will please come to order.

I thank all of you for coming today. I want to introduce my panel members: Congresswoman Doris Matsui from California, who has an enormous interest in health and agriculture subjects; and also Chellie Pingree, who is a freshman this year from Maine, who has a wonderful background in Common Cause. We are hoping for other Members who may or may not show up. In any case, we are delighted to have you here. My name is Louise Slaughter. I represent the 28th Congressional District of New York.

OPENING STATEMENT OF HON. LOUISE McINTOSH SLAUGHTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK AND CHAIR OF THE COMMITTEE ON RULES

The CHAIRWOMAN. I think this is a critically important issue. As a microbiologist, I can't stress enough the urgency of absolutely making sure our current stock of antibiotics does not become obsolete. Every year 2 million Americans acquire bacterial infections during their hospital stays; 70 percent of the infections will be resistant to drugs commonly used to treat them. Seventy percent. As a result, every day 38 patients in our hospitals die of those infections.

Sadly, children and infants are particularly susceptible to infections caused by antibiotic-resistant bacteria. For example, salmonella causes 1.4 million illnesses every year, and over one-third of all diagnoses occur in children under the age of 10. Additionally,

infants under the age of 1 are 10 times more likely than the general population to acquire a salmonella infection.

In 1995, 19 percent of salmonella strains were found to be multidrug-resistant. That means our children are left to undergo multiple treatments for otherwise simple infections because we have allowed the traditional treatments to become ineffective.

The cost of these infections and these ineffective treatments to our already strained health care system is astronomical. In fact, resistant bacterial infections increase health care costs by $4 billion to $5 billion each year. Currently, seven classes of antibiotics certified by the Food and Drug Administration as highly or critically important in human medicine are used in agriculture as animal feed additives. Among them are penicillin, tetracycline, macrolides, lincosamide, streptogramin, aminoglycoside, and sulfonamides. These classes of antibiotics are among the most critically important in our arsenal of defense against potentially fatal human disease. Penicillin, for example, used to treat infections from strep throat to meningitis; macrolides, sulfonamides used to prevent secondary infections in patients with AIDS and to treat pneumonia in HIV-infected patients. Tetracyclines are used to treat people potentially exposed to anthrax.

But despite their importance to human medicine, the drugs are added to animal feed as growth proponents and for routine disease prevention. In other words, these are not animals that are ill. This is the most staggering number of all: 70 percent of the antibiotics and related drugs produced in the United States—70 percent—are given to cattle, pigs, and chicken to promote growth and compensate for crowded, unsanitary, and stressful conditions. The nontherapeutic use of antibiotics in poultry skyrocketed from 2 million pounds in 1985 to 10.5 million pounds in the late 1990s.

This kind of habitual nontherapeutic use of antibiotics has been conclusively linked to a growing number of incidents of antimicrobial-resistant infections in humans and maybe contaminated groundwater with resistant bacteria in rural areas.

In fact, the National Academy of Sciences report states that a decrease in antimicrobial use in human medicine alone will have little effect on the current situation. Substantial efforts must be made to decrease inappropriate overuse in animals and in agriculture as well.

Resistant bacteria can be transferred from animals to humans in several ways. Perhaps, most glaringly, antibiotic-resistant bacteria can be found in the meat and poultry that we purchase every day at the grocery store. In fact, a New England Journal of Medicine study conducted in Washington, D.C., found that 20 percent of the meat sample was contaminated with salmonella, and 84 percent of those bacteria—that is salmonella—were resistant to antibiotics used in human medicine and animal agriculture.

Bacteria can also be transferred from animals to humans via workers in the livestock industry who handle animals, feed, and manure. Farmers may then transfer the bacteria to their family.

A third method is via the environment. Nearly 2 trillion pounds of manure generated in the U.S. annually contaminate our groundwater, our surface water, and our soil. Because this manure contains resistant bacteria, the resistant bacteria can be passed on to

humans that come in contact with that water or soil. And the problem has been well documented.

A 2002 analysis of more than 500 scientific articles published in the Journal of Clinical Infectious Diseases found that many lines of evidence linked antimicrobial-resistant human infections to foodborne pathogens of animal origin.

And the Institute of Medicine's 2003 report on microbial threats to health concluded: "Clearly, a decrease in the inappropriate use of antimicrobials in the human alone is not enough. Substantial efforts must be made to decrease the inappropriate overuse in animals and agriculture as well."

If you don't believe in evolution, just think what has happened to Staphylococcus aureus, which has now become MRSA. There is little doubt that antibiotic-resistant diseases are a growing public health menace demanding a high-priority response. Despite increased attention to the issue, the response has been inadequate. Part of the problem has been the FDA's failure to properly address the effect of the misuse of animal antibiotics and the efficacy of human beings.

Although the FDA could withdraw its approval for these antibiotics, its record of reviewing currently approved drugs under existing procedures indicate that it would take nearly a century to get these medically important antibiotics out of the feed given to food-producing animals. In October 2000, for example, the FDA began consideration of a proposal to withdraw its approval of therapeutic use of antibiotics in poultry. The review and the eventual withdrawal of approval took 5 years to complete.

Under its current regulations, the FDA must review each class of antibiotics separately. The legislation we are here to discuss today would phase out the use just of the seven classes of medically significant antibiotics that are currently approved for nontherapeutic use in animal agriculture. Make no mistake, this bill would in no way infringe upon the use of these drugs to treat a sick animal. It simply proscribes their nontherapeutic use.

When we go to the grocery store to pick up dinner, we should be able to buy food without worrying that eating it would expose our family to potentially deadly bacteria that will no longer respond to our medical treatments.

Unless we act now, we will unwittingly be permitting animals to serve as incubators for resistant bacteria. And it is time for Congress to stand with the scientists, the World Health Organization, the American Medical Association, and the National Academy of Sciences and do something to address the spread of resistant bacteria. We cannot afford, as I said, for our medicines to become obsolete.

I thank you for coming. I look forward to working with all of you and the other members of this committee to enact this bill and to protect the integrity of antibiotics and the health of all American families.

The CHAIRWOMAN. Ms. Matsui.

OPENING STATEMENT OF HON. DORIS O. MATSUI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. MATSUI. Thank you very much, Madam Chair. And I commend you for calling today's hearing and working so diligently on an important and salient issue. Your expertise on this subject matter is beyond question. The Congress is fortunate to have someone with your experience and knowledge working on the topic of antimicrobial resistance.

Madam Chair, during today's hearing I will try to represent two different perspectives, one as a Member of Congress, and one as the daughter of a farmer.

On the one hand, I am serving on the Energy and Commerce Committee as we are tackling health care reform. In this capacity I have come face to face with the immense challenges of our country faced with out-of-control health care costs. Our health care system is broken, our economy is reeling, and our budgets are out of sync because health care costs go up and up and up and never come down.

According to the National Academies of Science, health care in this country is about $4 billion more expensive every year because of drug-resistant bacteria. Here, in the House of Representatives, we have spent months trying to figure out how to reform our health care delivery system so that it reduces costs through efficiency and innovation, but one of the easiest and most effective ways to drive down costs is to ensure that people do not get sick in the first place. Fighting antimicrobial resistance is a key component of this kind of populationwide prevention strategy, and you have demonstrated, Madam Chair, impressive leadership on it. Your bill, the Preservation of Antibiotics for Medical Treatment Act, is a critical piece of public health legislation.

The FDA needs clear statutory direction to take aggressive action against this resistance. Once it does so, fewer people will be hospitalized with illnesses like diarrhea, staph infections, and food poisoning.

On average, every hospital stay caused by drug-resistant bacteria costs $6,000 to $10,000 extra. We are talking about billions of dollars that we could save in our health care system, and we are talking about untold numbers of lives, which should be the impetus for us to act on this legislation as soon as possible. I will urge my Energy and Commerce Committee colleagues to do so.

I grew up also as a farmer's daughter in the California Central Valley, and I know the kind of effort it takes to make a farm a productive business. My father worked harder than anyone I have ever seen, but he tried to do so in a way that was environmentally sustainable even at the time he was farming, which was over the last 30 years or so. He passed away about 10 years ago. He did this because it was the right thing to do and also because it was good business.

Today, just like back when I was a little girl, people in America want affordable food that comes from natural sources. They do not want artificial or factory-farmed meat, especially if that meat poses serious public health threats.

The facts are clear. Animals fed these antimicrobial drugs on a daily basis are a serious public health risk. Farmers and ranchers are this country's bedrock. They should be our strength and not our vulnerability. I am convinced that America's farmers and ranchers can be successful raising high-quality natural livestock. They can do so in a way that does not breed the superbugs that are showing up in our hospitals and emergency rooms more frequently every day.

The Preservation of Antibiotics for Medical Treatment Act will help us reach goals we all share. It will drive down health care costs, it will encourage more ranchers to use animal husbandry practices that we already know work, and it will give American consumers confidence that the foods they eat are safe and do not come with a price of endangering public health.

I look forward to working with the people testifying today and hearing their testimony. Thank you, Madam Chair.

The CHAIRWOMAN. Thank you, Ms. Matsui.

We are joined by Congressman Jared Polis of Colorado.

Ms. Pingree.

OPENING STATEMENT OF HON. CHELLIE PINGREE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Ms. PINGREE. Thank you very much, Madam Chair. I really appreciate the opportunity to participate in this open and very important hearing; and I want to commend the Chairwoman for introducing the bill and bringing the issue forward. As Ms. Matsui said, your professional training in microbiology and public health makes you the perfect advocate on this critical issue, and an invaluable asset to your colleagues in Congress. Thank you for your tireless dedication to protecting our Nation's health and well-being.

I am delighted that we have the opportunity to be here today in the Rules Committee to hear testimony on this very important issue. We spend so much time here on a regular basis listening to other committee bills. I sincerely look forward to hearing more about this bill today and hearing from our witnesses.

This bill, the Preservation of Antibiotics for Medical Treatment Act, would mark a critical step forward in the fight to protect our Nation's food supply. Americans have become so disconnected with their source of food, yet also fearful and frustrated about what is in it. They rarely participate in the process of growing produce or raising livestock, instead trusting that the food they buy at their local grocery store is safe for their families. Sadly, we know that all too often this is simply not the case.

Experts agree, antibiotic resistance is a growing problem in this country, as we have already heard, and it is taking its toll on our health and on our pocketbooks. We spend more than $4 billion each year combating the spread of new and deadly strains of bacteria, and we have lost countless lives in the process. This can be attributed in large part, as we have already heard, to the overuse and misuse of antibiotics as nontherapeutic feed supplements for animals that are not sick.

We cannot undo what has already been done, but by restricting the use of antibiotics to people and animals that are truly sick, we

can make sure that future generations have access to a safe food supply and effective antibiotic therapies.

This issue affects all of us. As consumers, parents, grandparents, we have the right to know what is being put into our food, and we deserve a government that invests in its resources into protecting our health.

I must say it is of particular interest to me not only as a Member of Congress, but as myself a former organic farmer. As Ms. Matsui said, she is the daughter of a farmer. I am the granddaughter of Scandinavian immigrants who were dairy farmers in Minnesota, but I took up my lot as an organic farmer in the State of Maine. I graduated from the College of the Atlantic with a degree in environmental sciences and spent many, many years selling milk, eggs, and vegetables to the people in my community. I can say without a doubt I hold the blue ribbon and the red ribbon in the politician's cow-milking contest, and I can guarantee you I tested my cows for mastitis. If one of them was sick, I gave them an antibiotic. Case closed. That is it. That is all we needed to do. I stopped selling the milk while the cow was infected, made sure my cow was healthy again, and got them back on track.

It is a completely unnecessary situation that they are in. And I continue to be involved in the organic food movement in my State. I know that the greatest growth of dairy farmers in my home State is those that are selling organic milk, some of them to Stonyfield Farms for the yogurt, others because consumers want to know what is in their food and buy healthy food.

We are facing a time of unprecedented challenges, and perhaps none more important than reforming our health system. While we are considering hundreds of different ways to cut costs and deliver more effective care, we must not forget that the regulation of antibiotic use in farm animals has the potential to save billions of dollars every year and to protect Americans from unnecessary suffering from resistant and aggressive strains of bacteria.

I again want to thank the Chairwoman for holding this hearing and the witnesses for taking the time to be here today. And I really look forward to hearing from each of you.

Thank you. I yield back.

The CHAIRWOMAN. Thank you.

Mr. Polis.

OPENING STATEMENT OF HON. JARED POLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. POLIS. Thank you, Madam Chair. I am proud to be a cosponsor of H.R. 1549, and would like to thank Chairwoman Slaughter for bringing this important bill forward.

Let me put a little bit of a human face on some of the issues of antibiotic-resistant bacteria. There is, in my congressional district in Boulder, Colorado, a Nobel Prize-winning physicist, Dr. Eric Cornell, teaches at the University of Colorado. A couple years ago, unrelated to his work, he had an infection of antibiotic-resistant bacteria in his arm, and they had to amputate his arm. He now has one arm because of this fast-growing, antibiotic-resistant bacteria that several people at the University of Colorado have contracted. These unfortunate—well beyond the greater public health threat,

the human toll of this has been felt by many of us right in our own Second Congressional District.

I hear a lot about these issues. My partner is a vegan, and in doing so he is constantly critical of our animal husbandry practices of commercial agriculture in this country. And so beyond the public health arguments, I would like to add two additional important considerations for why this bill is important and these efforts are important. One has to do with the treatment of the animals themselves, and the second emerges from that.

When you look at why people are seeking to use the nontherapeutic use of antibiotics, it is so they can crowd animals closer together and raise them in conditions that otherwise would not necessarily be healthy for those animals. This leads to stress among the animals and unhealthy conditions, which can directly lead, well beyond the direct public health negative outcomes, to simply a poor nutritional profile and deteriorating the health and nutrition of the meat for human consumption due to the stress of the animals caused by the overcrowding which has been enabled by the nontherapeutic use of antibiotics.

My district is also home to the holding company of Horizon Dairy and also Aurora Organic Dairy, the two producers of the antibiotic- and hormone-free milk, which together control, I believe, over 70 percent of the market share for those products. And, again, I think the consumers are wising up, and consumers are ahead of where we are from a regulatory perspective on these issues. People are realizing that to have residual antibiotic content in milk particularly for children is, in fact, not only a public health threat, but a very personal health threat that can lead to antibiotic-resistant bacteria for their children.

So for these reasons I strongly support H.R. 1549, and I look forward to hearing the testimony today.

I yield back.

The CHAIRWOMAN. Thank you, Mr. Polis.

Our first witness today will be Dr. Joshua Sharfstein. And I am happy to tell you that he is the Principal Deputy Commissioner, Health and Human Services, U.S. Food and Drug Administration. And I am happy to say that we have beefed up that budget considerably so you will be able to do your job better, Mr. Sharfstein, but we are delighted to have you here.

WITNESS TESTIMONY

STATEMENT OF JOSHUA SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER, DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION

Dr. SHARFSTEIN. Thank you very much. I am very pleased to be here. Madam Chairwoman and members of the committee, I am Dr. Joshua Sharfstein, the Principal Deputy Commissioner of FDA and the Department of Health and Human Services. I am also a pediatrician, and until recently a couple months ago, I was the health commissioner of Baltimore City.

Thank you for the opportunity to discuss the important public health issue today of antibiotic use in animals. In my testimony I will provide background information on antimicrobial resistance,

discuss FDA's involvement with the Interagency Task Force on Antimicrobial Resistance, set out a public health framework for assessing the use of antimicrobials in animals, and describe FDA's work with respect to nontherapeutic use of antimicrobials in food-producing animals. And I will also make several comments on the legislation that is under discussion today.

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 that left individuals with severe disabilities are now treatable or preventable. However, bacteria are adept at becoming resistant to antimicrobial drugs. Misuse and overuse of these drugs contribute to a rapid development of resistance. After several decades of successful antimicrobial use, we have seen and continue to see the emergence of multidrug-resistant bacterial pathogens which are less responsive to therapy. Oftentimes infections with these pathogens are more severe, more likely to cause hospitalization, and more likely to cause death.

Antimicrobial-resistant populations are emerging due to the combined impact of the various uses of antimicrobial drugs, including their use in humans and animals. And I can say as the health commissioner of Baltimore, it is a major public health issue that we face. And I will just mention that one of the last things that I did is we released a report from the RAND Corporation in the city about methicillin-resistant Staphylococcus aureus, MRSA, which found from 2000 to 2006 the number of cellulitis-associated hospitalizations, which are almost always from MRSA, increased by 74 percent, which was about an extra 1,000 hospitalizations per year in the city of Baltimore.

As of today, antimicrobial-resistant mechanisms have been reported for essentially 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. In the last decade there has been a significant increase in resistance to drugs of food-borne organisms, including salmonella and campylobacter, and there is no question from the perspective of public health that this is a serious issue of concern.

The U.S. Interagency Task Force on Antimicrobial Resistance was created in 1999 to develop a national plan to combat the antimicrobial resistance. FDA cochairs the task force, along with the CDC and the National Institutes of Health. This interagency group put together an action plan with four components.

Highlights of the plan includes surveillance to gather information and statistics about the emergence and spread of resistant microbes; prevention and control, including educational campaigns and the development of new therapeutics including vaccines, research including a research agenda on antimicrobial resistance in related fields to improve treatments and outcomes led by the National Institutes of Health, and product development. As antimicrobial drugs lose their effectiveness, new products must be developed to prevent, rapidly diagnose, and treat infections.

The priority goals and action items include developing new drugs, diagnostics, and vaccines, and stimulating the development of priority products, which market incentives are inadequate.

I am here on behalf of the Food and Drug Administration. Dr. Margaret Hamburg, the Commissioner, is out of the country, or otherwise I am sure she would be here. This is an issue of personal interest to her. The Institute of Medicine, of course, that you cited, she was one of the editors of prior to coming to the FDA. Working with the staff of the Center for Veterinary Medicine, FDA, both Dr. Hamburg and I strongly support action to limit the unnecessary use of antibiotics in animals to protect the public health.

There are four prominent labeled indications for use of these antimicrobials, including growth promotion, feed efficiency, prevention, control, and treatment. The vast majority of classes of antimicrobials used in animal agriculture have importance in human medicine. A few antimicrobial classes, such as ionophores, that are used in food-producing animals do not appear to impact human medicine at this time, although there are concerns that if you use a medicine, even if there is no human analogue, it could trigger the development of resistance that could cross over to human drugs.

Protecting public health requires the judicious use in animal agriculture of those antimicrobials of importance to human medicine. To protect patients you must limit the spread of antibiotic-resistant bacteria from the food supply to humans. And I want to review how these principles apply to each of the uses.

The first one I would like to talk about is growth promotion and feed efficiency. There is increasing evidence that use of antibiotics contributes to the high burden of resistance in bacteria. To avoid the unnecessary development of resistance under conditions of constant exposure, such as for growth promotion or feed-efficiency antibiotics, the use of antimicrobials should be limited to those situations where human and animal health are protected.

Purposes other than for the advancement of animal or human health should not be considered judicious use. Eliminating these uses will not compromise the safety of food. As a result, FDA supports ending the use of antibiotics for growth promotion and feed efficiency in the United States.

Second, I would like to talk about disease prevention and control. FDA believes that there are some prevention indications that are necessary and judicious to relieve or avoid animal suffering and death. Important factors in determining whether prevention use is appropriate should include, one, the evidence of effectiveness; two, evidence that such a preventive use is consistent with accepted veterinary practice; three, evidence is that the use is linked to a specific agent of bacteria; four, evidence that the use is appropriately targeted; and, five, evidence that no reasonable alternatives for intervention exist.

To promote the judicious use and protect human patients, FDA believes that all use of medically important medications for prevention control should be under the supervision of a veterinarian.

Finally, I would like to just mention briefly treatment. FDA supports the treatment of ill animals according to appropriate veterinary practice within a valid veterinary client-patient relationship.

The judicious use of antimicrobials in animal agriculture requires a strong commitment to surveillance and research, including monitoring resistance, studying the etiology and cause of resistance, tracking the use of antimicrobials in agriculture, assessing risk in different settings, and evaluating strategies to reduce resistance. Such data support science-based risk-management policies.

Let me just briefly mention some of the things that are going on at FDA with respect to antimicrobial drugs in food-producing animals.

First, FDA uses risk assessment methodologies, for example, something called Guidance 152, during the new animal drug evaluation process to quantify the human health impacts on antimicrobial use in animals.

Second, FDA conducts research to advance our understanding of resistance and to support regulatory decisions.

Third, we reach out to stakeholders on all sides of this issue.

Fourth, we assess the relationship between antimicrobial use and subsequent human health consequences using the National Antimicrobial Resistance Monitoring System, otherwise known as NARMS. NARMS takes advantages of the expertise and resources of a large number of Federal agencies, and the data from NARMS provide regulatory officials and the veterinary medical community with critical information about resistance in bacteria.

Finally, FDA participates in the international dialogue on the use of antimicrobials in animals, including with WHO and the Codex Alimentarius.

Let me just mention several comments on H.R. 1549. FDA supports the idea of H.R. 1549 to phase out the growth-promotion/feed-efficiency uses of antimicrobials in animals.

There is no question that the current statutory process of withdrawing new animal drug approval is very burdensome on the agency. FDA recommends that any proposed legislation facilitate the timely removal of nonjudicious uses of antimicrobial drugs in food-producing animals, and we would be happy to provide technical assistance on the bill.

At the same time, FDA believes that legislation should permit the limited judicious use of antimicrobials in animals for prevention and control as I previously discussed, and for treatment.

To conclude, antimicrobial resistance is an important issue for children as it is for their pediatricians, for the public as it is for public health directors, and for industry and consumers as it is for the FDA. We look forward to working with Congress on this important issue.

Thank you for the opportunity to testify. I look forward to your questions.

[The prepared statement of Dr. Sharfstein follows:]

PREPARED STATEMENT OF JOSHUA SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER, DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Madam Chairwoman and Members of the Committee, I am Joshua Sharfstein, Principal Deputy Commissioner at the Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). Thank you for

the opportunity to discuss the important public health issue of antibiotic use in animals.

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. Approximately 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 associated with bacterial pathogens displaying resistance to at least one antimicrobial drug. The trends toward increasing numbers of infection and increasing drug resistance show no sign of abating. 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. Resistant infections impact clinicians practicing in every field of medicine, including veterinarians.

In my testimony, I will provide background information on antimicrobial resistance, discuss FDA's involvement with the Interagency Task Force on Antimicrobial Resistance, set out a public health framework for assessing the use of antimicrobials in animals, and describe FDA's work with respect to the non-therapeutic use of antimicrobials in food-producing animals.

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 described 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 has been shown to contribute to the emergence of resistant microorganisms that can infect people. The inappropriate nontherapeutic use of antimicrobial drugs of human importance in food-producing animals is of particular concern. 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 that left individuals with severe disabilities are now treatable or preventable. However, because bacteria are so adept at becoming resistant to antimicrobial drugs, 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 due to the combined impact of the various uses of antimicrobial drugs, including their use in humans and animals. Many of these pathways are not yet clearly defined or understood. As of today, antimicrobial resistance mechanisms have been reported 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 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 (NIH).

The Task Force also includes the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the Department of Agriculture

(USDA), the Department of Defense, the 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.

PUBLIC HEALTH ACTION PLAN TO COMBAT ANTIMICROBIAL RESISTANCE

In 2001, the Task Force published the "Public Health Action Plan to Combat Antimicrobial Resistance" (Public Health Action Plan or the Action Plan). The Action Plan provides a blueprint for specific coordinated Federal actions to address the emerging threat of antimicrobial resistance. It reflects a broad-based consensus of Federal agencies, which was reached with input from consultants from state and local health agencies, universities, professional societies, pharmaceutical companies, health care delivery organizations, agricultural producers, consumer groups, and other members of the public.

The Action Plan has four major components: surveillance, prevention and control, research, and product development. Highlights of the Action Plan include:

Surveillance. Information and statistics about the emergence and spread of resistant microbes and the use of antimicrobial drugs can help experts interpret trends and identify strategies to prevent or control antimicrobial resistance. CDC is working with state health departments and other Task Force members to design and implement a strategy to coordinate national, regional, state, and local surveillance efforts. In addition, FDA, CDC, and USDA developed and expanded systems to monitor patterns of antimicrobial resistance among foodborne bacteria in human medicine, in agriculture, and in retail meat.

Prevention and Control. Research shows that controlling the use of antibacterial drugs can help reduce the incidence of antimicrobial resistance. In 2003, FDA partnered with CDC on its launch of its Get Smart: Know When Antibiotics Work campaign. The goal of the campaign is to educate consumers and health care professionals on the appropriate use of antibiotics. In partnership with doctors and other medical professionals, CDC has developed clinical guidelines for health professionals on how best to use antimicrobials, and supports pilot projects to identify effective strategies to promote appropriate antimicrobial drug use. FDA has promulgated labeling regulations for the appropriate use of systemic antibacterial drugs in humans. FDA's Center for Veterinary Medicine (CVM) has developed, in conjunction with stakeholders, in-depth antimicrobial prudent use principles for beef cattle, dairy cattle, swine, and poultry producers and veterinarians, and more recently, aquatic veterinarians.

Measures that reduce the need for antimicrobial use also serve to reduce the emergence of antimicrobial-resistant microorganisms. Prevention of bacterial infections through the use of vaccines has effectively eliminated or markedly decreased the problem of resistance in organisms such as *Haemophilus influenzae* type b (virtually eliminated in the United States, while still a problem in other parts of the world) and *Streptococcus pneumoniae*, also known as pneumococcus. Published research has confirmed that the latter pneumococcal vaccine has lowered common infections that are often treated with antimicrobials. Prevention of viral infections through the use of vaccines can also indirectly help reduce antibiotic use and minimize the emergence of antibiotic-resistant microorganisms. For example, viral infections, such as respiratory infections due to influenza, often lead to unnecessary antimicrobial use and are sometimes complicated by serious secondary infections caused by bacteria such as staphylococcus or pneumococcus. In addition, development of increasingly sensitive diagnostic assays for detection of resistance allows for rational targeted antimicrobial use.

Research. The Action Plan promotes expanding existing research in antimicrobial resistance and related fields in an effort to improve treatments and outcomes. NIH is leading a team of agencies to provide the research community with new information and technologies, including genetic blueprints for various microbes, to identify targets for desperately needed new diagnostics, treatments, and vaccines to combat the emergence and spread of resistant microbes. NIH supports clinical studies to test new antimicrobials and novel approaches to treating and preventing infections caused by resistant pathogens. NIH also continues to support and evaluate the development of new rapid diagnostic methods related to antimicrobial resistance, in conjunction with FDA's Center for Devices and Radiological Health (CDRH). In addition, AHRQ funds various studies on the use of antimicrobial drugs and antimicrobial resistance, including ongoing research on reducing unnecessary prescribing of antimicrobials to children. FDA's Center for Biologics Evaluation and Research (CBER) conducts research that facilitates vaccine development for diseases in which resistance is an issue, such as malaria, staphylococcus (MRSA), and enteric diseases.

Product development. As antimicrobial drugs lose their effectiveness, new products must be developed to prevent, rapidly diagnose, and treat infections. The priority goals and action items in the product development focus area of the Action Plan address ways to:

- Ensure researchers and drug developers are informed of current and projected gaps in the arsenal of antimicrobial drugs, vaccines, and diagnostics, and of potential markets for these products;
- Stimulate development of priority antimicrobial products for which market incentives are inadequate, while fostering their appropriate use;
- Optimize the development and use of veterinary drugs and related agricultural products that reduce the transfer of resistance to pathogens that can infect humans; and
- Facilitate development of effective prophylactic vaccines: in particular, focusing on vaccines against microbes that are known to develop antimicrobial resistance (e.g., MRSA), thereby reducing the need for antimicrobials and the occurrence of antimicrobial resistant strains.

The Task Force met with consultants in December 2007 to discuss suggestions and recommendations for revising and updating the Action Plan. The consultants included both domestic and foreign experts in human veterinary medicine, pharmaceutical and diagnostics manufacturing, animal husbandry, clinical microbiology, epidemiology, infectious disease and infection control. and state and local public health. The Action Plan is being revised and is expected to be released later this year.

A PUBLIC HEALTH APPROACH TO ANTIMICROBIAL USE IN ANIMALS

Antimicrobials used in animal agriculture are indicated for a variety of uses. There are four prominent label indications for use of these antimicrobials: growth promotion/feed efficiency; prevention; control; and treatment. The vast majority of classes of antimicrobials used in animal agriculture have importance in human medicine. A few antimicrobial classes (e.g., ionophores) used in food-producing animals do not appear to impact human medicine.

Protecting public health requires the judicious use in animal agriculture of those antimicrobials of importance in human medicine. I will now review how this principle applies to each use.

Growth promotion/feed efficiency

There is clear evidence that the use of antimicrobials in general selects for resistant organisms. To avoid unnecessary development of resistance under conditions of constant exposure (growth promotion/feed efficiency) to antibiotics, the use of antimicrobials should be limited to those situations where human and animal health are protected. Purposes other than for the advancement of animal or human health should not be considered judicious use. Eliminating these uses will not compromise the safety of food.

Disease prevention and control

FDA believes that some prevention indications are necessary and judicious to relieve or avoid animal suffering and death. Important factors in determining whether a prevention use is appropriate include: (1) evidence of effectiveness, (2) evidence that such a preventive use is consistent with accepted veterinary practice, (3) evidence that the use is linked to a specific etiologic agent, (4) evidence that the use is appropriately targeted, and (5) evidence that no reasonable alternatives for intervention exist. FDA also believes that the use of medications for prevention and control should be under the supervision of a veterinarian.

Treatment

FDA supports the treatment of ill animals according to appropriate veterinary practice within a valid veterinary-client-patient relationship.

Judicious use of antimicrobials in animal agriculture requires a strong commitment to surveillance and research, including monitoring antimicrobial resistance, studying the etiology of resistance, tracking the use of antimicrobials in agriculture, assessing risk in different settings, and evaluating strategies to reduce resistance. Such data will support science-based risk management policies.

SPECIFIC ACTIVITIES BY THE CENTER FOR VETERINARY MEDICINE (CVM)

CVM is addressing potential human health risks associated with the use of antimicrobial drugs in food-producing animals by: (1) using risk assessment methodologies (e.g., Guidance 152) during the new animal drug evaluation process to quantify the human health impact from antimicrobial use in animals, in conjunction with ro-

bust monitoring, research, and risk management; (2) actively conducting research to advance our understanding of antimicrobial resistance mechanisms and to support our regulatory decisions; (3) reaching out to stakeholders, including consumer groups, through public meetings to provide educational outreach activities and to strengthen and promote science-based approaches for managing the potential human health risks associated with the use of antimicrobial drugs in food-producing animals; (4) assessing relationships between antimicrobial use in agriculture and subsequent human health consequences through the National Antimicrobial Resistance Monitoring System (NARMS). CVM is the lead coordinator of NARMS. NARMS is a multi-faceted monitoring system that takes advantage of the expertise and resources of a number of Federal agencies and state public health laboratories. NARMS data provide regulatory officials and the veterinary medical community with critical information to help assess the risk associated with antimicrobial use in food animal production; and (5) participating in international dialogue on the use of antimicrobials in animals, including the World Health Organization (WHO) and the Codex Alimentarius ad hoc Intergovernmental Task Force on Antimicrobial Resistance.

CVM continues to collaborate with veterinary and animal producer associations to develop and distribute guidelines on the judicious use of antimicrobial drugs in food-producing animals.

COMMENTS ON H.R. 1549

FDA supports the idea of H.R. 1549 to phase out growth promotion/feed efficiency uses of antimicrobials in animals. The current statutory process of withdrawing a new animal drug approval is very burdensome on the agency. FDA recommends that any proposed legislation facilitate the timely removal of nonjudicious uses of antimicrobial drugs in food-producing animals. At the same time, FDA believes that legislation should permit the judicious use of antimicrobials in animals for prevention and control as discussed above.

CONCLUSION

Antimicrobial resistance is an important public health issue that can only be addressed by collaborative efforts of the relevant Federal agencies, state health departments, and the private sector. FDA looks forward to working with Congress on this important public health issue.

Thank you for the opportunity to discuss FDA's activities with regard to antimicrobial resistance.

I would be happy to answer any questions.

The CHAIRWOMAN. Thank you so much for being here, and welcome to the FDA. We are delighted to have you. You worked on the Hill, I understand, for the great Henry Waxman. That is always a good sign.

The timely removal that you were saying would be cumbersome for you, of removing those eight classes of antibiotics from animal feed, in my statement I mentioned that that could take a century. What would you all consider timely removal?

Dr. SHARFSTEIN. I think that we would like to see, for the growth-promotion/feed-efficiency uses, a much shorter time period than a century, but also the ability of the agency to accomplish that without having to expend a tremendous amount of resources in the process, both time and money. And so there are mechanisms to accomplish that. We don't want to be in a situation where we have bottled up many, many scientists writing papers for things that Congress could legislate and just make happen if we all think that is the right thing to do.

The CHAIRWOMAN. Now, you are a pediatrician. I am sure you would not recommend giving a nursery class of 3-year-olds antibiotics every day to make sure they didn't get an ear infection. So, obviously, you would not recommend this for animals. But does the FDA control that, or USDA?

Dr. SHARFSTEIN. The FDA controls the labels of drugs or how they would be used in animals.

The CHAIRWOMAN. So you can forbid it if the legislation were passed.

Dr. SHARFSTEIN. It would be under FDA.

The CHAIRWOMAN. That is good to know.

One of the things, obviously, that we are concerned about is the conditions under which these animals live. And I noted in the background, that Denmark, which banned the nontherapeutic use of antibiotics in animals in 1998, have found there was no significance significant impact on mortality or productivity. And I think it is terribly important that, after the ban, corresponding improvements in animal husbandry, such as better ventilation and cleaner barns, swine mortality and productivity were not affected at all. And I am sure that most of us who consume—I am sure that all of us want to think that they are raised in clean, healthy conditions, even though we know better.

We are going to do a food safety bill here, I think, coming up pretty soon, and then we will need to talk to you again, I think, about other things that you might want in there. Thank you so much for being here. Your testimony is most important, and we really look forward to working with you on making this a reality. Thank you so much.

Ms. Matsui.

Ms. MATSUI. Thank you very much. And it is so good to see you here.

Prevention of disease, whether it is in animal or humans, is a high priority of mine. Preventing sickness and disease before they occur just makes sense on many different levels, and I worked hard to make prevention a key element of the Congress' push on health care reform. And I support the CHAIRWOMAN's legislation because it doesn't limit a rancher's ability to use medicine in a rational way to prevent livestock disease. Prevention, though, is just a word, and it is not an effective strategy if we create more harmful diseases in the name of preventing minor ones.

Dr. Sharfstein, I found your testimony very compelling because it really does tread the fine line between the need to prevent diseases in our animal populations without actually doing ourselves more harm in the process.

In your testimony, you outlined how actions taken in the name of prevention can sometimes make things worse, as in the case of using antimicrobials to fight respiratory infections. Will you please elaborate on how dangerous it can be for animal producers to assume that simply blanketing their herds with antibiotics will not be counterproductive both to humans and to animals?

Dr. SHARFSTEIN. I think that the prevention area is obviously an area that needs a lot of attention in trying to figure out how to craft a policy, whether by legislation or by regulation. And I think there clearly are situations where you can prevent illness by giving medicine.

For example, in Baltimore, as the health commissioner, if we had a case of meningitis, we would give medicine to all the people who were in close contact. We had a very sad case of a teacher who died of meningitis, and we had to track down all the kids and make

sure they got medication. And they weren't sick, but we were giving them medication. And in that case, there is in pediatrics, for example, very strong evidence for the use of medicine in that situation. There is evidence that people who get treated will be less likely to get sick. You understand what you are treating. It is the meningococcus bacteria. You understand that you are using a medicine that is targeted to that bacteria.

And I think the concept for prevention is that, in animals as well, there are going to be some times when prevention is important, but that the decision on where that is permitted should be based on science, should be based on an understanding of what you are trying to prevent, the evidence that is there, the fact that there are no reasonable alternatives. And we want to use as few antibiotics in children, we want to use as few antibiotics as possible in animals, but when we are going to use medicines, it should be based on a solid foundation of evidence.

So trying to set up a mechanism for that is challenging, but I think as we go through one use at a time, just like we do in pediatrics, this use of antibiotics is appropriate, and this one isn't, that is what needs to happen.

Ms. MATSUI. So you are looking at a situation where it is going to be difficult to have a working definition of this notion of "prevention"; is that right?

Dr. SHARFSTEIN. I think it is one of the things that has to be worked out. I think in the bill it says "routine prevention." But how do you define routine prevention? That is somewhere in there. And I think that is the kind of thing like an agency like FDA has done before and can do. You know, we can talk about the kind of principles that would go into a determination like that or how you would assess what that is.

But I think the point of your question, I agree with you completely. Just calling something prevention doesn't make it based on evidence, doesn't make it appropriate to use. It has got to truly be based on evidence. And that kind of assessment has to happen.

Ms. MATSUI. But that is sort of your working definition on how we might move forward on this thing?

Dr. SHARFSTEIN. I think these are some principles. We put in—I don't think it is so much a working definition. I wouldn't quite go that far. But I think there are some principles that we would want to look at and make sure that we are limiting what is appropriate prevention to what is based on the science and supported by veterinarians.

Ms. MATSUI. But you believe the current agriculture practice in this country does not meet your sense of principles right now?

Dr. SHARFSTEIN. There are two things. First of all, there is use for growth promotion and feed efficiency, which FDA has taken the position should not be used like for that period. And then I have been struck as I am learning about this issue at just how little we really understand about what is going on on farms in terms of the use of antibiotics, and I think it is a high priority for Dr. Hamburg and myself to get a better understanding of that. It is one thing for FDA to have the rules, but we need to know that it is actually being followed, and we need to see that the use of antibiotics is truly coming down.

The CHAIRWOMAN. That is a welcome change.

Ms. MATSUI. Absolutely. On the FDA's web site, there is a list of 15 "judicious" use principles that are endorsed by the American Veterinary Medical Association for the use of antimicrobial drugs. One of these principles is that other therapeutic options should be considered prior to antimicrobial therapy.

It seems to me that the full range of other options has not yet been considered by many of our country's ranchers. Do you agree that more can be done within the meat-producing industry to use alternative methods to achieve the same end of keeping animals safe from harmful infections?

Dr. SHARFSTEIN. That is an excellent question. I don't know if I could give you an answer insofar that I am not really an expert on the practices of the producing industry, but I do believe that that analysis should be undertaken, though, before those uses are permitted. In other words, if it is the case that there are alternatives, good alternatives, those should really pursued. It shouldn't be a principle on the page; it should be something that really does apply.

Ms. MATSUI. Okay. There is another judicious use principle from the web site, to minimize environmental contamination with antimicrobials whenever possible. Will you clarify for me what this means? Does it mean not to let antimicrobials get into the water supply or into the vegetable fields? Is that what we are talking about here?

Dr. SHARFSTEIN. That is a good question, but I can't answer that one either. I am sorry. That is a principle of American Veterinary Medicine Association, so I don't know exactly what they intended with that principle.

I could say that we are concerned at FDA about the environmental impact of drugs not just for animals, but for humans also, and that is an issue that we would as public health officials want to engage on. And if there is—I think we recently were written a letter by the attorney general of Maryland about a particular issue in antibiotics and poultry, and we are going to look at that issue. If there is an environmental issue that we need to be aware of, we will take a look and see if there is something that we could do. But I couldn't quite exactly define it. I think I would say that we would look at the balance of the potential environmental impacts, and if there is a serious environmental harm, that is something that we should be aware of.

Ms. MATSUI. Thank you very much.

The CHAIRWOMAN. Ms. Pingree.

Ms. PINGREE. Thank you. Thank you, Madam Chair.

Thank you for your testimony, which was very interesting. And I appreciate your public health factor in Baltimore. That certainly adds to the dimensions of what we are talking about today. And I just want to follow up a little bit on what Representative Matsui was talking about.

In your recommendation, or potential recommendation, where you talked about allowing for continued therapeutic use, I just want to clarify. I think we all generally know that this is in widespread use right now; that without significant changes in the way

the animals are raised, the idea of infections and outbreaks of infections could easily continue at the rate they do now.

I am trying to understand when you mentioned that some of the criteria for not allowing it would be research that showed evidence of effectiveness. And has research already been done that shows that it is effective in preventing outbreaks when you distribute it widely through the feed, or is that something you want to determine?

Dr. SHARFSTEIN. I think that is something you want to determine. I think that it may be that people may be using antibiotics not knowing what they are treating or if they are even having an effect. But in the realm of routine use, we are saying it shouldn't even be permitted. If it is to prevent a disease, then what disease? Is it effective to prevent that disease? Have you looked at other ways to do it that are reasonable alternatives? Those are the sorts of things that should go into an assessment before that is permitted.

So I couldn't—in fact, I will tell you, in pediatrics it is very clear what you should be treating and what you shouldn't be treating. The American Academy of Pediatrics has guidelines. There is a huge campaign amongst pediatricians. In fact, I called one of my old teachers last night and told him I was going to catch up on the pediatric side of this issue before testifying. And he pointed me to some research that antibiotic use among pediatricians has come down by 30 percent, and that is partly because of government efforts. And we are actually tracking what pediatricians prescribe, that it is truly coming down, also has to do with parent expectations. Kids are doing fine, just fine with that, probably better, but without being prescribed quite as much.

And what we would like to see is something, I think, like that in animal use. There does not seem to be at this point a very clear—to me at least in kind of looking at it, a very clear list of what are the evidence-based uses of antibiotics for prevention in animals like there would be in pediatrics and other fields of medicine. And I think it has got to be that if the FDA is going to put a label on and permit a particular use like that, that it is very solidly backed up in science.

Ms. PINGREE. It seems like an extremely important criteria. And I just would want to be sure that if you were to allow therapeutic use or a broad definition of that, that we didn't stay with the status quo, because the example that you gave about the tragic loss of a teacher, which was a very good example, is about an outbreak of disease. And I think what we are talking about here is routine use that creates a constant use of the medications. And I wouldn't want to see that be called therapeutic use or necessary, because that is very different than a disease outbreak.

Dr. SHARFSTEIN. And that is one reason I talked about it separately.

Ms. PINGREE. Thank you.

The CHAIRWOMAN. Thank you, Ms. Pingree.

And we have been joined by Congressman Cardoza from California.

Mr. Polis.

Mr. POLIS. Thank you for your testimony.

Would you say that there should be a different definition between therapeutic and nontherapeutic use as applied to humans and as applied to animals, or the same definition could cover both humans and animals?

Dr. SHARFSTEIN. I mean, as I am thinking, I can't think of the use of antibiotics in humans for growth promotion. So, there are other things that are used for growth promotion sometimes in pediatrics that are quite controversial, but I don't know if the concept of nontherapeutic use really—I don't know to what extent that even exists.

The CHAIRWOMAN. Would the gentleman yield? That brings up a pet peeve of mine, and that is the overuse of antibiotics for viral diseases that pediatricians sometimes are guilty of doing. I think that also has helped contribute to it.

Dr. SHARFSTEIN. I was trying to think where someone would come out and say using it in a nontherapeutic way. That doesn't really exist in medicine. But certainly pediatrics has really taken aim at the use of antibiotics.

The CHAIRWOMAN. That is good news that it has come down 30 percent.

Dr. SHARFSTEIN. That is the 30 percent decline for certain illnesses it has gone down, and it is a very high priority. Therapeutic use is to treat illness. I think that is a pretty similar definition.

Mr. POLIS. So it would be the same working definition for both.

Dr. SHARFSTEIN. I think for therapeutic.

Mr. POLIS. In terms of the economic costs, would you agree that when we are—effectively, if you have an animal producer that is using antibiotics in a nontherapeutic way, thereby—well documented, of course—contributing to antibiotic-resistant bacteria, that there would then be a sizeable economic cost of that externality that then others would have to pay for, not the producer of that animal, but that somebody else would have to pay for treating people with secondary and tertiary antibiotics and other costs of treatment?

Dr. SHARFSTEIN. Yeah. I do believe it could be quite costly to treat antibiotic-resistant infections directly and indirectly.

Mr. POLIS. And maybe you could bring this down to your own experience as a doctor and M.D. For somebody who has an antibiotic-resistant infection, staph or strep or whatever it might be, what would then be the secondary and tertiary treatments for that individual? And approximately what might we be looking at from a cost perspective?

Dr. SHARFSTEIN. It depends on the infection.

Mr. POLIS. Take a typical example of, in your case, a kid who might, say, present with strep or something and doesn't react to the first line of medications.

Dr. SHARFSTEIN. Well, I think for something say a skin abscess that would be staph, you might want to treat that with a cephalosporin that would be relatively inexpensive. And you might wind up treating him with a more serious erythromycin. And I think that I couldn't tell you off the top of my head the price differential now, but it could be relatively significant. Plus, you have the chance that if you don't catch it soon enough, that you can't get

it with erythromycin because it has spread, and they are hospitalized.

And one of the things I did as health commissioner is I rounded at St. Agnus Hospital, and they presented two kids who came in with serious staph infections. And I said, wow, I probably saw one of those every month when I was a resident, and you have two the same night. And they say, we get them every day now. So—and I was only a resident about 10 years ago.

So there is the cost of the medicine. And then if you get hospitalized, which the evidence is that you are more likely to get hospitalized if it is resistant, then the costs escalate quite a bit.

Mr. POLIS. And I am sure that Dr. Cornell would be hard pressed to put a price on the loss of his arm and extreme health outcomes that have a detrimental health impact for the rest of their life. But I think clearly we have demonstrated that even in the best-case scenarios where the health outcome is positive, the secondary or tertiary treatments can cost several times what the normal intervention would cost.

I yield back.

The CHAIRWOMAN. Thank you, Mr. Polis.

Mr. Cardoza.

Mr. CARDOZA. Thank you, Madam Chair.

Sir, you work with USDA, correct?

Dr. SHARFSTEIN. I work with FDA.

Mr. CARDOZA. Now, it is my understanding that FDA—well, I personally know that every tanker load of milk that is delivered gets tested with an FDA-approved test; is that not correct?

Dr. SHARFSTEIN. I am seeing a lot of nodding.

Mr. CARDOZA. I think that is correct. And I am sorry that I have missed some of your testimony. I will go back and read it. But I am trying to understand this. So FDA has improved tests that they do of the milk that screens for antibiotic residues.

Dr. SHARFSTEIN. Okay.

Mr. CARDOZA. So is your contention that the test is inadequate? Or are you fearful that somehow, for example, in the milk, that antibiotics are causing children to ingest antibiotics that they shouldn't? I mean, what is the problem here? The FDA has an approved test. Every tanker load of milk is tested; .038 of the tanker loads in America have a positive, and that entire tanker load is then jettisoned at a cost of about $12,000 a tanker load. There is a pretty big incentive for farmers not to let residue be in the milk production. So I am trying to figure out what the nexus is.

Dr. SHARFSTEIN. I think when you think about the implications of the use of antibiotics in animals, there are three that people generally talk about. One is that there is bacteria that becomes resistant in the animal that the human then eats, the bacteria itself the human then eats. And that bacteria causes illness in the human by fluoroquinolones and campylobacters. And that would not apply to the milk because the milk should be pasteurized, and it shouldn't be containing, I think, pathogenic bacteria.

The second mechanism is that it is not dangerous bacteria, it is sort of the usual bacteria. But they are still resistant, and they can pass those genes on to human-illness bacteria in your body. That

is a big concern that people have, and probably also would not apply to the milk.

Third is the residue. Is there an amount of residue that causes selection within humans? And I have not been briefed on or testified about whether that is an issue with milk at all. I think what I am familiar with milk is more the first, through an indirect route, which is that if you are treating the dairy cows which may eventually wind up in the food supply, if they have been treated with antibiotics, can develop antibiotic-resistant bacteria, and then that antibiotic-resistant bacteria can cross into the human food chain when that dairy cow is slaughtered.

And I am familiar with some evidence I believe, if I am not mistaken, the Salmonella Newport multidrug-resistant infection, I believe, may have implicated dairy cows. So I hope I am wrong about that, I will correct it. But I think there is some evidence that cows that have been treated with antibiotics and then go into the food supply may be linked to certain problems with antibiotics that way, but not through the milk, that I am aware of.

Mr. CARDOZA. Well, as a legislative body—first of all, I think this is an appropriate discussion. My wife is a family doctor, and she is very concerned about overprescription of antibiotics and any medication that isn't therapeutically necessary. So I understand that, and I appreciate the Chairwoman's concern on this, because we certainly don't want to do anything that is jeopardizing the health and safety of our citizens. But I want to make sure that we focus in on what is really going on, and we have to know what is happening. And I am sorry, again, that I haven't had a chance to—I got delayed today and meant to be here for your opening statement. But you said you thought that there might be a connection. I really would like you to tell us for sure.

Dr. SHARFSTEIN. Sure. I think that the connection—I am not 100 percent sure of whether this particular example applies. But I am not uncertain about the issue of, if you are to treat a cow for dairy for many years, you would facilitate the production of resistant bacteria. And then the risk that we have been talking about is when that cow goes into the food supply directly, is there a risk of passing that on.

What I can't remember exactly is whether this particular example applies to that.

The CHAIRWOMAN. Would the gentleman yield just for a moment? Maybe I can help a little bit here.

We are talking about the use of antibiotics for cow and poultry that are not sick. In fact, 70 percent of all the antibiotics produced in the United States are given to animals that are not sick. That is the purpose of the hearing. We would like to save eight kinds of antibiotics which are most at use for human beings for the use of human beings.

Mr. CARDOZA. I thank the chairwoman.

And I thank the gentleman for his testimony. I will review it. I appreciate that.

I will have some other questions later.

The CHAIRWOMAN. Thank you very much. Welcome to Washington. We are delighted to have you here, and we look forward to working very closely with you on these issues. Thank you.

Dr. SHARFSTEIN. Thank you very much.

The CHAIRWOMAN. Our next panel is Dr. Margaret Mellon, Ph.D., scientist and director, Food and Environment Program of the Union of Concerned Scientists; Dr. Lance B. Price, Ph.D., director, Center for Metagenomics and Human Health, and associate investigator, Pathogen Genomics Division, the Translational Genomics Research Institute; and Dr. Robert Martin, senior officer of Pew Environment Group.

If you could come forward, please.

We really welcome all of you here today. We are not used to such an intellectual powerhouse at the table in the Rules Committee. It is quite an honor to have you here.

Why don't we begin with you, Dr. Mellon.

STATEMENT OF MARGARET MELLON, PH.D., SCIENTIST AND DIRECTOR, FOOD AND ENVIRONMENT PROGRAM, UNION OF CONCERNED SCIENTISTS

Dr. MELLON. Thank you. My name is Margaret Mellon, and I am here representing the Union of Concerned Scientists, a nonprofit science organization working for a healthy environment and a safer world.

I am also here on behalf of Keep Antibiotics Working, a coalition of environmental, agricultural, and humane organizations dedicated to addressing the overuse of antibiotics in production agriculture.

I am really grateful to have the opportunity to appear here today to discuss an urgent public health and food safety crisis: the loss of the effectiveness of drugs due to antibiotic resistance.

Before I begin, I want to thank Representative Slaughter for her steadfast leadership on this issue over almost a decade.

Now, to go on, I have prepared written testimony, but my message can be summarized very briefly: The miracle drugs of the 20th and 21st centuries are at risk, and the enormous use of antibiotics in production agriculture is partly to blame.

We all know that the more we use antibiotics, the more bacteria become resistant to them. What many do not know, however, is that we use huge quantities of antibiotics, something like 13 million pounds a year, every year, in the production of poultry, beef, and swine. Importantly, these antibiotics are the very same or in the same chemical class as those we use in human medicine. And that means when those drugs—the penicillins, tetracyclines, erythromycins—are used in hospitals or doctors' offices, they do not work.

Now, I want to be clear: Overuse of antibiotics occurs in both human medicine and in animal production, and both settings are responsible for the problem and need to take responsibility for solving it. But while the medical community, as Dr. Sharfstein made clear, has taken action on the issue, production agriculture has not.

We simply cannot continue to profligate use of antibiotics to produce food animals. We need to reduce that use, and we can, because most of the drugs used by food producers, as has been said, are not used to treat sick animals, but to increase feed efficiency or for routine disease prevention and control. Those aims can be ac-

complished by other ways, including better management, and it is time that we get about that process.

As has been said, the resistant bacteria generated in food animals have lots of ways of moving to humans, most prominently, but not solely, on food. But as a result, these bacteria are connected to many kinds of diseases, not just the foodborne illnesses like salmonella and campylobacter, but also to systemic blood infections, to urinary tract infections, and, most recently, to methicillin-resistant Staph aureus.

We have delayed on this issue for too long. Keep Antibiotics Working has been on the case for almost a decade now, with little or nothing to show for our efforts. But the story, I think, is the same for most of the food safety issues. For decades, public health advocacy has been stymied by vested interests. But, finally, Congress is poised to act on food safety. And, as it does, it is imperative that the resistance dimension of the issue not be ignored.

Mrs. Slaughter's bill, the "Preservation of Antibiotics for Medical Treatment Act," would require FDA to review the drugs in those classes that are used both in human and animal medicine, and if they cannot prove they are safe, get them off the market for purposes other than treating sick animals. The bill is supported by the American Medical Association, the American Nurses Association, the American Academy of Pediatrics, the Infectious Disease Society of America, and many other medical organizations.

Getting the antibiotics off the market would preserve the efficacy of drugs for both humans and animals. In the words of an editorial in the prestigious New England Journal of Medicine, "It is time to stop." In fact, it is way past that time.

Thank you.

[The prepared statement of Dr. Mellon follows:]

PREPARED STATEMENT OF MARGARET MELLON, PH.D., SCIENTIST AND DIRECTOR, FOOD AND ENVIRONMENT PROGRAM, UNION OF CONCERNED SCIENTISTS

My name is Margaret Mellon. I am the Director of the Food and Environment Program at the Union of Concerned Scientists (UCS). UCS is a leading science-based nonprofit working for a healthy environment and a safer world. I am here today on behalf of UCS and Keep Antibiotics Working (KAW), a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups, of which UCS is a member. Keep Antibiotics Working, whose organizations have more than ten million members, is dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in food animals.

We appreciate the opportunity to submit testimony before the House Committee on Rules on what the Centers for Disease Control has long considered one of the "most pressing public health problems:"[1] the urgent food safety and public health crisis of antibiotic resistance. KAW advocates that Congress at long last address this crisis, and, in particular, support the scientifically sound approach found in H.R. 1549, The Preservation of Antibiotics for Medical Treatment Act. We are grateful for Chairwoman Slaughter's long standing efforts to address this critical issue.

DISEASES RESISTANT TO ANTIBIOTICS: MAJOR THREATS TO FOOD SAFETY AND PUBLIC HEALTH

As is well known to the medical community, we face an urgent crisis of antibiotic resistance. Once considered miracle drugs, antibiotics are becoming less and less effective at treating infections and disease. Many Americans, including, I would guess, some in this room, have experienced this problem first hand. Sometimes when drugs don't work, it means several days of unnecessary pain and suffering while doctors

[1] Centers for Disease Control (CDC). 2004. Background on antibiotic resistance. Online at *www.cdc.gov/getsmart.*

figure out that another drug is needed. But increasingly, resistance leads to more dire consequences. Treating a patient with an ineffective drug can give an infection a chance to progress to a more serious illness. For cases where none of the available antibiotics work, resistance becomes a matter of life and death. In addition to rendering drugs ineffective, resistant strains are often more virulent than their susceptible counterparts.

Antibiotic resistance is of particular concern in terms of food safety. The CDC has found that half of all human Campyobacter infections[2] are drug resistant as are one in five Salmonella infections.[3] Nearly 100,000 of the Salmonella infections would resist treatment with at least five antibiotics. Salmonella and Campylobacter, the most common sources of food borne illnesses in the United States, account for well over a million resistant infections in this country each year.[4]

Longer hospital stays to treat food borne illnesses and other diseases dramatically increase the nation's health costs—by one estimate adding over $4 billion per year to the health care tab in the United States.[5] And, of course, more time away from work is a drag on our economy.

Antibiotic resistance is not a problem only for humans. The bottom line of antibiotic resistance—harder to treat diseases and higher medical costs—is also true for veterinary medicine.

Unfortunately, the resistance crisis will not be alleviated by the arrival of new drugs. The discovery of new classes of antibiotics, once almost a predictable occurrence, has become frustratingly difficult in recent decades. The unhappy truth is that there are virtually no new classes of antibiotic drugs in the pipeline.[6] Unless we act to preserve the antibiotics we have, the age of the miracle antibiotics may be coming to an end.

ANTIBIOTIC RESISTANCE RESULTS FROM ANTIBIOTIC USE

Exposure to antibiotics selects for those bacteria that can withstand the drug. Resistant organisms are encouraged in settings where antibiotics are heavily used—primarily human medicine, veterinary medicine, and food animal production. Microorganisms exist in an interconnected ecosystem and travel back and forth among humans, animals, and other elements in the environment. Thus, antibiotic-resistant microorganisms generated in the guts of pigs in the Iowa countryside don't stay on the farm. They can be transmitted to humans in at least three ways: carried on meat or poultry; colonizing farm workers who transmit them into the community; or moving through water and soil, which can lead to the contamination of fresh produce. Recently, lettuce, tomatoes, and spinach have all been found to be sources of food borne illness.

When the antibiotics used in raising food animals such as pigs are the same (or more precisely, in the same classes) as those used in doctors' offices, bacteria from the pigs will be impervious to therapies based on the drugs.[7]

The fundamental approach to prolonging the effectiveness of drugs is to curb unnecessary uses—whether in human medicine, veterinary medicine, or food animal production. Every sector needs to accept responsibility and curb its own unnecessary antibiotic use.

The medical profession has stepped up to the plate and identified and attempted to address the issue by establishing guidelines against unnecessary uses, like treatment of viral diseases, and aggressively seeking to reduce prescriptions for those uses. Periodically, it evaluates the effectiveness of its initiatives.

To date, the veterinary and industrial agriculture communities lag far behind the human medical community in taking similar steps to reduce unnecessary use. Instead it has spent its energies in minimizing or denying the problem.

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[2] Centers for Disease Control (CDC). 2005. National Antimicrobial Resistance Monitoring System (NARMS) for Enteric Bacteria: Human Isolates. Final Report. Atlanta, GA: U.S. Department of Health and Human Services, CDC.

[3] CDC. 2005. NARMS.

[4] Total number of illnesses from USDA (www.ers.usda.gov/Data/FoodBorneIllness) is multiplied by data from footnote 3 to obtain totals for resistant illness.

[5] National Academy of Sciences Institute of Medicine. 1998. Antimicrobial Resistance: Issues and Options. Washington, DC: National Academies Press, p. 1.

[6] Infectious Diseases Society of America. 2003. Bad bugs, no drugs: Defining the antimicrobial availability problem. Backgrounder. Online at www.idsociety.org/badbugsnodrugs.

[7] McEwen S, and Fedorka-Cray P. 2002. Antimicrobial use and resistance in animals. Clinical Infectious Diseases 34:S93–106.

PRODUCTION AGRICULTURE'S CONTRIBUTION TO THE PROBLEM

As it turns out, food animal production uses the lion's share of the antibiotics in the United States—some 13 million pounds of antibiotics every year, about 70 percent of the total. The estimates include drugs used in only three livestock sectors—poultry, swine, and beef cattle—and only for purposes other than treating sick animals—non-therapeutic purposes like growth promotion and routine disease prevention.[8] All of these antibiotics, among them penicillins, tetracyclines, and erythromycin—are in classes of drugs used in human medicine.[9] Most of these drugs are delivered to animals mixed in their feed.

Why do animal producers use such huge quantities of valuable drugs when most of the antibiotics are not used to treat disease? In part, because growth promotion and feed efficiency uses are thought to improve the bottom line even in healthy animals. But also because drugs are needed to compensate for crowded, stressful, and unhygienic conditions characteristic of many animal production operations.

THE LINK BETWEEN ANIMAL PRODUCTION AND REDUCED EFFICACY OF HUMAN DRUGS

In light of the enormous use in production agriculture of exactly the same drugs used in human medicine, it is difficult to imagine a credible scenario under which resistant bacteria generated in the billions of animals we grow for food would not find their way to human populations and erode the effectiveness of our antibiotic arsenal. And indeed a mountain of scientific studies now demonstrates that that is the case.

The list of antibiotic-resistant pathogens originating in animals is long. It includes the food borne illnesses mentioned above caused by Campylobacter and Salmonella. Contaminated retail meat used to be the primary source of such infections. But increasingly, produce like peppers and spinach is causing illness, likely the result of contamination by animal waste during the production and processing of crops.

Microorganisms originating in animals are also often associated with bloodstream infections that affect hospitalized patients. Resistance in Campylobacter and Salmonella is associated with increased bloodstream infections, increased hospitalization, and increased death.[10] Resistant urinary tract infections, which can be caused by a number of different animal-associated bacteria, including E coli, have also been linked to animal source.[11]

And the list continues to grow. Just last year, we learned that livestock can be an important source of life-threatening methicillin-resistant Staphylococcus aureus (MRSA). In Europe, strain of MRSA responsible for 20 percent of human MRSA infections in the Netherlands[12] has been shown to be transmitted from pigs to farmers and their families, veterinarians, and hospital staff.[13] The pig-associated strain of MRSA has now been found in Canada[14] and in the United States."[15] Small studies to determine whether the pig-associated strain will be found in hospitals and doctors' clinics in the United States are underway, but larger more comprehensive studies are needed.

Importantly, the list of resistant bacteria themselves traceable to animals does not convey the full scope of the problem. Bacteria are promiscuous. They can acquire

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[8] Mellon M, Benbrook C, and Benbrook K. 2001. Hogging it!: Estimates of Antimicrobial Abuse in Livestock. Cambridge, MA: Union of Concerned Scientists, p. 60. Online at *www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_industrial_agriculture/hogging-it-estimates-of.html.*

[9] Mellon M, Benbrook C, and Benbrook K. 2001. Hogging It!, pp. 51–53.

[10] Helms M, et al. 2005. Adverse health events associated with antimicrobial drug resistance in Campylobacter species: a registry-based cohort study. Journal of Infectious Diseases 191:1050–5; Varma JK, et al. 2005. Antimicrobial-resistant nontyphoidal Salmonella is associated with excess bloodstream infections and hospitalizations. Journal of Infectious Diseases 192:554–61.

[11] Hooton T, and Samadpour M. 2004. Is acute uncomplicated urinary tract infection a foodborne illness, and are animals the source? Clinical and Infectious Diseases 40:258–9.

[12] van Loo I, et al. 2007. Emergence of methicillin-resistant Staphylococcus aureus of animal origin in humans. Emerging Infectious Diseases [serial on the Internet] December. Online at *www.cdc.gov/EID/content/13/12/1834.htm.*

[13] Huijsdens X, et al. 2006. Community-acquired MRSA and pig farming. Annals of Clinical Microbiology and Antimicrobials 5:26. Online at *www.ann-clinmicrob.com/content/5/1/26.*; Voss A, et al. 2005. Methicillin-resistant Staphylococcus aureus in pig farming. Emerging Infectious Diseases 11:1965–6.

[14] Khanna T, et al. 2008. Methicillin resistant Staphylococcus aureus colonization in pigs and pig farmers. Veterinary Microbiolgy 128:298–303.

[15] Smith T, et al. 2008. Paper presented at the International Conference on Emerging Infectious Diseases, Centers for Disease Control and Prevention, Council of State and Territorial Epidemiologists, Atlanta, GA, March, and personal communication.

bits of DNA, including resistance traits, from unrelated bacteria. This means that the traits that originate in animal guts might move through the microbial ecosystem to confer resistance on bacteria not of animal origin. In addition, bacteria are known to harbor large circles of DNA that carry ten or more resistance traits.[16] In these circumstances, the use of one antibiotic, say penicillin, can simultaneously drive up the levels of resistance to other antibiotics, like tetracycline, cephalosporins, and fluoroquinolones.

THE LITERATURE IN THIS ARENA IS VOLUMINOUS AND THE CONCLUSION IS CLEAR: ANTIBIOTIC OVERUSE IN AGRICULTURE—JUST AS IN HUMAN MEDICINE—IS UNDERCUTTING THE EFFICACY OF IMPORTANT HUMAN THERAPIES AND GENERATING MORE VIRULENT PATHOGENS

Several major studies and reports make the point:

- In 2002, Clinical Infectious Diseases published a special supplement on the "Need to Improve Antimicrobial Use in Agriculture" that concluded the "[u]se of antimicrobials in food animals contributes to the growing problem of antimicrobial resistance in animal and human infections."
- In 2003, the World Health Organization concluded, "There is clear evidence of the human health consequences [from agricultural use of antibiotics, including] infections that would not have otherwise occurred, increased frequency of treatment failures (in some cases death) and increased severity of infections."
- In 2003, the National Academy of Sciences' Institute of Medicine came to the same conclusion, stating, "Clearly, a decrease in antimicrobial use in human medicine alone will have little effect on the current situation. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."
- In 2001, the prestigious New England Journal of Medicine published a special editorial whose title sums it up well—"Antimicrobial Use in Animal Feed—Time to Stop."

THE SOLUTION IS REDUCING ANTIBIOTIC USE

As long as the massive use of antibiotics continues, animals, particularly animal guts, will remain a fountain of resistant pathogens, dangerous to both animals and humans. The straightforward solution to the problem is to reduce the use of antibiotics in animal production and thereby diminish the pool of resistant organisms and traits.

Fortunately, the largest amounts of antibiotics in food animal production are used for growth promotion, feed efficiency, and routine disease control, uses that can be eliminated without damage to animal health or unacceptable increases in animal production costs or consumer meat prices.

As documented in the literature, these uses can be reduced or eliminated with modern management practices. The viability of such practices has been demonstrated in the industrial and alternative agricultural operations. On the industrial side, Tyson, Inc., a major poultry grower and retailer, was able to develop systems for all of its retail chicken that used no antibiotics at all. On the niche side, cattle grown out-of-doors and fed primarily grass rarely need antibiotics at all. Many American producers, like Laura's Lean Beef, Niman Ranch, and Coleman Natural, are thriving in the market place selling beef and pork produced without antibiotics.

A recent report from the USDA Economic Research Service looking at changes in U.S. agriculture supported the notion that-antibiotic use in agriculture could be reduced without significant costs to produce.[17] The USDA confirmed that large farms are more likely than small farms to use antibiotics in feed but noted that the benefits of this use is limited to certain stages of production, particularly pig nurseries. For other stages of production like finisher pigs, there were few benefits. The USDA also found that practices such as increased sanitation and vaccination could be substituted for antibiotics.

Data from Europe also support the feasibility of reducing antibiotic use even in intensely industrial poultry and swine systems. In 1999, Denmark, the world's leading pork exporter, ended all use of antimicrobial growth promoters. A World Health

[16] Partridge SR, et al. 2009. Gene cassettes and cassette arrays in mobile resistance integrons. Federation of European Microbiological Societies (FENS) Microbiological Reviews 33:757–84; Akwar HT, et al. 2008. Associations of antimicrobial uses with antimicrobial resistance of fecal *Escherichia coli* from pigs on 47 farrow-to-finish farms in Ontario and British Columbia. Canadian Journal of Veterinary Research 72:202–10; Gillings M, et al. 2008. The evolution of class 1 integrons and the rise of antibiotic resistance. Journal of Bacteriology 190:5095–100.

[17] USDA Economic Research Service. 2009. The Transformation of U.S. Livestock Agriculture: Scale, Efficiency, and Risks. Online at *www.ers.usda.gov/Publications/EIB43/EIB43e.pdf.*

Organization (WHO) analysis of the Danish experience has shown that ban has had little or no impact on agricultural productivity and animal welfare.[18] The comprehensive analysis, published in 2003, showed that there were no appreciable impacts from the antibiotic ban in broiler chickens or older, so-called "finisher," pigs. In young nursery pigs, also called "weaners", there was a modest increase in the number of pigs requiring antibiotics for the treatment of diarrhea, but the increase was completely offset by the overall decrease in antibiotic use. According to the WHO report, the overall drop in antibiotic use was 54 percent. In the years following the ban, the Danish pig herd continued to grow and the production losses associated with the ban in weaner pigs have been overcome.

POLICY RECOMMENDATION

Because as mentioned above, reduction in uses can often be accomplished by better management, production agriculture represents a golden opportunity to reduce the pressure driving up resistance traits in the microbial ecosystem.

A sensible and protective two-part policy would:

(a) Reduce antibiotic use wherever possible in animal production by establishing and enforcing clinical practice guidelines in veterinary medicine.

(b) Review, and where supported by the evidence, cancel the use of those antibiotics also used in human medicine (so-called medically important drugs) in animal agriculture for non-therapeutic purposes like growth promotion, feed efficiency, and routine disease prevention. The classes of medically important drugs are penicillins, tetracyclines, sulfonamides, lincosamides, streptogramins, aminoglycosides, and macrolides.

Such a policy would lead to substantial reductions in antibiotic use without depriving producers of antibiotics to treat sick animals. It is important to point out that a number of antibiotic-like drugs are not used in human medicine, and that, under this approach, these drugs would be available to producers for any purpose including feed efficiency or routine disease prevention.

To accomplish public health and food safety goals, the policy needs to be effective across the board. A level playing field will force innovation in the industry and enable producers to resist temptation to fall back on antibiotics to compensate for sloppy management practices.

REDUCE USE THROUGH PAMTA

The FDA has the authority to cancel antibiotics that are no longer safe from a resistance point of view, but so far has used it only in the case of fluoroquinolones in poultry.

The failure of the FDA to move gave impetus to the Preservation of Antibiotics for Medical Treatment Act (PAMTA). This legislation would require the FDA to review antibiotics used in animal agriculture to determine whether they put public health at risk by leading to increased resistance and to withdraw from the market in a timely manner those drugs that cannot be shown to be safe.

This legislation has been endorsed by over 350 organizations, including the American Medical Association, American Academy of Pediatrics, American Nurses Association, American Public Health Association, and Infectious Diseases Society of America.

DELAY ON ANTIBIOTICS: A DISADVANTAGE IN THE MARKETPLACE

The European Union (EU) now has an EU-wide ban on non-therapeutic uses of antibiotics.[19] New Zealand,[20] Thailand,[21] and Korea[22] also have either enacted or will soon enact bans on certain non-therapeutic antibiotic use.

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[18] Wegener H. 2008. Keynote Presentation. ASM Conferences Antimicrobial Resistance in Zoonotic Bacteria and Foodborne Pathogens, Copenhagen, Denmark, June 15–16.

[19] European Commission. 2005. Ban on antibiotics as growth promoters in animal feed enters into effect, IP/05/1687. Online at *http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1687&format=HTML&aged=0&language=EN&guiLanguage=en.*

[20] Government Accountability Office (GAO). 2004. Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals, GAO–04–490, April 22.

[21] Brooks E. 2008. Reconciling scarcity and demand through innovation. Food Business Asia, Issue 21, July/August. Online at *www.efeedlink.com/ShowDetail/03c885e3-7852-439a-9ef0-a8a0b66a749c.html.*

[22] GAO. 2004. Antibiotic Resistance.

As warned in a Government Accountability Office (GAO) report from 2004,[23] these countries also represent potential challenges to U.S. products in the global marketplace. Under the trade rules, countries can restrict imports that do not conform to certain rules, provided they adhere to those rules themselves. For example, Korea could potentially restrict imports that relied on medicated feed not allowed in Korea. The greater the number of export partners that adopt such bans, the more vulnerable our meat exports in the global marketplace. As further noted in the GAO report,[24] if a major importer were to restrict trade from the United States because of the use of non therapeutic antibiotics, that action would override any economic benefits of this practice.

The U.S. animal agriculture industry is at risk of following the example of the U.S. auto industry and failing to see where the market is going. Increasingly, consumers are seeking meat from animals raised without these antibiotics. International competitors are beginning to meet this demand. In addition to protecting public health, minimizing antibiotics use in livestock can help U.S. producers add consumer value to their products, and position themselves advantageously in the global marketplace. American producers should be supported in reducing their antibiotics use.

CONCLUSION

We have waited far too long for action to reduce the unnecessary uses of antibiotics in food animal production. While we have dithered, new resistant diseases have emerged, old diseases have gotten worse, and people have died.

There is simply no reason to continue the profligate use of valuable antibiotics for economic purposes or to compensate for the stressful, crowded animal production facilities. The improved management practices necessary to reduce, if not avoid, antibiotic use are available and feasible. Yet, production agriculture has been unwilling to acknowledge, much less act on, this problem. We cannot tolerate this situation any longer. To protect our food supply and the public health, we must pass PAMTA.

The CHAIRWOMAN. Thank you, Dr. Mellon.

Dr. Price.

STATEMENT OF LANCE B. PRICE, PH.D., DIRECTOR, CENTER FOR METAGENOMICS AND HUMAN HEALTH, ASSOCIATE INVESTIGATOR, PATHOGEN GENOMICS DIVISION, THE TRANSLATIONAL GENOMICS RESEARCH INSTITUTE

Dr. PRICE. Thank you. Chairwoman Slaughter and distinguished members of the committee, my name is Lance Price. Like you, I am a microbiologist, with over 15 years of research experience. I also have training in public health. I appear today to present testimony in support of the "Preservation of Antibiotics for Medical Treatment Act."

Antibiotics have saved countless lives since they were introduced in medicine more than 50 years ago. Antibiotics save lives by killing or inhibiting bacteria when they are administered at proper doses. However, each time that you use an antibiotic, you risk the emergence of resistance, so it is a double-edged sword.

When antibiotics are administered at low doses, a practice common in food animal production, you rapidly select for resistance. Concentrated animal feeding operations present an ideal setting for the growth of antibiotic-resistant bacteria. There are thousands of animals densely packed under unhygienic conditions and given routine antibiotics. When you treat an animal with antibiotics, you select for resistant bacteria to grow in their guts, and the bacteria are rapidly disseminated among the entire flock or herd via fecal contamination, which is rampant in concentrated animal feeding

[23] GAO. 2004. Antibiotic Resistance.
[24] GAO. 2004. Antibiotic Resistance.

operations. Furthermore, fecal waste inevitably contaminates animal carcasses during the slaughter process.

Just to underscore this point, I brought in a couple of products. I brought in raw pork and raw chicken. My research and from government research indicates that these are potential biohazards. These are just products that I bought at the grocery store. I don't know if you have noticed, but when you buy these things, there is often this liquid leaking out. I think that this liquid is a potential biohazard, and there is good evidence for that.

My own research and the research of NARMS indicates that there is a good chance that these two products are contaminated with antibiotic-resistant bacteria because of the antibiotic use in food animal production.

Now, the most direct way to eliminate the antibiotic-resistant bacteria on products such as these is to eliminate antibiotic use in food animal production. So this includes any routine uses, whether for growth promotion, prevention, control, or even therapy. And this is whether or not they are accepted by the American Veterinary Association. This is not a public health association. If they are used on a regular basis, then that is a problem.

And that brings me to my next point. If an animal production system requires routine antibiotic use to keep animals from becoming sick, then that system is broken. We do not try to prevent outbreaks of human disease using mass treatment of antibiotics, except in extremely rare situations like the anthrax mailings of 2001, like the meningitis case that we heard about.

The prevention of infectious diseases within human populations is based on public health and hygiene interventions—things like underground sewers, things like vaccinations. We would never do away with these public health interventions and rely solely on antibiotics to maintain human health. So why do we do this with animals?

The military learned long ago that if bunks were placed too close together, then the troops would fall ill to bacterial infections. The military's response was not to provide prophylactic antibiotics to all recruits. The military's response was to impose minimal distances between bunks, strategic placement of bunks, so that you don't share bacteria between the troops.

The food animal industry must be forced to modify their production methods in order to eliminate all routine antibiotic input. Successful models for large-scale, antibiotic-free animal production already exist and are used to produce millions of animals within the United States without the aid of antibiotics.

Given the human health risks posed by overuse of antibiotics in animal production and the existence of viable alternatives, we should ban all non-therapeutic and routine antibiotic use in animal production in order to preserve the utility of these lifesaving drugs for treating sick people.

An industry lobbyist might try to convince you not to regulate the antibiotic use in food and animal production by touting one of their favorite one-liners, "The science just isn't there." However, as a scientist and a public health researcher who does not have any financial stake in keeping antibiotics in food animal production, I am here to tell you that there is sufficient evidence to say that rou-

tine antibiotics in food animal production poses a substantial human health risk.

Infectious diseases do not respect political borders; they move freely—and now rapidly—around the world. The sooner we implement sound legislation to curb all unnecessary antibiotic use in the United States, the sooner we can begin leading the rest of the world to do the same and we can protect American citizens from antibiotic-resistant bacteria grown both in the United States and abroad.

The "Preservation of Antibiotics for Medical Treatment Act of 2009" is a solid first step towards becoming global leaders in the fight against untreatable antibiotic-resistant bacterial infections. I commend the distinguished Chairwoman for her commitment to this issue, and I thank the entire panel for the opportunity to speak today.

[The prepared statement of Dr. Price follows:]

PREPARED STATEMENT OF LANCE B. PRICE, PH.D., DIRECTOR, CENTER FOR METAGENOMICS AND HUMAN HEALTH, ASSOCIATE INVESTIGATOR, PATHOGEN GENOMICS DIVISION, THE TRANSLATIONAL GENOMICS RESEARCH INSTITUTE

Chairwoman Slaughter and distinguished members of the committee, my name is Lance Price. I am the director of the Center for Metagenomics and Human Health at the Translational Genomics Research Institute in Arizona. I am also a microbiologist with over 15 years of research experience. I appear today to present testimony in support of the "Preservation of Antibiotics for Medical Treatment Act of 2009".

Antibiotic resistance is one of the greatest public health threats that we face today. For decades, the discovery of new antibiotics out-paced the emergence of antibiotic resistant bacteria. In recent years, however, the rate of new antibiotic discovery has plummeted; and, we are now witnessing the emergence of bacterial pathogens that are resistant to all of our approved antibiotics. Sadly, thousands of Americans die every year from infections that were once treatable with antibiotics.

Antibiotics save human lives by killing or inhibiting bacteria when administered at proper doses and for sufficient time. When antibiotics are administered at low doses—a practice common in food animal production—then antibiotic resistance emerges quickly.

Concentrated animal feeding operations present an ideal setting for the growth of antibiotic resistant bacteria—thousands of animals are densely packed under unhygienic conditions and fed antibiotics at sub-therapeutic doses. Most of the 9 billion food animals raised in the United States are raised in concentrated animal feeding operations and administered antibiotics on a regular basis.

Antibiotics select for resistant bacteria in the gastrointestinal tract of treated animals. These resistant bacteria are rapidly disseminated to the entire flock or herd via fecal contamination. Fecal waste inevitably contaminates animal carcasses during the slaughter process; thus, antibiotic resistant bacteria are common contaminants of meat and poultry consumer products. Furthermore, the enormous quantities of fecal waste produced by food animals in the United States are applied to agricultural land with minimal treatment that is insufficient to kill many bacteria. Crops grown in these fields are prone to contamination by antibiotic resistant bacteria.

Surveys of human gastrointestinal tracts indicate that people carry antibiotic resistant bacteria and that these bacteria likely come from the consumption of contaminated foods. The antibiotic resistant bacteria found on food and in human gastrointestinal tracts include some of the same organisms that are currently plaguing our hospitals.

Regular antibiotic use in food animal production is an unnecessary public health risk and a crutch for improper animal husbandry practices. If an animal production system requires regular antibiotic inputs to keep the animals from becoming sick, then the system is broken. Except in extremely rare situations, we do not try to prevent outbreaks of human diseases using population scale antibiotic treatment. The prevention of infectious diseases within the human population is based largely on public health and hygiene interventions (e.g., underground sewage). We would never consider doing away with our hygiene-based interventions and relying solely on antibiotics to maintain human health, so why do we do this with animals? The mili-

tary learned long ago that if bunks were placed too close together then troops would fall ill from bacterial infections. The military's response was not to prescribe prophylactic antibiotics to all the recruits—the answer was to impose minimum distances between bunks.

The U.S. food animal industry must find alternatives to antibiotics for preventing the spread of bacterial infections among the animals they produce. Successful models for large-scale antibiotic-free, animal production already exist and are used to produce millions of animals in the U.S. every year. However, until there is legislation to prevent unnecessary use of antibiotics then most producers will continue to use antibiotics to patch their outdated practices. Given the potential health risks posed by the overuse of antibiotics and the nonessential nature of their use in food animal production, society would be better served by preserving the utility of these antibiotics for treating sick people.

Antibiotic resistance may be inevitable; however, we can slow the onset of resistance by eliminating all unnecessary uses of antibiotics. If we can slow the emergence of resistance, we give ourselves more time to develop alternative treatment strategies and discover new antibiotics. Eliminating the regular use of antibiotics by food animal producers should be one of our top priorities for slowing the emergence of antibiotic resistant bacteria. The "Preservation of Antibiotics for Medical Treatment Act of 2009" is a solid first step towards curbing unnecessary antibiotic use in food animal production.

I commend the distinguished Chairwoman for her commitment to address this important issue and thank you for the opportunity to appear before this committee today.

The CHAIRWOMAN. Thank you very much.

Mr. Martin.

STATEMENT OF ROBERT MARTIN, SENIOR OFFICER, PEW ENVIRONMENT GROUP

Mr. MARTIN. Thank you, Madam Chairman.

My name is Bob Martin. I am a senior officer at the Pew Environment Group. Previously, I was the executive director of the Pew Commission on Industrial Farm Animal Production. I very much appreciate the opportunity to appear here today on this important health issue, the silent part of our health care crisis, antibiotic-resistant infections. And I appreciate your introduction of the "Preservation of Antibiotics for Medical Treatment Act," as well.

The Pew Commission on Industrial Farm Animal Production was a 2½-year study commissioned/funded by the Pew Charitable Trust. It was an independent commission involving a cross-section of individuals. The commissioners had expertise in animal agriculture, production of animal agriculture, public health, medicine, veterinary medicine, ethics, and State and Federal policy development.

We were chaired by former Kansas Governor John Carlin, who had also been the Archivist of the United States. And one of our members was former Secretary of Agriculture Dan Glickman. We also have in the audience today, who will be speaking later, one of our commissioners, Mr. Fedele Bauccio, who was a leader among our commissioners as well.

The general charge of the commission was to develop consensus recommendations to solve the public health, environment, animal welfare, and rural community problems caused by industrial farm animal production. As I said, we developed consensus recommendations using a fairly exhaustive process. We conducted 11 meetings around the country and spent 250 hours deliberating on the information we received. We received thousands of pages of information from the animal ag industry and all interested parties. We had two

public hearings, one in North Carolina and one in Arkansas, where over 400 people attended the two meetings. We visited all types of industrial farm animal production in North Carolina, Iowa, Colorado, California, and Arkansas. We reviewed 170 peer-reviewed reports and commissioned eight reports of our own.

We had a couple of general findings. One of our general findings was that the current system of food animal production in the United States is unsustainable. It represents an unacceptable level of risk to public health, an unacceptable level of damage to the environment, is harmful to the animals housed in these facilities, and is detrimental to the long-term economic activity of the communities where they are housed.

Another general finding was that we found undue or significant influence at every turn by the industrial animal ag industry, whether it is policy development on the Federal or State level, policy enforcement on the Federal or State level, or academic research at our leading land grant schools.

We developed 24 consensus primary recommendations. Twelve of those recommendations concern public health issues, five on antibiotic use alone. Our primary, number-one concern from a public health aspect was the end of the non-therapeutic use of antibiotics in food animal production.

The second definition or the second recommendation that goes along with the first recommendation is how we defined therapeutic and non-therapeutic. We defined therapeutic use as being applied in the case of diagnosed microbial disease, period. All other use was non-therapeutic.

We did have a provision for prevention or prophylactic use that would be covered in the case of a disease outbreak in a flock of birds or a herd or in anticipation of a disease that would be caused by shipping or other production practices. However, it was very important in our definition of prevention or prophylactic use that it be for a very, very limited amount of time.

As the chairman indicated, the National Academies of Science has said that antibiotic resistance costs $5 billion a year. That is almost $18 a person for every person in the United States—man, woman, and child. And recently, in 2005, Tufts University upped that estimate to $50 billion a year of cost to the health care system.

In 1999, the National Academy of Science followed the 1998 study, saying that ending the non-therapeutic use of antibiotics in food animal production would increase prices, food prices, by $5 to $10 per consumer. So that is actually a savings of $12 to $7 a person if you go by the other study.

The Pew Commission believes there is more than enough science to warrant the banning of non-therapeutic use of antibiotics. There have been scientific studies that have linked antibiotic use on the farm to resistant campylobacter, E. coli, and salmonella infections.

And we also think that the Danish experience is very important, as the chairman said. They banned growth promotion, the use of antibiotics in 1998. The data has been analyzed for the last 10 years, and a study is being released in the Journal of the American Veterinary Medical Association by the authors of the study.

And what they found is, number one, in comparing the United States to the rest of the world, we use more antibiotics in food ani-

mal production than any country in the world. And that is on page 10 of my submitted statement.

In Denmark, looking specifically in Denmark, the total amount of antibiotics being used now post-ban is less than the total amount of antibiotics used pre-ban. That is the chart on page 11 of my written statement. It also shows that the pool of resistance in humans has declined post-ban. The resistance in the animal population has declined post-ban.

And while they did show an increase in mortality for a short period of time among weaners and feeder pigs, once they started instituting better animal husbandry practices—cleaner barns, more ventilation for the barns, more space for the animals, better waste handling—then the mortality has decreased significantly in swine production.

Productivity has actually gone up post-ban. There are more pigs, more piglets per sow. So the worry that there is going to be a world food shortage that some people would like to promote if we ban antibiotic use and non-therapeutic use of antibiotics in this country is not founded, based on the Danish experiment.

Again, I thank you for this important piece of legislation and for this hearing today. And I was very impressed with all the knowledge that the members of the panel have about this very important issue.

[The prepared statement of Mr. Martin follows:]

PREPARED STATEMENT OF ROBERT MARTIN, SENIOR OFFICER, PEW ENVIRONMENT GROUP

Good morning Madam Chair and members of the Rules Committee. My name is Robert P. Martin and I am a senior officer at The Pew Environment Group. Prior to my current position at The Pew Environment Group, I was the Executive Director of the Pew Commission on Industrial Farm Animal Production (PCIFAP). I appreciate the opportunity to appear today.

The Pew Commission on Industrial Farm Animal Production was an independent commission funded by a grant from The Pew Charitable Trusts to the Johns Hopkins Bloomberg School of Public Health to investigate the problems associated with industrial farm animal production (IFAP) operations and to make recommendations to solve them. Fifteen Commissioners with diverse backgrounds began meeting in March of 2006 to start their evidence-based review of the problems caused by IFAP. I am attaching a list of the Commissioners with my statement.

Over the next two years, the Commission conducted 11 meetings and received thousands of pages of material submitted by a wide range of stakeholders and interested parties, including the animal agriculture industry. Two public hearings were held to hear from the general public with an interest in IFAP issues. Approximately 400 people attended those hearings. Eight technical reports were commissioned from leading academics to provide information in the Commission's areas of interest. In addition, more than 170 peer-reviewed, independent academic studies were reviewed. The Commissioners themselves brought expertise in animal agriculture, public health, animal health, medicine, ethics, and rural sociology to the discussion. In addition, the Commission visited broiler, hog, dairy, egg, and swine IFAP operations, as well as a large cattle feedlot.

The Commission's findings make it clear that the present system of producing food animals in the United States is not sustainable and presents an unacceptable level of risk to public health, damage to the environment, as well as unnecessary harm to the animals we raise for food. In addition, the current system of industrial food animal production is detrimental to rural communities.

The Commission released its full report on April 29, 2008, that included 24 primary recommendations. The Commission was so concerned about the indiscriminate use of antibiotics in food animal production, and the potential threat to public health, that five of those recommendations deal with antibiotic use. The top two public health recommendations call for the end on the non-therapeutic use of anti-

biotics in food animal production and set strict definitions for their use. Those recommendations follow.

Recommendation #1 Restrict the use of antimicrobials in food animal production to reduce the risk of antimicrobial resistance to medically important antibiotics.

a. Phase out and ban use of antimicrobials for non-therapeutic (i.e. growth promoting) use in food animals [1]

b. Immediately ban any new approvals of antimicrobials for non-therapeutic uses in food animals [2] and retroactively investigate antimicrobials previously approved.

c. Strengthen recommendations in FDA Guidance #152 which requires the FDA determine that the drug is safe and effective for its intended use in the animal prior to approving an antimicrobial for a new animal drug application.

d. To facilitate reduction in IFAP use of antibiotics and educate producers on how to raise food animals without using non-therapeutic antibiotics, the USDA's extension service should be tasked to create and expand programs that teach producers the husbandry methods and best practices necessary to maintain the high level of efficiency and productivity they enjoy today.

BACKGROUND

In 1986 Sweden banned the use of antibiotics in food animal production except for therapeutic purposes and Denmark followed suit in 1998. A WHO (2002) report on the ban in Denmark found that "the termination of antimicrobial growth promoters in Denmark has dramatically reduced the food animal reservoir of enterococci resistant to these growth promoters, and therefore reduced a reservoir of genetic determinants (resistance genes) that encode antimicrobial resistance to several clinically important antimicrobial agents in humans." The report also determined that the overall health of the animals (mainly swine) was not affected and the cost to producers was not significant. Effective January 1, 2006, the European Union also banned the use of growth-promoting antibiotics (Meatnews.com, 2005).

In 1998, the National Academy of Sciences (NAS) Institute of Medicine (IOM) noted that antibiotic-resistant bacteria increase U.S. health care costs by a minimum of $4 billion to $5 billion annually (IOM, 1998). A year later, the NAS estimated that eliminating the use of antimicrobials as feed additives would cost each American consumer less than $5 to $10 per year, significantly less than the additional health care costs attributable to antimicrobial resistance (NAS, 1999). In 2005, Tufts University estimated that antibiotic resistant infections added $50 billion annually to the cost of health care in the United States. In a 2007 analysis of the literature, another study found that a hospital stay was $6,000 to $10,000 more expensive for a person infected with a resistant bacterium as opposed to an antibiotic-susceptible infection (Cosgrove et al., 2005). The American Medical Association, American Public Health Association, National Association of County and City Health Officials, and National Campaign for Sustainable Agriculture are among the more than 300 organizations representing health, consumer, agricultural, environmental, humane, and other interests supporting enactment of legislation to phase out non-therapeutic use in farm animals of medically important antibiotics and calling for an immediate ban on antibiotics vital to human health.

The Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) amends the Federal Food, Drug, and Cosmetic Act to withdraw approvals for feed-additive use of seven specific classes of antibiotics [3] penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides—each of which contains antibiotics also used in human medicine (2009a). PAMTA provides for the automatic and immediate restriction of any other antibiotic used only in animals if the drug becomes important in human medicine, unless FDA determines that such use will not contribute to the development of resistance in microbes that have the potential to affect humans. FDA Guidance #152 defines an antibiotic as potentially important in human medicine if FDA issues an Investigational New Drug determination or receives a New Drug Application for the compound (2009a).

[1] The PCIFAP defines non-therapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e., any use of the drug as a food or water additive for growth promotion, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

[2] The PCIFAP defines non-therapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e., any use of the drug as a food or water additive for growth promotion, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

[3] Fluoroquinolones are approved in animals only for therapeutic use (not for non-therapeutic use), and thus are not covered under PAMTA.

Most antibiotics currently used in animal production systems for non-therapeutic purposes were approved before the Food and Drug Administration (FDA) began giving in-depth consideration to resistance during the drug approval process. The FDA has not established a schedule for reviewing existing approvals, although Guidance #152 notes the importance of doing so. Specifically, Guidance #152 sets forth the responsibility of the FDA Center for Veterinary Medicine (CVM), which is charged with regulating antimicrobials approved for use in animals: "prior to approving an antimicrobial new animal drug application, FDA must determine that the drug is safe and effective for its intended use in the animal. The Agency must also determine that the antimicrobial new animal drug intended for use in food-producing animals is safe with regard to human health (FDA–CVM, 2003)." The Guidance also says that "the FDA believes that human exposure through the ingestion of antimicrobial-resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals." However, it goes on to warn that the "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, the guidance describes the Agency's current thinking on the topic and should be viewed only as guidance, unless specific regulatory or statutory requirements are cited. The use of the word 'should' in Agency guidance means that something is suggested or recommended, but not required" (FDA–CVM, 2003).

The Commission believes that the "recommendations" in Guidance #152 should be made legally enforceable and applied retroactively to previously approved antimicrobials. Additional funding for FDA is required to achieve this recommendation. If any reviews of antibiotic use under Guidance #152 have been conducted by the Center for Veterinary Medicine, the results of the review should be released immediately.

Recommendation #2. Clarify antimicrobial definitions to provide clear estimates of use and facilitate clear policies on antimicrobial use.

a. The Commission defines as non-therapeutic[4] any use of antimicrobials in food animals in the absence of microbial disease or known (documented) microbial disease exposure; thus, any use of the drug as an additive for growth promotion, feed efficiency, weight gain, routine disease prevention in the absence of documented exposure, or other routine purpose is considered non-therapeutic.[5]

b. The Commission defines as therapeutic the use of antimicrobials in food animals with diagnosed microbial disease.

c. The Commission defines as prophylactic the use of antimicrobials in healthy animals in advance of an expected exposure to an infectious agent or after such an exposure but before onset of laboratory-confirmed clinical disease as determined by a licensed professional.

BACKGROUND

In 2000 the WHO, United National Food and Agriculture Organization (FAO), and World Organization for Animal Health (0IE, Fr. Office International des Epizooties) agreed on definitions of antimicrobial use in animal agriculture based on a consensus (WHO 2000). Government agencies in the United States, including the USDA and FDA, govern aspects of antimicrobial use in food animals but have varying definitions of such use. Consistent definitions should be adopted for the use of all U.S. oversight groups that estimate types of antimicrobial use and for the development of law and policy. The Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) defines non-therapeutic use as "any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose (2009a)." If the bill becomes law, this will be the legal definition of non-therapeutic use for all executive agencies and therefore legally enforceable.

THE DANISH EXPERIENCE

In 1998, Denmark banned the use of antibiotics as growth promoters. Now, after 11 years of data are available, an updated assessment of the impacts of that ban will be published in the Journal of the American Veterinary Medical Association (JAVMA) later this year. It is important to understand the results of the ban on antibiotics used for growth promotion in Denmark, presently the European nation

[4] For the Commission's recommendations, the members considered many definitions; a complete list of sources is in Appendix I.

[5] This definition is adapted from PAMTA 2007.

with the largest swine production, to have an idea of what would happen in the United States if a ban were implemented.

The Danish study is titled, Use of Antimicrobials in the Danish Swine Production, 1992–2007; The Meat of the Matter and Lesson Learned. The primary author of the study, Dr. Frank Aarestrup of the National Food Institute of the Technical University in Denmark, has met recently with United States producers at a conference at Kansas State University to discuss the findings of his team.

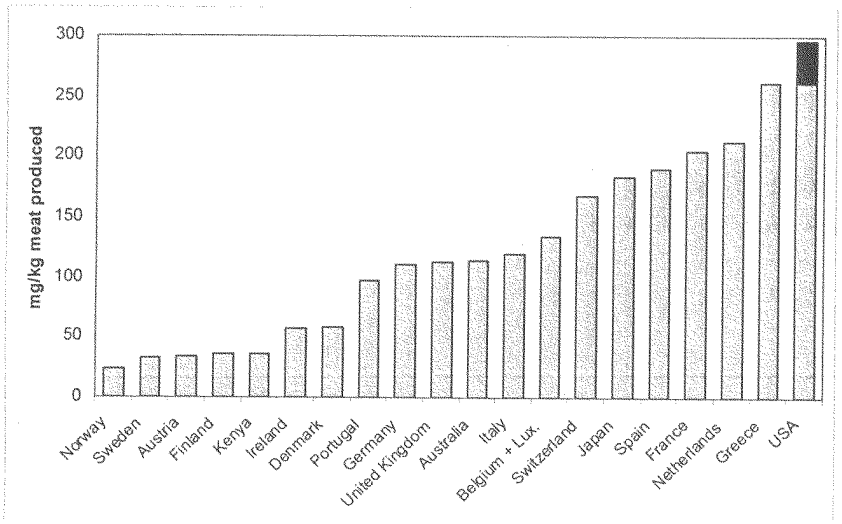
• The United States leads the world in the use of antibotics in food animal production, whether you use estimates from the Animal Health Institute or the Union of Concerned Scientists, according to Dr. Aarestrup. (Figure 1)

Figure 1

Dr. Frank M. Aarestrup, Director

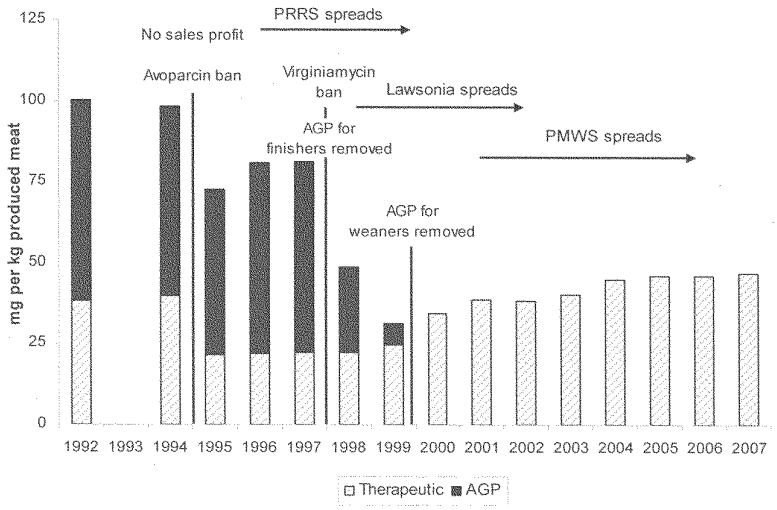
National Food Institute

Technical University of Denmark



• Once the growth promotion ban was instituted in 1998, therapeutic use rose slightly from 1999 until 2003, but has leveled off since 2003. However, the total amount of antibotics used post-ban is less than half the amount used in 1992 and the lower than the total amount used each year from 1992 to 1999. (Figure 2)

Figure 2
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark



• Mortality in weaners increased for a brief time post ban and weight gain declined in the same period. However, according to a convention I had with the study's author, mortality rates declined and weight gain recovered once production practices were improved, including better ventilation in the barns, more space provided for the animals, and more frequent cleaning of the barns. (Figures 3 and 4)

Figure 3
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark

Board (Callesen, 2002).

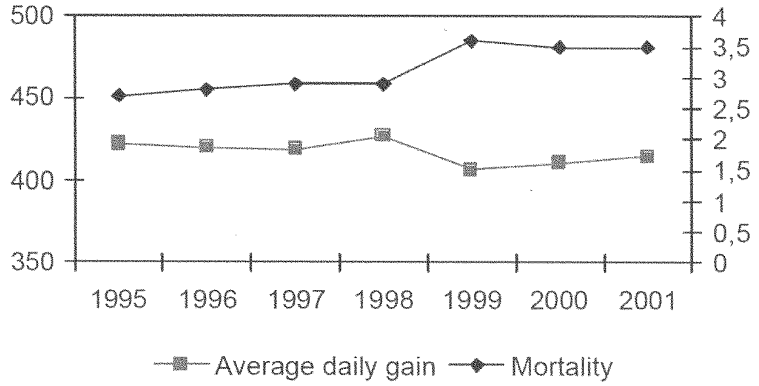
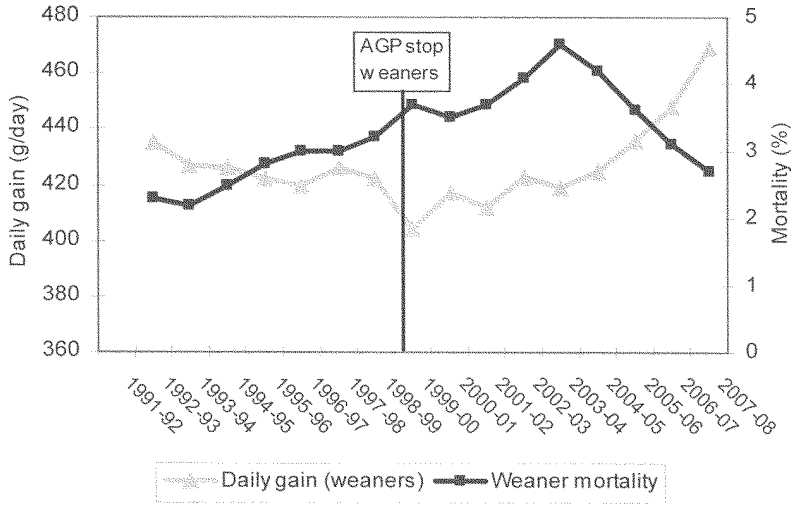


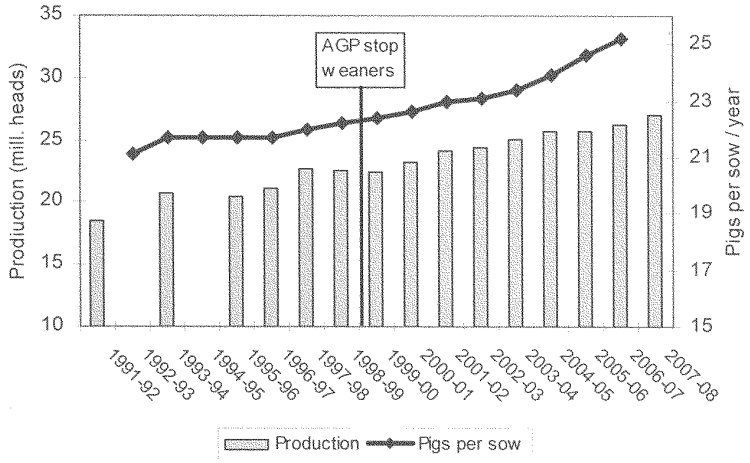
Figure 32. Productivity in Weaners: Danish Pork Board (Callesen, 2002).

Figure 4
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark



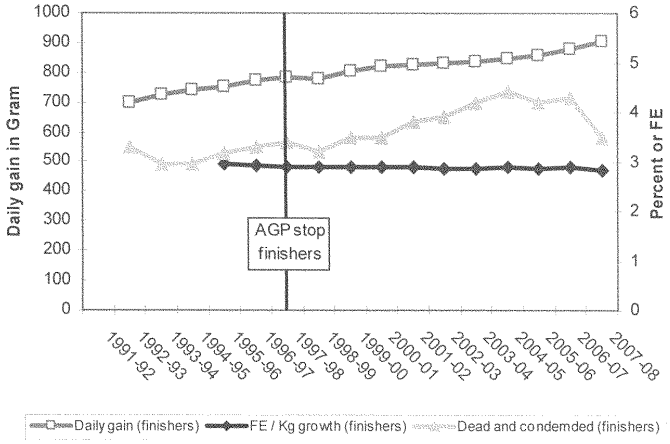
- **The numbers of piglets per sow increased post-ban. (Figure 5)**

Figure 5
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark



• Mortality in finisher pigs increased slightly post-ban but declined significant in 2006 and 2007 following improvement in production practices such as improved ventilation in barns and improved waste handling and barn cleaning; growth of finishers remained steady post-ban, with the daily gain on finisher pigs increasing post-ban. (Figure 6)

Figure 6
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark



GENERAL CONCLUSIONS FROM THE DANISH STUDY

• Total antimicrobial consumption in swine has been reduced from 100 mg/kg to 49 mg/kg from 1992 to 2008.
• Limited (if any) long term effect on overall productivity.
• Decrease in antimicrobial resistance has followed reduced use.

The Pew Commission on Industrial Farm Animal Production made our recommendations in an effort to stem the advance of antibiotic resistance. It has been shown that antibiotics once rendered ineffective due to overuse can become effective again once that overuse is stopped. It is important to note that the Pew Commission never advocated ending all antibiotic use in food animal production. Such a recommendation would be irresponsible. We did seek to maintain the effectiveness of antibiotics to treat sick animals by limiting the routine use.

Madam Chair, I commend you for introducing this important legislation and for conducting this hearing today. The increase in bacterial antibiotic resistance, and the inappropriate use in food animal production, is a serious—if silent—threat to our public health.

Thank you.

PEW COMMISSION ON
INDUSTRIAL FARM
ANIMAL PRODUCTION

The Pew Commission on Industrial Farm Animal Production (PCFIAP) was a two-year study funded by The Pew Charitable Trusts through a grant to Johns Hopkins Bloomberg School of Public Health.

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Former Executive Director
National Catholic Rural Life Conference

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Executive-in-residence
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Archivist of the United States (1995–2005)
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Fedele Bauccio, MBA
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Lisa Bertelson, Research Associate

The CHAIRWOMAN. Thank you.

We certainly appreciate all three of you being here today. Your knowledge is important to us.

First, I again want to thank you for the great work you have done. The Union of Concerned Scientists, for as long as I can remember, has really stood up for good science in a country where cheap science and bad science seems to be pretty prevalent. And I can't tell you how much I have appreciated that over the years.

I have to say that, in the last 8 or 9 years, my sense about the FDA, which I always thought was the gold standard for the world, has fallen to the point where I really hold the FDA in minimum low regard. I am so pleased that we see some light at the end of the tunnel now, with some new persons there.

I was pleased you brought up the Denmark study again, because I think that is a terribly important thing for us to do.

One of the questions that I wanted to ask for any of the three of you is about the FDA's 2004 queries. The company that makes penicillin for use in food animals, did they present any evidence that it is safe for people that you know of? This was a 2004 inquiry.

Dr. MELLON. Not that we know of. We know of a request sent to the companies by the FDA for evidence of food safety, but we don't know that any of the companies responded.

The CHAIRWOMAN. But the FDA simply just allowed it to go on.

Dr. MELLON. The FDA simply hasn't acted on——

The CHAIRWOMAN. Well, we don't have any results from that study in 2004, is that correct? They released no report at all?

Dr. MELLON. That is exactly right. It is amazing to me that, despite repeated past requests from Congress, that risk assessments that apparently have been done by the FDA have not been released, either to Congress or the public.

The CHAIRWOMAN. Yeah.

Cephalosporin, I think that has been an interesting example that had been prohibited; the FDA prohibited it July 3rd, 2008. And the Federal Register determined extra-label uses of cephalosporin presented a risk to human health, and the CDC agreed. But on November 28th, 2008, the FDA revoked the order prohibiting the extra-label use of cephalosporins in food-producing animals. They said that they had had too many comments on the order.

Are you all aware of that?

Dr. MELLON. I certainly am.

The CHAIRWOMAN. Those are the agents who were supposed to be taking care of us.

Dr. MELLON. They did. They revoked the order. And the Union of Concerned Scientists and Keep Antibiotics Working have requested that the agency reinstate the order. But, so far, we have not heard back from the FDA.

The CHAIRWOMAN. That is something I think that those of us on the panel can take up with the FDA.

Dr. Price, when you talked about the transfer, resistance transfer, that is a little hard to grasp. I think if you would explain to us how that is transferred among bacteria, we would appreciate it.

Dr. PRICE. Sure, sure.

So, antibiotic resistance in bacteria is coded for or elicited by either mutations in the DNA or fragments of DNA called resistance

genes. A lot of those genes are on what we call mobile resistance elements, these little pieces of DNA that bacteria can hand back and forth, although without hands, right, but they can pass back and forth. It is sort of like a lateral pass in football, but in this case you make a copy of it before you hand it off.

Or maybe you could think about spy secrets that allow you to escape arrest. You know, you make a copy of the secret and pass it on to one of your other spies, and you have now the information that it takes to escape that antibiotic.

So every time you are using antibiotics, you are selecting for all of those bacteria that are containing that information. And so, maybe that passing of information is rare, but when you apply that antibiotic, then all of those that don't have the information die off, or most of them die off, and the ones that do have the information grow. And so the system becomes dominated by the organisms that hold that information, hold those resistance genes.

Does that help?

The CHAIRWOMAN. It helps. Do you think genomics is going to play a role?

Dr. PRICE. I think that is a backwards way to approach this. I think taking antibiotics out of food animal production is the way to do it.

The CHAIRWOMAN. Well, that is what we would all prefer to do. That is the hope, of course, with this bill.

Now, the industry that feeds antibiotics to their animals on a daily basis calls it "routine preventative use." If we call it prevention but we use it every day, isn't that an indication that we have a system that makes those animals prone to catching the disease?

Dr. PRICE. I said it in my statement and I will repeat it right now: If you have to use repeated antibiotics, routine antibiotics to keep animals from being sick or to make animals healthy again, you have a broken system.

The CHAIRWOMAN. Mr. Martin, you know that this bill is the result of all the work done at Pew, for which we greatly thank you.

Concerning the terms for non-therapeutic, therapeutic, and prophylactic use of antibiotics, the commission considered it important that they be clearly defined. Tell us how you came to those conclusions.

Mr. MARTIN. Well, we had leaders in medicine and veterinary medicine, and I think through the period of our inquiry, what we found is just what we have heard today at the hearing and what the chairwoman has expressed: Unless you very clearly define the terms, the industry will use antibiotics on a routine basis and call it disease control or prevention.

And so we decided to make a very narrow definition of therapeutic use after, you know, several hours of discussion internally and consulting with other human health experts and veterinary medical experts.

And I would just like to reiterate what Dr. Price said. I mean, the system is broken. It is the lack of animal husbandry, that antibiotics are a patch on a broken system. They are a crutch that allows us to overcrowd the animals and to not treat the waste properly.

And they are also a linchpin, the commission found—I am getting a little bit off subject here—but they are a linchpin in keeping the animals together that escalates the development of novel flu viruses. We had a real concern that, because antibiotics allow the animals to be overcrowded and because of the intense exposure of individuals with the animals, that a novel flu virus would be generated, similar to the swine flu that we see.

The CHAIRWOMAN. And we got one, didn't we?

I know that you have worked with lots of individuals. Did you work with the animal agriculture industry as well?

Mr. MARTIN. We did.

The CHAIRWOMAN. To what result?

Mr. MARTIN. Well, in the report we said that the response to the commission by the animal ag industry was pretty broad. It ranged from wary cooperation to open hostility.

We did work with the Animal Ag Alliance, and they helped us get some access to some facilities, because it is very hard to get in to see some of these industrial operations. We consulted a lot of academics that received funding from the industry.

In the end, I think that they were pretty upset because we called for broad-scale changes.

The CHAIRWOMAN. Thank you all very much.

Ms. Matsui.

Ms. MATSUI. Thank you, Madam Chair.

And thank you all for being here today. And I truly respect your expertise and your experience in this matter.

I am really interested in the economic imperative for why this legislation is needed. In the testimony that we received, it is clear that the failure to take action could have dire economic consequences. We have heard that failure to act on this bill means that we will continue spending over $4 billion a year on preventable hospital visits. We also heard that failure to act exposes our U.S. food industry to trade challenges in a global marketplace.

Through April of this year, the country's farmers exported almost $937 million worth of meat. That is about 277,000 metric tons of meat in the first 4 months of 2009 alone. This is a huge industry for our country at a critical time in history, and we can't afford to leave our meat industry behind by market changes that we fail to see or react to.

Dr. Mellon, you have devoted a great deal of your testimony to the potential market disadvantages that U.S. meat producers would face if we failed to enact Chairwoman Slaughter's legislation. I am someone who does recognize the critical role that international trade plays in our country's economy. So I am hoping you will be able to elaborate on your analysis of this.

You used Korea, Thailand, and New Zealand as examples of countries that compete with U.S. beef and that could conceivably restrict beef imports that do not conform to their own quality standards. How would these countries taking such action hurt American beef producers?

Dr. MELLON. Well, any country that has already restricted the non-therapeutic use of antibiotics in its own food animal production has what I would call a kind of card in its pocket that it can play anytime it chooses.

And the card is as follows: Under the trade rules, a country is allowed to restrict the imports of products coming into the country where those products do not adhere to rules that the country is willing to impose on itself. So, where a country has itself decided to restrict antibiotic use, it has the card to play to restrict U.S. imports into that country because we do not adhere to those rules, and for so long as we don't.

We don't know if they are going to play that card, but many of our competitors are looking for, you know, virtually any angle in what is a very competitive international marketplace.

So that is the kind—they could establish rules, and those rules would not fall under a WTO challenge as long as, as I said, they are not allowing in products that don't adhere to rules that they are willing to impose on themselves.

Ms. MATSUI. So you are basically saying they could use that as an excuse to not——

Dr. MELLON. To restrict imports, yes. To not import our beef, or any other product.

Ms. MATSUI. Okay. Then can you estimate what sort of economic impact such a development would have on American beef producers? Are we talking in millions or billions of dollars?

Dr. MELLON. I really wouldn't want to venture into that area. It is not my area of expertise.

But I think it would—I mean, just because the size of the international marketplace is so large, that it could be important. I mean, I think the handwriting is on the wall. And I think the American meat industry is a lot like the auto industry; they just can't see that it is in their own advantage to start doing what needs to be done.

Ms. MATSUI. So do you feel like there are other countries that are moving towards limiting——

Dr. MELLON. Yes.

Ms. MATSUI [continuing]. Antibiotic use so they can legally erect trade barriers against the United States?

Dr. MELLON. No, I wouldn't—I would say that certainly, you know, based on the Danish experience, the country is restricting antibiotic use in order to protect the health of its own citizens. But I think that smart producers—and Denmark, I believe, is the world's largest exporter of pork; I mean, this is no small industry there—that they understand that there will be trade advantages as well. They would rather be ahead of the game than behind it.

Ms. MATSUI. Thank you.

Can you go on with the Denmark experience? Because my understanding is they have experienced little economic dislocation. I mean, they must have had some dislocation.

Mr. MARTIN. Actually, not. I was fortunate enough to be on a conference call with the author of the study that is going to be published next month. There has been very little economic dislocation.

But to answer the question about disruption in the marketplace, I think it would cost the American meat industry billions of dollars if a challenge like that were issued. And I think you only have to look at what happens when there is a BSE scare, what happens to exports.

Russia periodically bans imports of U.S. pork because of concerns about antibiotic residue on the export. And the entire European Union has joined Denmark in the ban on non-therapeutic use of antibiotics in food animals, so in 2006 they did an EU-wide ban. So I think the potential for a trade challenge is pretty serious.

But there has not been a lot of economic dislocation based on the Denmark study. They did find that I think more people had to be involved in agriculture to produce the animals, but it wasn't this major disruption that the domestic U.S. industry would like you to believe.

Ms. MATSUI. Okay. Thank you very much.

The CHAIRWOMAN. Ms. Pingree.

Ms. PINGREE. Thank you, Madam Chairman.

And thank you for your interesting and very informative testimony. As you heard me say earlier, I am a strong supporter of what we are here to talk about today and have a little experience, so I was very pleased to hear all of you reinforce that. Thank you very much.

I am just going to ask you a couple things, just to reinforce what you were already talking about. And thank you to Ms. Mellon for that, sort of, reinforcing the economic impact of what we are hearing about here and how it has already had unintended consequences, certainly in the health field, but how it could continue to be an economic disadvantage in our exports. And I thought it was important just to reinforce how significant this could be if we continue down this path.

And I want to thank Dr. Price for reminding us again that, if a system requires constant use of antibiotics, it is already unhealthy.

And, as I mentioned before, my educational background and my life experience is around organic farming. That is true with plants, animals. It seems like such a simple premise to me, and the fact we can't get from there to here doesn't make any sense to me. The fact that we would even have to have this hearing, knowing what we know about loss of life and economic issues doesn't make any sense.

So I just want to actually ask my only question of Mr. Martin. Thank you for the work that Pew did. That was obviously very helpful in bringing us to this point.

You mentioned in passing the issue of undue influence and that you saw it at several levels. As far as I am concerned, we wouldn't be here today if there wasn't undue influence in reinforcing bad decisions being made.

So could you kind of stretch that out a little bit? I am interested in hearing what you said with a little more length attached to it so we can really think about what the root problem is here and why we don't fix it.

Mr. MARTIN. Well, I think one of the main root problems is the lack of public funding for research at land grant schools. There have been widespread cutbacks, both at the State and Federal level that should be doing research, which, if it is public dollars, it will be for the common good. That cutback has been replaced by industry-funded research. And you can't blame an industry for wanting to fund research that promotes its business model or the perpetua-

tion of its product, but that is not always in the vein of public health or in keeping broader public health in mind.

There is also a lot of influence by some of the species promotional groups, like the National Pork Producers Council, influencing State and Federal policymakers and enforcement of existing regulations and laws.

Ms. PINGREE. Uh-huh. Well, thank you.

Thanks again to all you.

The CHAIRWOMAN. Mr. Cardoza.

Mr. CARDOZA. Thank you, Madam Chairman.

I believe someone on the panel has said in the past that 70 percent of all antibiotics used in food animals are for non-therapeutic purposes, is that right? Isn't it true that half of that 70 percent figure is ionophores, which aren't really antibiotics?

Dr. MELLON. No, I can take that question.

Seventy percent of—well, I guess I should preface it by saying, there are two broad classes of chemicals that we are talking about here, antibiotics that are used in human medicine and antibiotics that are not. Often the entire class, including both antibiotics that are used in human medicine and those that are not, are called antimicrobials. And the figure that was cited in the report that the Union of Concerned Scientists actually published is that 70 percent of the antimicrobials used are used in animals, in only three species and for non-therapeutic use.

Now, as we made clear and as I made clear in my testimony, only half of the 24 million pounds are drugs that that we use in human medicine and are, therefore, of concern, I think, to the folks here. But, in fact, the 70 percent number stands, whether it is a percentage of all of the antimicrobials used or whether it is all of the more narrowly defined antibiotics.

Mr. CARDOZA. Is the entire 70 percent used by the animal consuming it, or are some of those antimicrobials dips or used to sterilize?

Dr. MELLON. No. The 13 million pound number that we came up with represents antibiotics that were fed to animals for non-therapeutic purposes, mostly in feed, occasionally in water. It does not include the use of antibiotics for dips and for other purposes.

And I would say, across the board, regardless of the purpose for which antibiotics are used, we do not have adequate data to answer the questions with the specificity and accuracy I would like to be able to answer them.

Mr. CARDOZA. To get to the data question, the farm bill we passed last year, it was included that USDA and FDA are to collect that data, is that correct?

Dr. MELLON. Well, in ADUFA last year, the Animal Drug——

Mr. CARDOZA. There were also some provisions with regard to control in the farm bill, if I am not mistaken.

Dr. MELLON. There are no provisions that I am aware of in the farm bill that would require the collection——

Mr. CARDOZA. The collection.

Dr. MELLON. Yes. There is some research that is authorized in the farm bill to, kind of, provide the background for the issue, to figure out why antibiotics are used to trace their movement off the farm. That is in the farm bill. It is a program that, although au-

thorized, there are no funds appropriated for it, which we would very much like to see happening. It is a kind of data that we would very much like to have.

But on top of that, we also would like to have what they have in Denmark, for example. They are able to tell you precisely the quantities of antibiotics used in their animal agriculture and for what purposes. So they can really follow it over time.

Mr. CARDOZA. I think that is very valid. I totally support having people have knowledge. For example, I am the chairman of the Organic Subcommittee on the Agriculture Committee. So I believe that people need to be able to make choices and to know what they are getting.

As you talk about Denmark, and that has been mentioned several times today, when they banned the non-therapeutic use of antibiotics, it is my understanding that therapeutic use went up dramatically. In fact, it went up 135 percent between 1996 and 2005.

Dr. MELLON. It did go up some, primarily for the treatment of disease in young pigs. But it did not go up as much as overall use came down.

Mr. CARDOZA. The reason why I raised this is because we have seen this a number of times in the Agriculture Committee when we studied this over the years. There is a reason why some diseases are treated, and we are concerned with what those diseases could cause in the human population as well. So there is some reason to be concerned not just with the treatment but with the disease that they are trying to get at. So that may go to other questions about how to prevent those diseases in other ways. But it is not just always a zero-sum game.

Dr. MELLON. Absolutely. You are most correct.

Mr. CARDOZA. Thank you.

Dr. Price, are you a vegetarian?

Dr. PRICE. No.

Mr. CARDOZA. The way you handled that chicken, I thought that was maybe the first time you have ever done it.

Dr. PRICE. I have handled a lot of chicken, actually, testing it for drug-resistant bacteria.

Mr. CARDOZA. Well, the reason I wanted to talk to you about that, you mentioned that commercially produced chicken had toxic bacteria on it. Free-range chicken, would that have the same kind of toxins or potentially the same health effects? Would you cook it any different?

Dr. PRICE. Well, I have done studies comparing poultry products from animals raised without antibiotics and conventionally raised products. And I was looking for fluoroquinolone-resistant campylobacter. This is the second leading cause of bacterial diarrhea in the United States, just behind salmonella. They, kind of, compete for first place.

And there was a significant difference and a substantial difference—I probably need to go back to the numbers and I can give those exact numbers to you, but it was about a tenfold difference between those organic and raised-without-antibiotics products compared to conventionally raised. So there is much more

fluoroquinolone-resistant campylobacter on the conventional products.

Mr. CARDOZA. Was that a peer-reviewed study?

Dr. PRICE. It was.

Mr. CARDOZA. If you would get that to me, I would appreciate it.

Dr. PRICE. I would be happy to. I have two different studies I conducted on that. I will share those both with you.

Mr. CARDOZA. Was the chicken that you compared, was it prior to processing or after processing? I know there are some treatments that are used in processing that sometimes take care of some of those.

Dr. PRICE. No, this was grocery store. Just like this.

Mr. CARDOZA. Thank you. I would like to have that study.

Dr. PRICE. I would be happy to share it with you.

Mr. CARDOZA. Madam Chairman, I will withhold further questions.

Mr. MARTIN. May I go back just to the——

The CHAIRWOMAN. Yes, Mr. Martin.

Mr. MARTIN. I think the Danish experience is very important. And I just wanted to reiterate, on page 11 of my written testimony, this is the actual chart that will be issued in the Journal of American Veterinary Medical Association next month. It is by the doctor who conducted this study.

It shows that this is the pre-ban antibiotic use, both therapeutic and growth promoter, and this is the antibiotic use post-ban. It does go up some, but it has leveled off, it looks like, starting in about 2004 to 2008.

But you can see that it is a dramatic reduction in use when you combine non-therapeutic and therapeutic. And I think you have to look at that combined figure to get an accurate idea.

Dr. PRICE. And I think there was a temporary spike due to—there were some outbreaks initially and it went down.

The CHAIRWOMAN. Oh, I think you have mentioned that, with outbreaks.

Mr. CARDOZA. I have one further question. Now, is that by weight, or is that by—because if you are mixing it in feed and you have diluted it somehow and it is a less dilute—I mean, if you provided a strong concentration but it is a very small pill, how are you measuring it?

Mr. MARTIN. It is measured—well, and I think in your packet, Dr. Aarestrup and Dr. Wegener have actually submitted a written testimony that it will probably be better for them to address than me. But it shows milligrams used per kilograms of meat produced.

Mr. CARDOZA. Thank you.

The CHAIRWOMAN. Thank you all very much. We really appreciate your being here, and your testimony has been invaluable. Thank you so much.

Our next panel will be two Members of Congress, Congresswoman Schakowsky from Illinois and Congressman Boswell from Iowa. If they will come forward, please.

Dr. Price is going to take his chicken there, right?

Ms. Schakowsky, can we begin with you?

STATEMENT OF THE HON. JANICE SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Madam Chairman. I really appreciate the opportunity to come and talk to your committee.

You know, some vulnerabilities are thrust upon us as a Nation, and others, like the one we are discussing, are really self-imposed.

We all felt extremely vulnerable after 9/11, and we have looked for all of the ways that we could protect ourselves and all the potential attacks that might come upon us. We talked about biologic weapons that might threaten our country. And when the H1N1 virus came out, I know it wasn't a bacterial infection, but we said, oh, is this the big one, and are we ready for that, and is this going to be the plague of our generation?

Well, on this battlefield, it seems as if we are disarming ourselves. And we are not doing it for good, solid health reasons. We are doing it in order to grow animals faster or, you know, to promote growth and not to promote health.

And you have heard all the science, that the Food and Drug Administration has seven classes of antibiotics that are highly or critically important in human medicine, and they are used as feed additives. I am not going to go over the science, which I think has been very adequately presented.

But my friend, for example, is one of these people who has had breast cancer and has had trouble with her arms since then, is very susceptible to bacterial infections and spends a lot more time in the hospital for every admission when she gets such an infection.

And here we are at this moment looking for ways that we are going to be able to provide health care to all Americans and do it in an economical way.

And, again, you have heard some of those numbers. Of the estimated 1.4 million people infected with salmonella each year, about one in five cases is resistant to antibiotics. What does that mean? It means longer stays in a hospital, more medical care. Of the 2.4 million annual campylobacter infections, about half are drug-resistant, many resistant to two or more antibiotics. So we have to keep trying more and more things.

We know that 2 million Americans acquire bacterial infections during their hospital stays every year. Seventy percent of their infections are resistant to the drugs commonly used to treat them.

So we are bringing ourselves down at a moment when we want to protect ourselves as a Nation and we certainly want to protect the health care of Americans.

The University of Illinois researchers found in 2001 and 2007 that routine tetracycline used at hog farms was contaminating groundwater with tetracycline-resistant bacteria, which were then sharing resistance with other bacteria through gene transfer. So the researchers concluded that, quote, "Groundwater may be a potential source of antibiotic resistance in the food chain."

The Illinois Department of Health calculates that the incidence of one type of resistant bacteria, MRSA, has risen 57 percent, to over 10,000 cases, in just 4 years.

So it seems to me, when the solution is at hand—and we have heard testimony about other countries that have done this without

any dramatic effect at all to the industry—when we are talking about using these antibiotics not for therapeutic reasons in animals, and we are not really discussing that right now, that we ought to do the smart thing.

As you may know, Madam Chairman, my hope was to introduce this legislation, your legislation, as part of the overall health reform that we are doing right now. We do have language in there now that would look at this issue and the importance of this issue. I did it as much, again, for the health of the country as an effort to save money on health care and do it in a smart way.

So my hope is that this committee and that the full House then will look at this as a stand-alone issue, pass your legislation, H.R. 1549, for all the reasons that I mentioned and with all the absolutely unassailable data behind us to back up its effectiveness and its importance.

Thank you.

[The prepared statement of Ms. Schakowsky follows:]

PREPARED STATEMENT OF THE HON. JANICE SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

• Madam Chairwoman, I am pleased to offer my testimony today in support of your bill, the Preservation of Antibiotics for Medical Treatment Act of 2009.

• This bill would require the FDA to end the non-therapeutic use of antibiotics in livestock—a practice that is contributing to increasing prevalence of antibiotic-resistant diseases.

• Food-borne illnesses are now becoming more difficult to treat due to the increase in antibiotic-resistant strains and the decreased effectiveness of antibiotics routinely used as a first-line defense.

• Two million Americans acquire bacterial infections during their hospital stay every year, and 70 percent of their infections are resistant to the drugs commonly used to treat them.

• In fact, resistant bacterial infections increase health care costs by $4 billion to $5 billion each year.

• In addition, foodborne illnesses, which affect millions of Americans each year, are increasingly are resistant to one or more antibiotics, making them more difficult, and sometimes impossible, to treat.

• Of the estimated 1.4 million people infected with Salmonella each year, about one in five cases are resistant to antibiotics.

• Of the 2.4 million annual *Campylobacter* infections, about half are 27) drug resistant, many resistant to two or more antibiotics.

• A contributing factor to this rise in antibiotic resistance is the routine feeding of important human antibiotics like penicillin, tetracycline, and ciproflaxin to food animals.

• Seven classes of antibiotics certified by the Food and Drug Administration (FDA) as "highly" or "critically" important in human medicine are used in agriculture as animal feed additives.

• Many factory farms give these antibiotics in the daily feed to cows, chickens, and pigs—not to treat disease, but to promote growth, improve feed efficiency, and compensate for overcrowding and bad sanitation.

• These classes of antibiotics are among the most critically important in our arsenal of defense against potentially fatal human diseases.

• Approximately 70 percent of antibiotics and related drugs produced in the U.S. are given to cattle, pigs, and chicken to promote growth and to compensate for crowded, unsanitary, stressful conditions.

• This kind of habitual, nontherapuetic use of antibiotics has been conclusively linked to a growing number of incidents of antimicrobial-resistant infections in humans, and may be contaminating ground water with resistant bacteria in rural areas.

• University of Illinois researchers found in 2001 and 2007 that routine tetracycline use at hog farms was contaminating groundwater with tetracycline-resistant bacteria, which were then sharing resistance with other bacteria through gene transfer.

• The researchers concluded, "groundwater may be a potential source of antibiotic resistance in the food chain."
• The Illinois Department of Health calculates that the incidence of one type of resistant bacteria—methicillin-resistant *Staphylococcus aureus* (MRSA)—has risen nearly 57% to over 10,000 cases in just 4 years.
• We should be addressing food safety from farm to fork, including practices in food animal production—like routine antibiotic use—that can make our food less safe to eat and costs billions of dollars each year in health care costs.
• I urge the Members of this committee to support passage of H.R. 1549.

The CHAIRWOMAN. Thank you very much.

Mr. Boswell.

STATEMENT OF THE HON. LEONARD BOSWELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BOSWELL. Well, thank you, Madam Chairman and the committee, for allowing me to appear before you today and to share my testimony.

I might be a little different from my good friend from Chicago, and I do mean good friend. We came here together, and we do a lot of things together. But I believe that we are growing animals not just for rapid growth but for healthy animals and healthy food, to keep people healthy. And I believe that, and you will probably understand that as I share my testimony.

I have spent most of my life involved in animal agriculture, and I have seen firsthand the responsible use of antibiotics. I understand the issues that affect the livestock, dairy, and poultry industries, having spent most of my youth working in livestock production. And today I still have a hand in managing a cow-calf operation on my farm in southern Iowa.

Once I retired from 20 years in the Army, I moved back to Iowa to return to farming. I knew things had changed, so I wanted to learn about it. So I sat down with my local veterinarian, who actually manages our little cow-calf operation today, and his senior partner and people from Iowa State University, if you will, to discuss the use of antibiotics to treat sick animals and prevent future illness.

From my experience with producers and veterinarians, the thoughtful use of antibiotics is not the exception, it is the rule.

Part of that was my young son was going to have a calf in 4–H. He was just a junior high youngster, and I wanted him to learn. I thought maybe he would farm someday. Well, he is not, but nevertheless, so much for that. But I wanted him to understand what he was doing, and I thought, well, parents kind of like to take care of their kids, so when I went to the fair I would probably end up buying it and we would probably send it to the locker and take it from there. So I wanted to be sure what I fed my children was healthy.

During the 110th Congress, it was my privilege to serve as the chairman of the Agricultural Subcommittee on Livestock, Dairy, and Poultry. On September the 25th of last year, we held a hearing to review the advances in animal health within the livestock industry. And I have a report here I would like to submit for the record, if I may.

The CHAIRWOMAN. Without objection.

Mr. BOSWELL. Thank you.

We specifically looked at how antibiotics are used on America's livestock farms. Our witnesses included veterinarians from USDA's Animal Health and Plant Inspection Service and FDA's Center for Veterinary Medicine (CVM), producers, veterinary practitioners, and academics from across the country. We believe that we heard from a good cross-section of the users of animal health products, the doctors responsible for the use of the antibiotics, and the experts studying the resistance trends for the use of antibiotics in animals.

As the subcommittee members listened to the witnesses, it became very clear that America's livestock, dairy, and poultry producers have the responsibility to safeguard animal health and public health, a responsibility they take very seriously.

They are committed to using antibiotics responsibly and have developed responsible use guidelines for each of their respective industries. They didn't develop these guidelines because Congress told them to do so. They developed the guidelines because it was the right thing to do for their animals and their consumers.

I think that the perspectives the witnesses shared at our hearing last year are important to discuss here today about H.R. 1549. I would like to take a few moments to talk about what we learned from the hearing in terms of what H.R. 1549 would do to the livestock industry.

As I understand, H.R. 1549 would remove seven classes of antibiotics from the market unless sponsors can demonstrate that they are safe and effective. Well, I can tell you our witnesses clearly outlined the rigorous approval process animal antibiotics must go through to gain approval already. All antibiotics used to keep animals healthy have passed the in-depth FDA process and have been shown to be safe and effective and have undergone review for their potential to cause increased antibiotic resistance.

H.R. 1549 would require antibiotic sponsors to prove again what has already been proven during the initial FDA approval. This FDA process is a stringent, science-based, regulatory review, and it takes years and takes millions of dollars. Requiring another step undermines the FDA's progress of reviewing the human health impacts of individual animal drugs based on science and risk assessment.

H.R. 1549 overlooks the legitimate veterinarian need to preserve the antibiotics used in food animals to ensure that healthy animals enter the food chain. There are few new antibiotics anticipated for approval by the FDA, so if H.R. 1549 is enacted and these products are removed from the marketplace, America's livestock producers will be left with few, if any, medicines to prevent and control animal disease. H.R. 1549 will result in more sick animals, and it is my fear and my concern that it will leave us with a potentially less safe food supply.

In the mid-1990s, the European Union made a decision to phase out the use of antibiotics as growth promoters. Denmark, which has been talked about, has a pork industry roughly equivalent to the size of the pork herd in my State of Iowa, which is the largest pork-producing State in our country. And they instituted a full voluntary plan in 1998 which became mandatory in 2000.

Many proponents of restricting the use of certain antibiotics as a model often point to this ban instituted in Denmark, citing the major drop in amount of antibiotics used in pork production in that country. Well, come on. When you ban the use of a product, it is self-evident that usage rates would drop.

Interestingly, what the proponents never seem to discuss are the other effects of the ban. I would like to call your attention to the testimony received in my subcommittee where these effects were discussed in detail. Some of our witnesses had even visited Denmark and even seen firsthand the downturn in swine health in that country. After the ban became fully implemented, Danish pork producers saw an immediate increase in post-weaning diarrhea and an increase in piglet mortality, which has had long-lasting effects on the Danish pig industry.

The increase in piglet deaths and the overall impact on animal wellbeing might be acceptable if it resulted in improvements to the public health, but such improvements have not materialized. And while overall use of antibiotics in Denmark declined, there has been a marked increase in the therapeutic use of antibiotics, those used to treat and control diseases. Today, the use of therapeutic antibiotics in Danish pigs now surpass what was used to prevent disease and promote growth prior to the ban and continues to rise each year.

As for cost, a 2009 Iowa State University study estimated that the effect of a ban on States similar to Denmark's would raise the cost of production by $6 per pig in the first year after such a prohibition. Ten years after the ban, the cumulative cost to U.S. pork production would exceed $1 billion.

A recent study by Dr. Scott Herd, professor of Iowa State University's College of Veterinary Medicine and former U.S. Department of Agriculture Deputy Under Secretary for Food Safety, demonstrated that when pigs have been sick during their life, those pigs will have a greater presence of food safety pathogens on their carcasses. This is a serious implication that must be considered when looking at the cost and benefits of antibiotic use in livestock.

In our discussions on antibiotic use in food animal production, we need to be clear what the issue really is. H.R. 1549 is confusing the problem of antibiotic resistance in general with a faulty proposition that blames human resistance issues on antibiotic use in animals. Most informed scientists in public health professions acknowledge that the problem of antibiotic resistance in humans is overwhelmingly an issue related to human drug use.

A 2006 report from the Institute of Food Technologists and International Scientific Studies said, quote, "Eliminating antibiotic drugs from food animal production may have little positive effect on the resistant bacteria that threaten human health." In fact, eliminating healthy antibiotics may be detrimental to public health.

As our witnesses outlined on my subcommittee, antibiotic-resistant bacteria develop from many factors, including human use of antibiotics and routine household use of disinfectants, such as antibacterial soap.

According to a paper published in 2001 in the Journal of the American Veterinary Medical Association, people and their pets, on

a per-pound basis, use 10 times the amount of antibiotics that are used in food animal production. More than 95 percent of the antibiotics used for animals are devoted to treating them for disease conditions, not as growth promoters, as many seem to claim.

Protecting human health and providing safe food are paramount concerns of America's livestock producers. That is why we test for antibiotic residue as part of our food safety programs. The FDA establishes withdrawal times or withholding periods, which are times after drug treatment when milk and eggs are not to be used for food and during which animals are not to be slaughtered.

Two-thirds of this bill has been enacted into law and should be allowed to work before removing products from the market. Provisions requiring more USDA research into the causes of and solutions to antibiotic resistance were passed as part of the farm bill in 2008.

The animal drug user fee amendments of 2000 require the FDA to collect antibiotic sales data from companies and make a summary of that data public. The provisions were designed to provide better information to researchers conducting risk assessments and should be allowed to yield information before products are removed from the market. Congress has already taken action, and we should see results from our action before we start removing antibiotics from the market.

As your witnesses today discuss a topic that is important to the livestock producers in not just my district in my home State but yours as well, I sincerely hope you consider what my subcommittee learned last Congress.

H.R. 1549 will have detrimental effects not only on our farmers who feed the world safe and wholesome meat and products, but also on public health.

Again, I want to thank you for allowing me the opportunity to testify today. I hope as a farmer and as a user of antibiotics I have offered you some insight into the livestock industry's perspective. In the United States, we are very blessed to have the safest, most plentiful, and the most affordable food supply in the world. As policymakers, we must take a hard look at how our decisions affect human health and our ability to feed ourselves and the world.

And just as a closing note, Dr. Borlaug, the Nobel Peace Prize winner and also the World Food Prize winner, tells us that the global population is growing at a rate of 90 million a year. You have to feed them with safe, affordable, plentiful food. That is a part of what we are all about.

Thank you for your considerations.

[The prepared statement of Mr. Boswell follows:]

PREPARED STATEMENT OF THE HON. LEONARD BOSWELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Chairwoman Slaughter, Ranking Member Drier and members of the Rules Committee, I would like to thank you for allowing me the opportunity to testify here today. I have spent most of my life involved in animal agriculture and have seen first-hand the responsible use of antibiotics.

I understand the issues that affect the livestock, dairy and poultry industries having spent most of my youth working in livestock production and today I still have a hand in managing a cow-calf operation on my farm in Lamoni, Iowa. Once I retired from 20 years in the Army I moved back to Iowa to begin farming. I sat down with my local veterinarian to discuss the use of antibiotics to treat sick animals and

prevent future illness. From my experience with producers and veterinarians, the thoughtful use of antibiotics is not the exception, it's the rule.

During the 110th Congress, it was my privilege to serve as Chairman of the Agriculture Subcommittee on Livestock, Dairy and Poultry. On September 25th of last year, we held a hearing to review the advances in animal health within the livestock industry. We were specifically looking at how antibiotics are used on America's livestock farms. Our witnesses included veterinarians from USDA's Animal Health and Plant Inspection Service and FDA's Center for Veterinary Medicine (CVM), producers, veterinary practitioners and academics from across the country. We believe that we heard from a good cross-section of the users of the animal health products, the doctors responsible for the use of antibiotics and the experts studying the resistance trends from use of antibiotics in animals.

As the Subcommittee members listened to the witnesses, it became very clear that America's livestock, dairy and poultry producers have a responsibility to safeguard animal health and public health. A responsibility they take very seriously. They are committed to using antibiotics responsibly and have developed responsible-use guidelines for each of their respective industries. They didn't develop these guidelines because Congress told them to do so; they developed the guidelines because it was the right thing to do for their animals and their consumers.

I think that the perspectives the witnesses shared at our hearing last year are important to the discussion here today about H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act of 2009. I would like to take a few moments to take what we learned from that hearing in terms of what H.R. 1549 would do to the livestock industry.

H.R. 1549 would remove seven classes of antibiotics from the market unless sponsors can demonstrate that they are safe and effective. Our witnesses clearly outlined the rigorous approval process that animal antibiotics must go through to gain approval already. All antibiotics used to keep animals healthy have passed the in-depth FDA process, and have been shown to be safe and effective and have undergone review for their potential to cause increased antibiotic resistance. H.R. 1549 would require antibiotic sponsors to prove again what has already been proven during their initial FDA approval. This FDA process is a stringent, science-based regulatory review takes years and millions of dollars. Requiring another step undermines the FDA's process of reviewing the human health impacts of individual animal drugs based on science and risk assessment.

Our witnesses also shared with us that not many antibiotics are currently available for use in livestock. H.R. 1549 overlooks the legitimate veterinary need to preserve these antibiotic classes for use in food animals to ensure that healthy animals enter the food chain. There are few new antibiotics anticipated for approval by FDA, so if H.R. 1549 is enacted and products are removed from the market place, America's livestock producers will be left with few, if any, medicines to prevent and control animal disease. H.R. 1549 will result in more sick animals and it is my fear that it will leave us with a potentially less safe food supply.

In the mid-1990's the European Union made a decision to phase out the use of antibiotics as growth promoters. Denmark, which had a pork industry roughly equivalent to the size of the pork herd in Iowa (which is the largest pork producing state in the country), instituted a full voluntary ban in 1998 which became mandatory in 2000. Many proponents of restricting the use of certain animal antibiotics as a model often point to this ban instituted in Denmark, citing a drop in total tons of antibiotics used in pork production in that country. When you ban the use of a product, it is self-evident that usage rates would drop. Citing this obvious consequence as a rationale for restrictions in other countries borders on the illogical. Interestingly, what the proponents never seem to discuss are the other effects of that ban. I would like to call your attention to the testimony received in my Subcommittee where these effects were discussed in detail. Some of our witnesses had even visited Denmark and seen first-hand the downturn in swine health in that country.

After the ban became fully implemented in 1999, Danish pork producers saw an immediate increase in post-weaning diarrhea and an increase in piglet mortality, which has had long lasting effects on the Danish pig industry. The increase in piglet deaths and the overall impact on animal well-being might be acceptable if it resulted in improvements to public health, but such improvements have not materialized. And while overall use of antibiotics in Denmark declined, there has been a marked increase in the therapeutic use of antibiotics—those used to treat and control diseases. Today, the use of therapeutic antibiotics in Danish pigs now surpasses what was used to prevent disease and promote growth prior to the ban in 1999 and continues to rise each year. I think the Danish pork industry can now attest to the validity of the age-old cliché "an ounce of prevention is worth a pound of cure!"

As for costs, a 2009 Iowa State University study estimated that the effect of a ban in the United States similar to Denmark's would raise the cost of production by $6 per pig in the first year after such a prohibition; 10 years after the ban, the cumulative cost to the U.S. pork industry would exceed $1 billion.

A recent study by Dr. Scott Hurd, associate professor at Iowa State University's College of Veterinary Medicine and former U.S. Department of Agriculture Deputy Under Secretary for Food Safety, demonstrated that when pigs have been sick during their life, those pigs will have a greater presence of food-safety pathogens on their carcasses. This is a serious implication that must be considered when looking at the costs and benefits of antibiotic use in livestock.

In all discussions on antibiotic use in food animal production, we need to be clear what the issue really is. H.R. 1549 is confusing the problem of antibiotic resistance in general with the faulty proposition that blames human resistance issues on antibiotic use in animals. Most informed scientists and public health professions acknowledge that the problem of antibiotic resistance in humans is overwhelmingly an issue related to human drug use.

A 2006 report from the Institute of Food Technologists, an international scientific society, said "eliminating antibiotic drugs from food animal production may have little positive effect on resistant bacteria that threaten human health." In fact, eliminating animal antibiotics may be detrimental to public health.

As our witnesses outlined for my subcommittee, antibiotic-resistant bacteria develop from many factors, including human use of antibiotics and routine household use of disinfectants such as antibacterial soap. According to a paper published in 2001 in the Journal of the American Veterinary Medical Association, people and their pets on a per-pound basis use 10 times the amount of antibiotics that are used in food animal production. More than 95 percent of the antibiotics used for animals are devoted to treating them for disease conditions, not as growth promoters as many claim.

Protecting human health and providing safe food are paramount concerns of America's livestock producers. That is why we test for antibiotics residue as part of our food safety programs. The FDA establishes withdrawal times or withholding periods which are times after drug treatment when milk and eggs are not to be used for food, and during which animals are not to be slaughtered.

If I may speak specifically to H.R. 1549, two-thirds of the bill has been enacted into law and should be allowed to work before removing products from market. Provisions requiring more USDA research into the causes of and solutions to antibiotic resistance were passed as part of the Farm Bill in 2008. The Animal Drug User Fee Amendments of 2008 require FDA to collect antibiotic sales data from companies and make a summary of that data public. The provisions were designed to provide better information to researchers conducting risk assessments and should be allowed to yield information before products are removed from the market. Congress has already taken action, and we should see the results from our action before we start removing antibiotics from the market.

Risk assessments are an important tool in approving antibiotics and ensuring that they are not harming public health. Voluntary risk assessments have been done by sponsors, and FDA is now requiring specific risk assessments for new and existing antibiotic products. Dr. Randy Singer, a veterinarian and epidemiologist working at the University of Minnesota, testified last September about a risk assessment in which he participated. His team assessed the risk of the agricultural use of the macrolide family of antibiotics poses to human health. The research hypothesis was that since macrolide-antibiotics are also used in human medicine, the use of macrolide antibiotics in animal agriculture could compromise the efficacy of these antibiotics in human medicine and potentially increase the number of macrolide-resistant bacterial infections in people. The team developed a risk assessment model following the format of FDA's guidance document #152. Dr. Singer and his team of researchers found that all macrolide antibiotic uses in animal agriculture in the U.S. posed a very low risk to human health. The highest risk was associated with macrolide-resistant Campylobacter infections acquired from poultry, but this risk was still estimated to be less than 1 in 10 million and would thus meet the standard of "reasonable certainty of no harm" employed by FDA–CVM.

Dr. Singer also shared with us that animal illness likely plays a critical role in reducing the chances of contamination during processing. He participated with a team that developed a mathematical model relating animal illness to human illness. In this model, there was a large increase in human illness associated with small increases in animal illness. This suggested to the group that agricultural management strategies that fail to employ the judicious use of antibiotics may have significant negative impacts on human health. While I accept that there are those who will always believe that antibiotics administered in feed at low doses over several

weeks raise hypothetical concerns about their potential to increase rates of resistance, in my opinion the evidence is undeniable that these applications improve animal health. Antibiotic uses in animals therefore have human health benefits. This goes back to our livestock producers' moral obligation to care for their animals and protect public health.

If policy decisions are going to be made regarding antibiotic use, we need to use the proper tool for making those decisions; risk assessments are the most appropriate tool, as Dr. Singer described to my subcommittee. Decisions made without considering the results of scientific risk assessments will result in unintended consequences, including increased animal death and disease and increased risks to public health as we saw in the Denmark example.

As your witnesses today discuss a topic that is important to the livestock producers in not just my district and home state but yours as well, I sincerely hope that you consider what my subcommittee learned last Congress. H.R. 1549 will have detrimental effects, not only on our farmers who feed the world safe and wholesome meat and meat products, but also on public health.

Again I would like to thank you for allowing me the opportunity to testify before you today. I hope as a farmer and user of antibiotics I have offered you some insight into the livestock industry's perspective. In the United States we are very blessed to have the safest, most plentiful, and most affordable food supply in the world. As policy makers we must take a hard look at how our decisions affect human health and our ability to feed ourselves and the world.

I'd be happy to answer any questions. Thank you.

The CHAIRWOMAN. Thank you very much.

Ms. SCHAKOWSKY. Madam Chairwoman, if I could correct my testimony. It was the food safety bill that I wanted to add, and there is language in there to look at this issue. And it could be in the overall health reform bill because that would be important.

The CHAIRWOMAN. I sure hope so.

Mr. Boswell, you and I have been good friends and I think the world of you, but I can't agree with you on this at all. The Denmark study that you mentioned has been refuted by the scientists who really understand this. And Dr. Mellon herself talked about this great data collection that the FDA is supposed to do. There wasn't a cent of money put in that bill for them to be able to do that.

Our first witness was a new person at the FDA who says this is one of the most serious issues, he is a pediatrician, and that there would be absolutely no question about giving children, say 3-year-old children in a day care center antibiotics every day so they don't get an earache.

We are finding it in the water. As a microbiologist, it has been really offensive to me, as I mentioned earlier, to watch what has happened to Staphylococcus aureus. And we have salmonella infections so badly we can't eat lettuce. The FDA—and I have made that clear earlier. Let me give you an example. I will just read this to you.

Cephalosporin, is like many drugs used for purposes other than those indicated on the label. Extra label use is legal unless the FDA prohibits it. And they did that in an order published June 3rd—I want you to pay attention to these dates. On July 3, 2008, in the Federal Registry, the FDA said that extra label of cephalosporin in food production animals presents a risk to human health and should be prohibited. Now, that was July. CDC said that they agreed and they supported the decision. Their letter came on November 7, 2008. On November 28, the FDA revoked the order, prohibiting the extra label use of cephalosporin in food animals, because they said they had received too many comments on

the order. That is how the FDA protects human beings in this country.

Are you concerned that the EU has banned the use of antibiotics in meat, and that that would be a great loss on the trade, agriculture trade?

Mr. BOSWELL. Well, I suppose it would. But the point I think we are trying to make and I think that is substantiated is that the use of therapeutic has gone up.

The CHAIRWOMAN. Well, therapeutic is fine. We don't want sick animals. It is the nontherapeutic and the preventative use of antibiotics mostly because animals are kept in some pretty awful conditions and the disease spreads so quickly among them and between them that it is—yes? Go ahead.

Mr. BOSWELL. You are a very strong lady, and I want you to understand that.

The CHAIRWOMAN. I am that. I know. I can't help it.

Mr. BOSWELL. I appreciate that and I have learned that over the last several years. And we have had some good discussions.

The CHAIRWOMAN. Yes, we have. Yes, we have.

Mr. BOSWELL. And I know you come from agriculture country, upstate New York, even though you sound like you come from Kentucky. I don't understand all this.

But the study by Ohio State University found that salmonella in conventional pig herds was 39 percent of those studied tested positive in comparison. But, you know, the Center for Disease Control in Atlanta, and we have the Animal Disease Control Center there. And we are taking this very seriously. I don't want anybody to have unhealthy food and nobody here does. We know that. And we are spending a lot and we are doing a lot to improve the health of animals.

One of the reasons I had the hearing last year was I knew, because I am out there among the producers. I make a point to do that from time to time. And that they are very serious about how they separate the animals, how they handle them, and how they go in and talk to the scientists and do the different things to make sure that they have the right atmosphere, certain air circulation, and all those things, and they make continuous adjustments and they want to do it right. Not one of us in production wants to produce a sick animal or something that would affect human beings.

The CHAIRWOMAN. Our major concern here is these seven antibiotics which are really so efficacious in human beings. We are really finding that so many of them are no longer useful in humans, which, as Ms. Schakowsky pointed out in her testimony, creates dreadful hospital stays and death. You can die from MRSA in 24 hours. Staph aureus didn't kill anybody, to my knowledge, back in the days when I was in school.

But in any case, that is our question. Are there any other questions of these witnesses? Ms. Matsui.

Ms. MATSUI. Thank you both for being here today. And, you know, I appreciate both of you being strong advocates for your positions because I think both of you have very valid positions. I am here because I think about the children. That is really what I—I have grandkids 2 and 5 years old. And I may not have thought

about it so much until I began to see little kids again and understand what is so important to them. And I also tell you, Mr. Boswell, that I am a daughter of a farmer, and I know the hard work it takes to produce the food that many of us take for granted.

Mr. BOSWELL. And I have grandchildren, too, and I am just as concerned for mine as you are.

Ms. MATSUI. I know you are. And I know, and I understand how hard farmers work in order to bring us the healthy food that we need.

And, Ms. Schakowsky, how do you see this legislation helping to improve children's lives in this country?

Ms. SCHAKOWSKY. I have four grandchildren myself, and I know that we all care about our grandchildren. But I think the nightmare scenario is that something that perhaps when we were young would have been a routine dose of penicillin or some other antibiotic suddenly is impotent, and now we are struggling to find exactly what it is that is going to prevent this from becoming even a life-threatening situation what started out as a bad knee scrape or something like that.

And so I think that while obviously we want to treat sick animals, the use of these antibiotics in farm animals do, I think, endanger our health, and there is evidence to say that. This is not speculation. We know the increase of morbidity because of antibiotic resistance.

Ms. MATSUI. In my home State in California, we have been buffeted in recent years by outbreaks of salmonella and E. coli, and our agriculture industry has suffered as a result, particularly the spinach and the tomato sectors. And I also know that FDA had to recall 96,000 pounds of Illinois beef in May because of concerns about E. coli.

How do you see Chairwoman Slaughter's legislation helping to eliminate these kind of harmful market disruptions?

Ms. SCHAKOWSKY. You know as a member of the Energy and Commerce Committee, over and over again we have—that was really the stimulus behind the food safety bill. We have had to confront families that have lost loved ones, people who have been very sick because of a foodborne illness. And we are concerned that the nontherapeutic use of antibiotics has been linked to the number of incidents of foodborne illness and that it needs to be addressed.

Ms. MATSUI. Mr. Boswell, I am not a vegetarian. I do like beef and pork.

Mr. BOSWELL. I know that. I had dinner with you one time.

Ms. MATSUI. I know. And so I really want to make sure, I do like this, my little kiddies like this, and so I want to ensure the economic stability of our Nation's farmers, too. And one of the concerns that was brought to us, that Chairwoman Slaughter brought, that Dr. Mellon brought forth, the trade factor, the factor that we may be disadvantaged because we are not moving ahead as the EU and probably countries like Korea and Thailand as far as setting up situations where they are not going to be using antibiotics. So, that they can actually say to us: We are not going to have your meat products at all because you don't have the standards that we necessarily must have in our country.

I feel certainly that that is something that we can't have happen, and I think it is something that we ought to be thinking about as far as an agricultural industry about some of those global problems that might disadvantage us.

Mr. BOSWELL. I think your point is very valid. And I can assure you that the different products, pork producers, beef producers, poultry, they are very conscious of that and they want to continue the science, they are going to be watching it very closely. They don't want to give up that market for that reason, either. And I don't think they will.

And I would just like to add this. Jan referred to the time when we were young. I can remember when people worried about us dying as humans from smallpox and mumps and all those different things, and we figured out that doesn't happen anymore. And we do the same thing with our animals. And we have regulations when you have got to go off of it and let's get it out of the system and so on. I think we are trying very hard to do that and do it right.

Now, that doesn't mean there is not room for improvement, but we are willing to do that, and in appreciation of everything you have said, but I feel the same way.

Ms. MATSUI. Thank you.

The CHAIRWOMAN. Ms. Pingree.

Ms. PINGREE. Thank you very much. Thank you for your testimony. I think we have already had some good follow-up questions. I will just reinforce one point that is important to me. Thank you very much, Mr. Boswell, for your testimony about the work that was done on your committee. And since everyone else is putting up their credentials, I just want you to know that my family, we are all Scandinavian immigrants to Iowa, and my uncle and cousins still own a family farm there. So we are still deeply involved in the agriculture industry, but I moved East and took up organic farming and kind of looked at it from a different perspective.

And I want to reinforce what Ms. Schakowsky said, that I feel like all of the testimony that we have heard has reinforced this idea that this is something that we can change, that we are bringing this on ourselves, that our industry will survive, that with better health practices and limited use of antibiotics, therapeutic use of antibiotics, our animals will do just fine. It has been my experience in farming generally that that is how things work, and that we could make this transition without causing these undue consequences, whether they are economic loss to our farmers because countries like Denmark are changing their practices, or the incredible cost of hospitalization and loss of life through unintended consequences with antibiotics.

And I will say my one grandmother was a Dane. And I don't think they are stupid, I think they know what they are doing. And I think the reduction in the use of antibiotics there has been significant. Everything that we heard in our testimony today did not say that they use equal amounts of therapeutic antibiotics. It said they increased the amount of therapeutic antibiotics. But that is a targeted use. It is easier to remove from the animal before you ship it to market or ship their milk or ship their product. It is very different than talking about blanket use of antibiotics in the feed, and

I think that is misuse of the data when people refer to it in that way.

Thank you both.

The CHAIRWOMAN. Mr. Polis.

Mr. POLIS. Thank you, Madam Chair.

There are no farmers in my family. I am not from Iowa. My family, since arriving from Eastern European shuttles around the year 1900, has been city dwellers and occasionally suburban dwellers. But we do eat meat, most of us. And so we have a concern about these issues as well.

Ms. SCHAKOWSKY. But we cook it do death. Right?

Mr. POLIS. Exactly.

Mr. BOSWELL. I hate to surprise you, but I do also cook it.

Mr. POLIS. The question is that you mentioned that you are worried that livestock producers will be left with few, if any, medicines to prevent and control animal disease. And I think there is a difference between the prevention and then the control or treatment of animal diseases. Specifically, you earlier mentioned as well in answer to one of your questions smallpox and mumps. We have a number of vaccinations, inoculations. We have these for cattle, we have these for animals. These are prevention. These are not antibiotics, they are vaccinations. Sometimes they are weakened agents of the infection itself. Sometimes they are alternatives. But we do not for human health use antibiotics which are specifically designed to kill bacteria. And frequently more than just the bacteria they target, they kill other friendly bacteria. We don't use the antibiotics in humans for prevention.

And so my question is, obviously in different kinds of animals—humans are an animal, cows are an animal. We are all in this. Why would we have a different health code with regard to the use of antibiotics, and why would we want to use them as a preventative agent in some species but not in another species?

Mr. BOSWELL. My answer to that is we have gone to science. We have gone to the research universities, and we have learned from them that this is the thing that would give us a healthier animal, healthier food, and healthier humans.

Mr. POLIS. I just want to be clear. So you do dispute, we had earlier expert testimony that indicated that it is a belief among at least the scientists who presented to us——

Mr. BOSWELL. You have experts here and experts there. Which expert are you going to put in charge of the situation? I think we have to be very careful about jumping out here and doing something that could be detrimental to our food supply.

Mr. POLIS. And your contention is that the use of antibiotics as a preventative treatment in animals has not contributed to antibiotic resistant bacteria in humans?

Mr. BOSWELL. That is what science tells me.

Mr. POLIS. Thank you.

The CHAIRWOMAN. Mr. Cardoza.

Mr. CARDOZA. Thank you, Madam Chair. I think the points that I was trying to make earlier have been made very well by Mr. Boswell, and these are very concerning issues. They are really legitimate, concerning issues, and we need to use the best science and complete science. There is reason—one of the things that people al-

ways forget is farmers are in the business to try at the end of the day to make a profit. They don't want to spend any more money on extra products that they don't have to. I have got to tell you that one of the most frugal folks I have ever met are farmers, and they don't like buying extra products. They do it for a reason. And one of the things that we don't have on this panel is any—on any of the panels today are farmers who are actually engaged in the production of these products, because they have significant challenges sometimes to try to make sure the bacteria content in milk is such and so, and they have a number of different challenges that they have to meet very strenuous regulatory food safety regulations that we have imposed on them.

And I will concur that there are differences between animal operations. Some of them are perfect and, frankly, some of them I would rather eat there than some of the other places I have eaten. Others are horrible, and those are the ones that we need to target and work on. And I think that is the kind of work that Mr. Boswell and I do on the Agriculture Committee.

We had a hearing earlier in my committee last year on the question of the peanuts and the salmonella in the peanuts. And I happened to be one of the individuals who got sick from those peanuts. And I tell you, I spent 2 days feeling pretty rotten laying on my couch, continuing to vote, but I could barely raise my head for a couple days other than to drag myself to vote. And it is a very serious concern. We take this very seriously.

The other thing I will tell you is that farmers are some of the folks that are the most concerned about this, because they don't want anything to affect their product and put a taint on their marketing ability. And I will still submit this: That American foods are as safe or safer than anyplace else in the world. Consistently we get testimony to that effect.

Now, Mr. Boswell put in his testimony that there is 10 times the consumption of antibiotics in humans and in pets as there are in farm animals.

Mr. BOSWELL. On a per pound basis.

Mr. CARDOZA. On a per pound basis. And I want to make sure that this is the same kind of pounds, because we were talking with the other gentleman about the quantity and the strength of those pesticides.

And the other thing I would like to point out is that in Denmark we have not seen a decrease in the resistant bacterias, as I am told, in humans even despite the ban.

So those two facts lead me to believe this: That we need to do more and significant research on this topic to find out what is really going on. Let's let truth in the science dictate the policy. And that is one thing that we have done on the Farm Bill. It is another what we have done in the other act—I always forget the acronym. Somebody help me here. ADSA. It is the animal act—that is right. And I think that we really need to get to the bottom of this and we need to make sure that we do everything we need to to make sure that food is safe and that we are not promoting these microbial organisms that are getting out of control.

So, Madam Chair, thank you again for doing the hearing and bringing this issue forward. And I would like to let Mr. Boswell answer.

Mr. BOSWELL. Well, Mr. Cardoza, I agree with you. You know, again, I think it is a fact that we have the safest, most plentiful, least expensive food in the world, and there is a reason for it. One is everybody in this room contributes to it. Everybody does, whether you live downtown New York or Los Angeles or wherever. We subsidize our farms to some degree. But we get something for it. That is big. You think about someplace in the world where you can't get enough to eat let alone it be healthy and safe. So it is a big thing.

We have to be very careful about it, and we are willing to do this. And right now pork producers are losing money. Cattle producers are losing money. Dairy farmers have been losing money for over a year. They are in a very, very ticklish situation. And so if we don't want to affect this plentiful, safe, affordable food supply, we have to think carefully.

I would pledge, Madam Chairman, to work with Mr. Cardoza, who is on your committee and on our Ag Committee, to continue to put effort in to go back to our commodity groups and keep pushing if we need to, but at least monitoring to make sure that they are doing what they set out to do to start with to be sure and keep our food supply safe.

The CHAIRWOMAN. My organic farmers are making money. I just throw that out there for public consumption.

Mr. POLIS. If you would yield for a moment on that, Madam Chair.

The CHAIRWOMAN. Yes, I will.

Mr. POLIS. I mentioned earlier that in my congressional district is the corporate headquarters of Horizon Dairy as well as Aurora Organic Dairy, which is a private label organic dairy. And it is clear by the success and amazing growth rates of these companies, they have grown high double digits growth in the last decade, that consumers really get this and are willing to—I count myself as one of them, by the way. Consumers are willing to pay a premium for milk in this case that is free of antibiotics.

So I think in this case, again, and as I think our next panel will also demonstrate, consumers are already a little bit ahead of where regulators are on this issue.

The CHAIRWOMAN. Thank you both so much for coming. We really appreciate it. Thank you for giving us your time.

Mr. CARDOZA. Madam Chair, may I insert my statement?

The CHAIRWOMAN. Without objection, of course. And the Chair will yield to Mr. Polis for an introduction.

[The prepared statement of Mr. Cardoza follows:]

PREPARED STATEMENT OF THE HON. DENNIS CARDOZA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Thank you, Madam Chairwoman, for holding this important hearing today.

As a Representative of a rural farming district, I know first-hand that antibiotics are critical to the health and safety of the livestock and dairy industries. They are also vitally important to *human* health because healthy animals, in turn, produce safe and healthy foods. Each livestock industry will be affected *significantly* by this legislation, and I think it is important to understand this impact on both the animals and their welfare, *AS WELL AS ON* human health and food safety.

My district in California's Central Valley is home to a significant portion of the milk production in this country. I personally know how producers treat their animals during the milk production process and how carefully that milk is screened before it is accepted into a processing plant. In fact, a sample from *every single tanker of milk* is tested before milk is unloaded to be processed at these facilities. These screen tests were evaluated and approved by the FDA. If a milk sample tests positive for animal medication residue, the entire tanker is rejected and the famer must pay for the entire load. This costs the farmer approximately $12,000 per tanker and acts as a strong financial incentive to ensure that no treated cows are milked. From 1996–2005, positive milk tank samples declined by 70%. And in 2007, less than 0.032% of all milk tanker samples tested positive for residues of animal medications. This proves that the program is effective at detecting and deterring animal medications in milk. In addition, it is extremely important that veterinarians have the tools to prevent and control infections such as mastitis and metritis. By controlling these painful infections, we keep dairy cows productive, and keep their milk wholesome, abundant and safe. If dairy producers are not able to use antibiotics to prevent these infections, the animal will suffer and even more antibiotics would be needed to treat the infections after they occur. In Europe, we've seen the push to ban antibiotics backfire. Animals in Europe now have an increase in animal disease, an increase in the use of therapeutic antibiotics to treat these diseases, and no improvement in human antibiotic resistance patterns. Recently published, peer-review articles document these impacts and warn us that political decisions can carry unintended consequences.

I urge my colleagues on this committee to look at this issue carefully and to fully weigh the implications of this kind of legislation. Too often, we neglect to consider the unintended consequences of our actions. The health and safety of our domestic food supply is too important to not consider all of the implications.

I once again thank the distinguished Chairwoman for holding this hearing today, and I yield back the balance of my time.

Mr. POLIS. Well, it is my great privilege here today to introduce Mr. Steve Ells, who founded the first Chipotle in my congressional district in 1993. And as a result of my residual Jewish heritage, I have an aversion to pork so I avoid pork myself. But the closest that I came to eating pork was after I first met Mr. Ells, must have been 6 or 7 years ago, and he told me about how they were purchasing pork from these amazing organic farms. I had to wait several years to get my fulfillment. It was about a year and a half or 2 years ago when they now announced that they are raising naturally raised chicken. I sent him a congratulatory e-mail when they made that announcement, and it has made a huge difference. And I continue to be a regular customer of Chipotle. He and Chipotle are changing the way the world thinks about and how it eats fast food.

Steve Ells is a classically trained chef, has received considerable praise for his vision and leadership with Chipotle. And in 2006, Chipotle had a very successful public offering and has been featured in the Wall Street Journal and a number of other publications. Mr. Ells holds a bachelor's degree in art history from the University of Colorado at Boulder in my district, and is a graduate of the Culinary Institute of America.

It truly is testimony to his vision as a business leader that he considers the fact that Chipotle has the highest food cost as a percentage of revenue of any restaurant company as an asset, as something that they brag about to show that they have this vision that food cost can in fact be an inverse metric in their business and an asset to show that they have a valuable consumer value proposition, really is great testimony to a tremendous vision which has left as its legacy a company with over 900 restaurants around the country, annual revenues in excess of $1.3 billion.

It truly is a great honor to introduce to our committee my good friend, Steve Ells.

The CHAIRWOMAN. It is so nice to have him here.

Please take your seat, Mr. Ells, and it is my great honor to introduce Mr. Bauccio. I am certainly happy to have you here. Mr. Bauccio began his career as a dishwasher in 1960, with Saga Corporation's Education Division. And in 1987, Bon Appetit Management Company was born for the first time. His dream of the company as committed to culinary expertise became a reality, and his customers noticed and they fueled quick growth for the small San Francisco-based company. He also was the President of the Stuart Anderson restaurant chain, had over 25 years of experience, and knew that institutional feeding was ready for something more.

In 1999, Fedele led his team once again to raise the bar for on-site food service making a commitment to socially responsible food sourcing. Today, Bon Appetit spends over $55 million annually on food from within a 150-mile radius of each cafe, using only sustainable seafood sources, turkey breasts, and chicken raised without antibiotics as a routine feed additive, features natural beef burgers, and leads the industry in using cage-free shell eggs.

In 2007, the company debuted its low carbon diet, the first program to make the connection between food and climate change. Bon Appetit is now a $500 million company with over 400 cafes in 28 States serving over 80 million meals a year. He is the recipient of the 1992 Restaurants and Institutions Ivy Award, and in 1998 was presented with the Nation's Restaurant News Golden Chain Award for Excellence. He was named the 2008 Innovator of the Year by Nation's Restaurant News, and received the prestigious Going Green Award by the Natural Resources Defense Council. That is really impressive.

He is a board member of the Compass Group of North America, serves on the board of Dynamic Payment Ventures in San Francisco, Chairman of the University of San Francisco Hospitality Management Board, and serves on the President's Advisory Council of the University of Portland.

We are so happy to have the two of you. And it is always a pleasure to eat in one of you restaurants. With that, I welcome you to the committee. And which one of you would like to begin? All right.

STATEMENT OF FEDELE BAUCCIO, PRESIDENT AND CEO, BON APPÉTIT MANAGEMENT COMPANY

Mr. BAUCCIO. Chairwoman Slaughter, honorable members of the Rules Committee, I am Fedele Bauccio, CEO of Bon Appétit Management Company, a national on-site restaurant company that, as you heard, serves 80 million meals each year at over 500 locations, and I think we are now in 32 states.

As a company, we are committed to two goals, culinary expertise and social responsibility. And in that vein, I appreciate the opportunity to be here today to voice my strong support for H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act.

It is imperative that we as a country discontinue the use of antibiotics for nontherapeutic purposes in animals. In addition to being harmful to the animals themselves, this common practice of using antibiotics as feed additives has led to dramatically increased anti-

biotic resistance in humans and become a serious public health problem. I feel so strongly about this issue that I have banned most meat that has been raised in this manner to be served in my restaurants. And I would ban it entirely, but there isn't enough supply for us to be able to make that commitment yet.

Our concern about this issue goes back 7 years. In 2002, I learned that an estimated 70 percent of antibiotics used in this country are fed to farm animals that are not sick in order to promote growth or prophylactically treat diseases caused by questionable animal husbandry practices.

As I learned more and realized how widespread these practices are in the meat production industry, Bon Appétit formed a partnership with Environmental Defense Fund to look at how we could take the lead and discourage antibiotic use in meat and poultry production. Our partnership resulted in the creation of the farthest reaching corporate policy on antibiotics used to date. We only buy chicken raised without nontherapeutic routine use of human antibiotics as feed additives. In 2005, we extended this policy to turkey breast. We took this policy another step further, and since March 2007 we only serve hamburgers from natural beef with no trim.

While there is no strict legal definition of the word "natural," our suppliers commit to using no antibiotics, no growth hormones, no animal byproducts in feed, and treating their animals humanely.

Our biggest challenge in implementing our antibiotics policy has always been sourcing the products. We have recruited both major poultry producers as well as small local producers as suppliers. We only purchase food from those who provide written confirmation of their compliance. But there are not enough suppliers to meet our standards everywhere. We use a purchasing preference to acquire suppliers in many markets, but we don't have the concentration of business in all our markets across the United States to buy enough chicken or turkey or beef to tip the scales as we have in some locations, and we can't find a national pork supplier who will commit to taking care of us across the whole United States. Many producers are afraid to change even with an economic incentive. They need a push from this bill, and that could be the leverage of change we need.

From 2006 to 2008, I served as a member of the Pew Commission on Industrial Farm Animal Production. I learned from physicians, poultry producers, farmers, and representatives on the committee as well as those who testified before us. I came away from that experience enriched and much better educated about animal husbandry. One of the many things I concluded is that there is absolutely no good reason and certainly no good moral reason for feeding medically important human antibiotics to animals that we eat. No reason at all. None.

The bottom line is Americans want safe food. Food is nourishment. It shouldn't be something that does us harm. Antibiotic resistance is harmful. These drugs are meant to treat humans and animals when we are really sick and need them, not as a feed additive so they won't be effective when humans need them.

Let's get our priorities straight. The time to ban antibiotics as a feed additive is long overdue. I strongly support this measure. Thank you.

[The prepared statement of Mr. Bauccio follows:]

PREPARED STATEMENT OF FEDELE BAUCCIO, PRESIDENT AND CEO, BON APPÉTIT MANAGEMENT COMPANY

Chairwoman Slaughter, honorable members of the Rules Committee, I am Fedele Bauccio, CEO of Bon Appétit Management Company, a national onsite restaurant company that serves 80 million meals each year at 400 cafés in 29 states. As a company we are committed to two goals, culinary expertise and social responsibility, and in that vein I appreciate the opportunity to be here today to voice my strong support for H.R. 1549, The Preservation of Antibiotics for Medical Treatment Act.

It is imperative that we, as a country, discontinue the use of antibiotics for nontherapeutic purposes in animals. In addition to being harmful to the animals themselves, this common practice of using antibiotics as feed additives has led to dramatically increased antibiotic resistance in humans and has become a serious public health problem. I feel so strongly about this issue that I have banned most meat that has been raised in this manner to be served in my restaurants, and I'd ban it entirely but there isn't enough supply for us to be able to make that commitment yet.

Our concern about this issue goes back seven years. In 2002, I learned that an estimated 70 percent of the antibiotics used in this country are fed to farm animals that are not sick in order to promote growth or prophylactically treat diseases caused by questionable animal husbandry practices. As I learned more and realized how widespread these practices are in the meat production industry, Bon Appétit formed a partnership with Environmental Defense Fund to look at how we could take the lead and discourage antibiotic use in meat and poultry production. Our partnership resulted in the creation of the farthest-reaching corporate policy on antibiotics use to date: Bon Appétit only buys chicken raised without the "nontherapeutic" routine use of human antibiotics as feed additives. In 2005, we extended this policy to turkey breast. We took this policy another step further and, since March 2007, we only serve hamburgers made from natural beef with no trim. While there is no strict legal definition of "natural," our suppliers commit to using no antibiotics, no added growth hormones, no animal by products in feed and treating the animals humanely.

Our biggest challenge in implementing our antibiotics policy has always been sourcing the products. We have recruited both major poultry producers as well as small, local producers as suppliers. We only purchase food from those who provided written confirmation of their compliance. But there are not enough suppliers who meet our standards everywhere. We use a purchasing preference to induce suppliers in many markets, but we don't have the concentration of business in all markets to buy enough chicken or turkey or beef in some states to tip the scales as we have in other locations, and we can't find a national pork producer who will commit at all. Many producers are afraid to change, even with an economic incentive. They need a push. H.R. 1549 could be that lever of change we need.

From 2006 to 2008, I served as a member of the Pew Commission on Industrial Farm Animal Production. I learned from physicians, poultry producers, farmers and industry representatives on the committee, as well as those who testified before us. I came away from that experience enriched and much better educated about animal husbandry. One of the many things I concluded is that there is absolutely no good reason, and certainly no good moral reason, for feeding medically important human antibiotics to animals that we eat. None.

The bottom line is, Americans want safe food. Food is nourishment. It shouldn't be something that does us harm. Antibiotic resistance is harmful. These drugs were meant to treat humans and animals when we're really sick and need them, not as a feed additive for animals so they won't be effective when humans need them. Let's get our priorities straight. The time to ban antibiotics as a feed additive is long overdue. I strongly support this measure. Thank you.

The CHAIRWOMAN. Thank you very much.

Mr. Ells.

STATEMENT OF STEVE ELLS, CHAIRMAN AND CEO, CHIPOTLE MEXICAN GRILL

Mr. ELLS. Thank you. Thank you, Madam Chair, and thanks to the members of the Rules Committee for allowing me to speak to this very important act which we strongly, strongly support. I am

Steve Ells, and I am the founder, Chairman, and co-CEO of Chipotle.

A decade ago, we began a quest for more sustainably raised ingredients and to make those ingredients available so that everybody who wanted to could have access to these sustainably raised foods. Traditionally, these sustainably raised foods were available at high-end grocers and very expensive, fancy restaurants in bigger cities, but we wanted to make these kinds of foods available so everybody could eat better.

Since I started the first Chipotle 16 years ago, actually 16 years ago this day, I wanted to show that just because Chipotle is fast and convenient doesn't mean it has to be a traditional or typical fast food experience with all the trappings of the fast food restaurant. We wanted to cook fresh food, food that was prepared in front of the customer in an open kitchen so there was complete transparency, and we wanted to serve it in an interactive format so people could get exactly what they want not only for taste but for nutrition.

Well, a decade ago I realized that fresh food is not enough anymore; that you really need to know where your food comes from and how it was raised and the effect on the environment and the effect on animal welfare and the effect on ultimately the health of the person eating the food. And so there are a lot of ramifications, and fresh didn't cut it.

I came to this conclusion because I had read an article about the way Niman Ranch was raising pigs up in Iowa, and so being curious, I went up and visited some of the farms. And I asked the folks, the farmers, these independent family farmers, what was so special about the way they were raising the pigs. It looked great to me, they were either raising them out on open pasture or in deeply bedded barns depending on the season, and they were feeding them a protocol that is similar, without antibiotics, an all vegetarian feed, and definitely in a humane way with room to roam around. And they informed me that the vast majority of pork raised in the United States, some 98 plus percent is raised in factories, is raised in confinement operations. And so being very curious about this, I went to see a lot of these factory farms. And at that moment, I knew that I didn't want the kind of exploitation that I saw to be part of the reason Chipotle was successful.

So pork was the first thing to come under what we call Food with Integrity or our Naturally Raised Program, and we started using only pork that met the very strict protocols, again, without antibiotics and the other things that I mentioned.

Since that time, since we were very successful in introducing the naturally raised pork, we also introduced over the years naturally raised chicken, and today 100 percent of our chicken is raised without antibiotics. And we also have introduced naturally raised beef. And because of supply issues we are only able to supply about 60 percent of our needs with naturally raised, but we are working very diligently with farmers and ranchers to increase that supply also.

Chipotle is unique because of the economic model. We are successful because we have found a way to serve more expensive and sustainably raised ingredients, but in a way that really does re-

main accessible and affordable for consumers. At the same time, though, we are able to produce attractive financial results to our shareholders. And it is a really difficult balance to strike. Most restaurant companies can only remain affordable and produce attractive returns by lowering their food costs, and this downward pressure on food costs has resulted in the industry driving down costs to the detriment of animal welfare and the environment and the overuse of antibiotics especially.

So our journey to find better ingredients from more sustainable sources has been and remains difficult. There is no question about it, and progress has been slow at times and costly throughout. But that said, we are proud that we have been able to remain successful while serving food from these better sources rather than supporting a system that is often based on exploitation.

We are still relatively a small piece of the puzzle, though, and a very small piece of the Nation's overall food supply. And so while our quest might be made easier if other food companies chose to follow similar paths and suppliers changed their practices accordingly, we know very well the issues and complexities that have kept them from doing so.

Passing this Preservation of Antibiotics for Medical Treatment Act is an important step in driving the kind of change that we have chosen to work toward over the last decade but that too many others have ignored.

Madam Chair and members of this committee, ours is a company that has a long track record of remaining out of discussions involving politics and matters of public policy, but this is a cause we deeply believe in. So on behalf of Chipotle, our 900 restaurants, our 25,000 employees, and our 2.5 million weekly customers, we thank you for introducing the Preservation of Antibiotics for Medical Treatment Act, and hope that it is given the consideration it deserves. Thank you all very much.

[The prepared statement of Mr. Ells follows:]

PREPARED STATEMENT OF STEVE ELLS, CHAIRMAN AND CEO, CHIPOTLE MEXICAN GRILL

Good afternoon Madame Chair and members of the Rules Committee.

My name is Steve Ells and I am the founder, chairman and co-CEO of Chipotle Mexican Grill. I appreciate your giving me the opportunity to appear here today to speak to what I believe is a very important issue.

When I founded Chipotle 16 years ago in 1993, I had what was a novel idea at the time. I wanted to show that food that was served fast didn't have to be a typical fast food experience. All of the food we served was prepared in the restaurant using only fresh, high-quality ingredients. That restaurant had an open kitchen so our customers could watch as their food was cooked and their orders were prepared. It was all very transparent. There was nothing to hide.

We take the same approach today, even though we now have some 900 restaurants around the country and annual revenue in excess of $1.3 billion. As we have grown, our vision has evolved. Now, we are changing the way the world thinks about and eats fast food. We are doing this by serving food made with ingredients from more sustainable sources. The cornerstone of this effort is a vision we call "Food with Integrity" and it is shaping not only the kind of food we serve, but the way we run our company.

This vision is not a response to recent consumer interest in "green" products, it is something we have been working toward for a decade now; well before "green" was the buzzword it is today. Nor was it rooted in any great epiphany that, ten years from now, consumers would want more natural, organic and local food. And it was not the result of scientific study about possible harm caused by using antibiotics in the food system, or the environmental impacts of large scale industrial ag-

riculture. Our vision has always been based simply on doing what we thought was right.

The decisions we are making to support more sustainable agriculture have presented us with many challenges—and wouldn't be possible at all for most companies of similar size. And they come at a cost. The food we buy costs us more than it would to source food from large industrial processors. In fact, Chipotle now has the highest food cost (as a percentage of revenue) of any restaurant company, regardless of category.

As a publicly traded company, this is very significant. But serving food from more sustainable sources is so important to us, that we have built our business model in a way that lets us invest more in better food. We've had to find efficiencies in all other areas of our business so we can afford to serve this better food at prices that remain reasonable for our customers.

Through all of this, we have learned that many of our customers don't really know where their food comes from and how it is raised. And they don't want to be burdened with this information when they sit down in a restaurant to enjoy a meal with friends or family. For many people, paying the higher price of sustainably raised food simply isn't possible. So it is our responsibility to understand and care about where our food comes from, and find ways to keep it affordable and accessible so everyone can eat better.

Our quest for ingredients from more sustainable sources began when I was reworking the recipe for our pork carnitas. At the time, the pork we were using came from large, industrial suppliers. And I was not entirely aware of what this meant, or just how significant the environmental, economic, and social issues associated with this kind of animal production were—not to mention the horrific animal welfare standards that are involved.

My explorations led me to the farms of Niman Ranch, a network of about 50 individual family owned farms that were raising pigs in a traditional way; on open pastures or in deeply bedded barns, without the use of antibiotics or added hormones or drugs that behave like hormones, and fed a pure vegetarian diet with no animal byproducts. I tested new recipes using Niman pork and found that pigs raised this way produced better tasting pork, marbled with more back fat to protect the animals from the elements.

My research also took me to confinement hog operations, where some 60 million pigs are raised each year and spend their entire lives in large, barracks-like metal buildings. They never experience the sensation of the sun on their backs, or breathe fresh outdoor air. They spend their lives on hard, slatted flooring, forced to sleep where they urinate and defecate. Their waste is pushed down to lagoons where it festers just a few feet below them. They never have the opportunity to roam or root on open pastures or in deeply bedded barns as is their nature. Some five million breeding sows spend much of their lives confined to "gestation crates" or "sow stalls" that are so small they can't even turn around.

The crowding and contamination associated with this artificial living environment fosters disease, especially respiratory illnesses, so the pigs are fed some 10 million pounds of antibiotics, according to estimates from the Union of Concerned Scientists—an amount that is three times greater than all antibiotics used to treat human illness.

Upon seeing this stark comparison for myself, I quickly decided that I did not want Chipotle's success to be tied to this kind of exploitation. And that gave rise to my epiphany: Serving food that is merely fresh is not enough anymore. To serve the best-tasting food, you need to understand how animals are raised and how vegetables are grown, as those variables directly influence the taste of the food. They also have significant bearing on a number of other important issues—animal welfare, the environment, and the people who raise the animals and grow the produce.

As a result, we began serving pork from Niman Ranch in all of our restaurants (about 50 at the time) in 2000. But pork from pigs raised this way costs more, so we had to raise the price of a carnitas burrito or order of tacos by a dollar (from $4.50 to $5.50). What was the cheapest item on our menu became the most expensive. So we produced communications pieces for our restaurants explaining this change, and the reasons for it, and began educating our customers about these issues; issues that were, and still are, new to many of them.

Over the years, this decision has had a significant and positive impact on the farms of Niman Ranch, which had about 50 family farms participating in their hog program at the time. Today, they have more than 600, in part because of Chipotle's commitment to serving pork from pigs that are raised this way. In all, our efforts in this area are helping to create and sustain opportunities for thousands of family owned farms that have shunned the use of antibiotics in favor of better animal husbandry to ensure the health of their animals.

This move also transformed the way we run our business, giving rise to the vision we call Food with Integrity. It set us on a journey to examine each of the ingredients we use to make our food, and how we could get them from more sustainable sources. We have made considerable progress over the last decade.

Today, we serve more naturally raised meat—coming from animals that are raised in a humane way, never given antibiotics or added hormones, and fed a pure vegetarian diet with no animal byproducts—than any other restaurant company in the world: More than 60 million pounds this year alone. This includes 100 percent of the pork and chicken we serve, and more than 60 percent of all of our beef.

Our commitment to sourcing better ingredients from more sustainable and healthful sources extends beyond meat. Today, a growing percentage of the beans we serve (currently 35 percent) is organically grown. We are the only national restaurant company with a significant commitment to locally grown produce, serving at least 35 percent of at least one produce item from local farms in each of our restaurants when it is seasonally available. And we were the first national restaurant company to commit to serving dairy (cheese and sour cream in our case) made with milk from cows that are never treated with the synthetic hormone rBGH.

Chipotle is a unique success story in that we have found a way to serve more expensive, sustainably raised ingredients, but in a way that remains affordable to the average customer. At the same time, we are able to produce attractive financial results for our shareholders. This is a difficult balance to strike. Most restaurant companies can only remain affordable and produce attractive returns by lowering food costs. This downward pressure on food costs has resulted in the industry driving down costs to the detriment of animal welfare, the environment, and the overuse of antibiotics.

Our journey to find better ingredients, from more sustainable sources has been and remains difficult, and progress has been slow at times, and costly throughout. That said, we are proud that we have been able to remain successful while serving food from these better sources rather than supporting a system that is often exploitative. But we are still a relatively small piece of the puzzle that makes up the nation's food supply.

While our quest might be made easier if other food companies chose to follow similar paths and suppliers changed their practices accordingly, we know very well the issues and complexities that have kept them from doing so. Passing the "Preserving Antibiotics for Medical Treatment Act" is an important step in driving the kind of change we have chosen to work toward for the last decade, but that too many others have ignored.

Madame Chair and members of the committee, ours is company that has a long track record of remaining out of discussions involving politics and matters of public policy, but this is a cause we deeply believe in. On behalf of Chipotle, our 900 restaurants, our 25,000 employees, and our 2.5 million weekly customers, we thank you for introducing the Preservation of Antibiotics for Medical Treatment Act and hope it is given the consideration it deserves.

Thank you again for allowing me to speak with you today.

The CHAIRWOMAN. I am so grateful to both of you. I am old enough to remember when a pork chop really tasted good. I feel sorry for people who only have been able to eat factory raised meat, and really appreciate so much that there is someplace that we can go and take our grandchildren and know that what they are having is fresh and good. There is simply no substitute for it.

The tragedy of the overuse and now the resistance of antibiotics is one of the most ridiculous things that we have ever done in this country. People who can recall after the Second World War remember that it was really antibiotics at that point that saved our troops and the great experiment. I was getting my master's degree in Kentucky at the time and remember that antibiotics were used—nobody really understood what they were about, and they were putting penicillin in toothpaste at the time and several people were dying of anaphylactic shock. So that was what I had done my master's thesis on.

I can't believe that after that miraculous—that the discovery of antibiotics, which really made the biggest difference in the health of people in the world, could have been so misused that it was just

an everyday occurrence to just throw it to the chickens in the feed. It makes absolutely no sense. I don't think anybody else in the country would have done it.

And as a scientist, I can tell you the thing I love the most about science is it is true and it is accurate. The notion that science has several angles to it and you pick your scientist is abhorrent to me. We have really got to try, and I believe we can. I am so pleased to hear, and you were here as well, the young man from FDA. So I think that there is some hope there that we can have some change and that science once again will be important.

I have to tell you that we had to pass legislation in this Congress to allow women to be used as health subjects for research projects because they were not used and that we had to write legislation to allow scientists to be able to present at NIH what work they have been doing on it. You can see how far we have come, at the same time though how far we have fallen particularly with the use of antibiotics. It makes absolutely no sense.

And I think that the industry's concern, I should hope about trade policy more than any other thing that we might be able to talk about, is so important. But the fact that both of you are so successful should say to everybody in the country that it is important that we have a supply of that kind of food for your restaurants, and that more and more gives us the assurance that when we go in that we are not eating that residue.

We should never in this world have had salmonella infections from spinach. There is no reason in the world for that except that the FDA I think was asleep at the switch. And the more abhorrent thing to me is feeding the carcasses of dead animals to animals. The thought is so abhorrent to me. And, you know, that thought was really one of the reasons that we begged the FDA to really pay more attention because it had a lot to do, I think, with mad cow disease. At least that is what we think.

Thank you so much. I can't thank you enough. We want to tell the whole world where to go to have lunch.

Ms. Pingree.

Ms. PINGREE. Thank you. Thank you again to the Chair for holding these hearings and for using your years of expertise really to inform all of us about how long we could have been fixing this problem and we didn't. And thank you to both of you for your fascinating testimony, for taking the risks in your own business to do the right thing and by doing so being a good example for everyone in business who uses the excuse, well, I couldn't possibly make money if I did that. And both of you have shown not only are you keeping your customers healthier and happier, you have proven that you can also be successful in business as well.

I just would recount what we have said many times, this seems like a problem that should be simple to solve. Economically, scientifically, we have kind of heard it said over and over again that we would be better off if we reduced the use of antibiotics. And it is heartening to hear both of you say that you would buy more if you could. And I think all of us have said in one way or another it is the organic farmers in our districts who are doing well. We heard our colleague from the Ag Committee talk about how many farmers aren't doing well in this particular economy. So it just is

hard to understand what is standing in the way of good science, good economy, and helping our farmers to be more successful and our consumers to be happier and our constituents to stay healthier.

So hopefully your businesses will continue to expand and grow, and we will find ways to create incentives for more businesses to provide the healthy products that you need. Thank you very much.

The CHAIRWOMAN. Mr. Polis.

Mr. POLIS. You know, I wish that Mr. Boswell was still here because I think that to a certain extent the concerns of some of the producing districts of my colleague, Mr. Cardoza as well, and perhaps to a lesser extent some of your districts might produce some of this but mine doesn't in any major economic way, is that this would somehow hurt their ability to make money. But we find, quite to the contrary, that those of us who represent—and I represent a consuming district—my consumers would be thrilled to pay a few pennies more for their food knowing that it comes—and they voted with their dollars already, and that is what has led to the tremendous success of your businesses.

We have lagged behind on the public health and government regulation front, well behind these pioneers in the private sector which have already championed these practices, and proven beyond a doubt that not only is it good for consumers and public health, it is good for producers as well. And I think that that is the message that we need to drive home with our colleagues, the gentleman from Iowa and the gentleman from California, and others, who might be worried about this impact with producers to instead seize the opportunity.

My question for Mr. Ells is in regard to one of your statements. You mentioned the downward pressure on food costs has resulted in the detriment of animal welfare, the environment, and the overuse of antibiotics. I would like to add to that something that my colleague, our Chairwoman Ms. Slaughter, said, that it also detracts from the taste of the product itself, the taste and nutritional value of the product itself.

If you could comment about the outcome of poor animal welfare, the crowding, poor muscular development, whatever it is. But you as a culinary chef, et cetera, can give personal testimony to the taste profile and the difference between animals that are raised in a healthy way and ones that are raised with antibiotics and hormones.

Mr. ELLS. Sure. Absolutely. It is the reason that I went up to Iowa in the first place, to find better tasting pork. And sometimes when I talk about our mission I forget to mention that, of course we are a restaurant first, and we have to provide great tasting food in order to have a great business. And so that is something that we absolutely do. And so investing in better quality food results in better taste, which results in more visits by customers and so on.

But additionally I would like to comment about this notion of this food costing more because—and I am not a scientist, but I have heard the argument that it doesn't really cost more; that perhaps that confinement-raised pork chop might be a few cents less per pound, but you certainly make that up in health issues and environmental degradation and the loss of the independent family farmer and that effect on the loss of our some of our rural commu-

nities. And so the real cost of that cheap pork chop is something very great indeed.

Mr. POLIS. Thank you. And I think the economic concept you are referring to is externalities. And I raised this in my question in the original testimony with the first doctor who testified with regard to the cost of treating people who have contracted antibiotic resistant bacteria. I would also contradict again the good gentleman from Iowa that I believe the bulk of evidence, scientific consensus, does show that at least a large and significant part of antibiotic resistant bacteria that affects humans does stem from overuse of antibiotics in animals.

Given that, all of those costs associated with treating people who encounter antibiotic resistant bacteria—and, by the way, animals that encounter antibiotic resistant bacteria is not accounted for in simply the simple cost equation that many of the producers are facing. If we had an accounting for those real costs as part of the production formula, I think that producers by and large would determine that it made economic sense to only use antibiotics for treatment rather than for prevention. And I think that this bill furthers that end, and that is why I am proud to be a cosponsor and also applaud Chairwoman Slaughter for holding this important hearing today.

And I yield back.

The CHAIRWOMAN. Thank you all so much. And I want to thank our panel of scientists who stayed with us all afternoon. Thank you for your help.

I have got a little housekeeping we have to do before we can adjourn.

I ask unanimous consent of my panel that the record be kept open 7 days for the submission of written testimony and extraneous materials. And I also ask unanimous consent that the record be kept open for 7 days for the submission of written questions. Without objection.

I ask unanimous consent that the following be inserted into the record: The written testimony of all of our witnesses, along with their CVs and Truth in Testimony forms where applicable; the letter from the Honorable Leonard Boswell to Chairwoman Slaughter dated July 8, 2009; statement by Bill Niman and Nicolette Hahn Niman; article by Peter Collignon, et al., entitled "World Health Organization Ranking of Antimicrobials According to Their Importance in Human Medicine: A Critical Step for Developing Risk Management Strategies for the Use of Antimicrobials in Food Production Animals"; letters from Dr. Anne A. Gershon, M.D., with Infectious Diseases Society of America to Chairwoman Slaughter, dated July 10, 2009; testimony of Dr. Frank Moller Aarestrup and Dr. Henrik Wegener of the National Food Institute, Technical University of Denmark; transcript from the Subcommittee on Livestock, Dairy, and Poultry, Committee on Agriculture hearing to review the advances of animal health within the livestock industry, Thursday, September 25, 2008; and the Keep Antibiotics Working Fact Sheet and letter to Dr. Joshua Sharfstein, MD, Deputy Commissioner of FDA from Mr. Richard R. Wood, Chair of Keep Antibiotics Working Steering Committee.

Thanks to you all. Thanks very much to you. The Rules Committee is now adjourned.

[Whereupon, at 5:30 p.m., the committee was adjourned.]

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

CURRICULUM VITAE AND TRUTH IN TESTIMONY FORMS FOR WITNESSES TESTIFYING BEFORE THE COMMITTEE (WHERE APPLICABLE)

JOSHUA M. SHARFSTEIN, M.D.

Dr. Joshua M. Sharfstein was appointed by President Obama to be the FDA Principal Deputy Commissioner, Food and Drugs, in March, 2009.

From December 2005 through March 2009, Dr. Sharfstein was the Commissioner of Health for the City of Baltimore, Maryland. In this position, he led efforts to expand literacy efforts in pediatric primary care, facilitate the transition to Medicare Part D for disabled adults, engage college students in public health activities, increase influenza vaccination of healthcare workers, and expand access to effective treatment for opioid addiction. Under his leadership, the Baltimore Health Department and its affiliated agencies have won multiple national awards for innovative programs, and in 2008, Dr. Sharfstein was named Public Official of the Year by Governing Magazine.

From July 2001 to December 2005, Dr. Sharfstein served as minority professional staff of the Government Reform Committee of the U.S. House of Representatives for Congressman Henry A. Waxman. Dr. Sharfstein is a 1991 graduate of Harvard College, a 1996 graduate of Harvard Medical School, a 1999 graduate of the combined residency program in pediatrics at Boston Children's Hospital and Boston Medical Center, and a 2001 graduate of the fellowship in general pediatrics at the Boston University School of Medicine.

RESUME

MARGARET G. MELLON
Union of Concerned Scientists
1825 K Street, NW, Suite 800
Washington, DC 20006
(202) 223-6133

EXPERIENCE

September 1993-Present

Director
Food and Environment Program
Union of Concerned Scientists

Directs program that promotes sustainable agriculture by evaluating the role of agricultural biotechnology and the use of antibiotics in animal agriculture.

April 1987-September 1993

Program Director
National Wildlife Federation

Directed the NWF's Biotechnology Policy Center established in 1987 to evaluate biotechnology from an environmental perspective. The Center staff commented on proposed rules, testified before Congress, and spoke frequently on biotechnology issues.

Summers 1988-Present

Visiting Professor
Vermont Law School

Teaches a popular summer course in "Biotechnology: Law and Ethics" at the Vermont Law School in South Royalton, Vermont, and has also lectured at the School of Law of the University of Virginia and the University of Maryland Law School.

February 1985-April 1987

Program Director
Environmental Law Institute

Directed and coordinated the Toxic Substances Program of the Institute, including its research and public education activities. The program conducted research on innovative regulation of toxic substances with an emphasis on the interaction between state and federal programs.

Margaret G. Mellon
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1980 Summer and 1981-1984	Associate Beveridge & Diamond, P.C. Practiced in the areas of environmental law and international trade. Projects included preparation of rebuttal comments on EPA's proposed airborne carcinogen policy; work on major environmental litigation involving the Westway highway project in New York City; and work in an anti-dumping action covering sodium nitrate from Chile.
1976-1978	Research Fellow University of Virginia, School of Medicine National Institutes of Health Postdoctoral Research Fellow, School of Medicine, Department of Microbiology, University of Virginia.
1967-1970	Instructor Purdue University Taught Introductory Biology for majors and pre-meds and Social Implications of Biology for non-majors.

EDUCATION

B.S., Biology	1967 Purdue University
M.S., Biology	1969 Purdue University
Ph.D., Biology	1976 University of Virginia School of Science
J.D.	1981 University of Virginia School of Law

HONORS

Andrew Fleming Award for Outstanding Graduate Research in Biology, University of Virginia (1976).
National Resources Council of America Award of Achievement of Excellence in Publications (1989).
Distinguished Alumni Award, Purdue University School of Science (1993).
Fellow of the American Association for the Advancement of Science (1994).

PROFESSIONAL AFFILIATIONS

Bar of the District of Columbia
American Association for the Advancement of Science

Margaret G. Mellon
(page three)

APPOINTMENTS United States Department of Agriculture's Advisory Committee on Agricultural Biotechnology and the 21st Century (3 terms)

PUBLICATIONS

Legal and Policy

Mellon, M. "A View from the Advocacy Community." In David, Kenneth, and Paul B. Thompson, eds. *What Can Nanotechnology Learn From Biotechnology?: Social and Ethical Lessons for Nanoscience from the Debate over Agrifood Biotechnology and GMOs*. Elsevier, Inc.: 2008.

Mellon, M. and J. Rissler, *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply,* Union of Concerned Scientists (2004).

Mellon, M., C. Benbrook, and K. Lutz Benbrook, *Hogging It! Estimates of Antimicrobial Abuse in Livestock,* Union of Concerned Scientists (2001).

Mellon, M. and J. Rissler, *Now or Never: Serious New Plans to Save a Natural Pest Control*, Union of Concerned Scientists (1998).

Rissler, J. and M. Mellon, *The Ecological Risks of Engineered Crops,* The MIT Press (1996).

Rissler, J. and M. Mellon, *Perils Amidst The Promise: Ecological Risks of Transgenic Plants in a Global Market*, Union of Concerned Scientists (1993).

Mellon, M., The Perils of Genetically Engineered Herbicide Resistance, *Biology, The Web of Life,* D. Chiras, ed. (1993).

Mellon, M., An Environmentalist Perspective, *The Genetic Revolution*, B. Davis, ed. (1991).

Mellon, M., and J. Rissler, Public Access to Biotechnology Applications, *Natural Resources and Environment* 4:29 (1990).

Mellon, M., *Biotechnology and the Environment,* National Wildlife Federation (1988).

Mellon, M., *Environmental Protection Law*, S. Novick, D. Steaver, and M. Mellon, eds. (1987).

Mellon, M., and C. Montgomery, *Community Action to Prevent Chemical Accidents* (1987).

Mellon, M., L. Ritts, S. Garrod, and M. Vailante, *The Regulation of Toxic and Oxidant Air Pollution in North America* (1986).

Margaret G. Mellon
(page four)

Scientific

Hunt, D.M., M.G. Mellon, and S.U. Emerson, "Viral Transcriptases," 169-184, in The Rhabdoviruses, D.H.L. Bishop, ed., 1979, CRC Press, Boca Raton.

Mellon, M.G., and S.U. Emerson, "Rebinding of Transcriptase Components (L and NS Proteins) to the Nucleocapsid Template of Vesicular Stomatitis Virus," 1978, Journal of Virology 27:560-567

Mellon, M.G., and S.U. Emerson, "The Binding of L and NS Proteins to the Ribonucleocapsid of Vesicular Stomatitus Virus" 292 in Negative Strand Viruses, B.W.J. Mahy and R.D. Barry, eds., 1978, Academic Press, London.

Mellon, M.G., and L.I Rebhun, "Studies on the Accessible Sulfhydryls of Polymerizable Tubulin," 149-63 in Cold Spring Harbor Conferences on Cell Proliferation, vol III, R. Goldman, T. Pollard, and J. Rosenbaum, eds., 1976, Cold Spring Harbor, New York.

Mellon, M.G., and L.I. Rebhun, "Sulfhydryls and the In Vitro Polymerization of Tubulin," 1976, Journal of Cell Biology, 70:226-238.

Mellon, M.G., Microtubules In Vitro: the pH Dependent Depolymerization Products of Microtubules and the Involvement of Sulfhydryls in Polymerization, Ph.D. Thesis, 1976, University of Virginia.

Rebhun, L.I., M.G. Mellon, D. Jemiolo, J. Nath, and N. Ivy, "Regulation of the Size and Birefringence of the In Vivo Mitotic Apparatus," 1974, J. Supramol. Struct. 2:466.

Rebhun, L.I., D. Jemiolo, N. Ivy, M.G. Mellon, and J. Nath. "Regulation of the In Vivo Mitotic Apparatus by Glycols and Metabolic Inhibitors," 1974, Ann. New York Acad. Science 484:23.

Committee on Rules
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

Your Name: **Margaret Mellon**		
1. Are you testifying on behalf of a Federal, State, or Local Government entity?		**No**
2. Are you testifying on behalf of an entity other than a Government entity?	**Yes**	
3. Please list any federal grants or contracts (including subgrants or subcontracts) which you have received since October 1, 2007: **None**		
4. Other than yourself, please list what entity or entities you are representing: **The Union of Concerned Scientists** **Keep Antibiotics Working Coalition**		
5. If your answer to question number 2 is yes, please list any offices or elected positions held or briefly describe your representational capacity with the entities disclosed in question number 4: **I am the Director of the Food and Environment Program for the Union of Concerned Scientists;** **and on the executive committee of the Keep Antibiotics Working Coalition**		
6. If your answer to question number 2 is yes, do any of the entities disclosed in question number 4 have parent organizations, subsidiaries, or partnerships to the entities for whom you are not representing? **No.**		**No**
7. If the answer to question number 2 is yes, please list any federal grants or contracts (including subgrants or subcontracts) which were received by the entities listed under question 4 since October 1, 2007, which exceed 10% of the entities revenue in the year received, including the source and amount of each grant or contract to be listed:		

None

Signature: Margaret A. Miller Date: July 13, 2009

101 North Park St. Flagstaff, AZ 86001
Cell Phone (443) 527-8750
E-Mail: lprice@tgen.org

LANCE B. PRICE

EDUCATION

2006	Johns Hopkins University, Baltimore, MD *Doctor of Philosophy* in Environmental Health Sciences
2000	Northern Arizona University, Flagstaff, AZ *Master of Science* in Biology
1994	Northern Arizona University, Flagstaff, AZ *Bachelor of Science* in Microbiology

WORK EXPERIENCE

Current — the Translational Genomics Research Institute (TGen), Division of Pathogen Genomics, Flagstaff, AZ
Associate Investigator
Director, Center for Metagenomics and Human Health

- Developing and utilizing novel tools to study the human microbiome
- Assessing the public health consequences of non-therapeutic antibiotic use

Current — Northern Arizona University, Flagstaff, AZ
Adjunct Faculty

- Developing a highly multiplexed, microarray-based single nucleotide polymorphism interrogation assay for *Burholderia*, *Brucella* and *Francisella*

Current — Johns Hopkins University Center for a Livable Future, Baltimore, MD
Scientific Advisor

- Advising research fellows and staff; communicating the public health impacts of industrial food animal production

01/06-02/08 — Johns Hopkins University School of Medicine, Baltimore, MD
Director of Pathogenesis and Molecular Diagnosis of Infectious Diseases

- Characterizing microbial flora of chronic wounds using metagenomics

08/03-12/06 — Johns Hopkins University, Baltimore, MD
Graduate Research Assistant

- Assessing public health risks associated with industrial poultry production

12/05-08/06 — Pew Commission on Industrial Farm Animal Production, Baltimore, MD
Research Specialist

- Summarizing data on the public health impacts of industrial food animal production

04/02-08/03 — Johns Hopkins University, Baltimore, MD
Research Associate

- Assessing public health risks associated with antimicrobial use in industrial poultry production

11/00-04/02 — Intralytix, Inc., Baltimore, MD
Research Scientist

- Developing phage-based therapeutics

09/97-07/00 Keim Genetic Laboratory, Northern Arizona University, Flagstaff, AZ
Research Scientist
- Analyzing genetic markers in *Bacillus anthracis* and *Yersinia pestis*

01/96-05/97 Northern Arizona University, Flagstaff, AZ
Laboratory Instructor
- Teaching Biology of Microorganisms, Immunology and Environmental Microbiology

01/95-05/97 Northern Arizona University, Flagstaff, AZ
Graduate Research Assistant
- Characterizing halocin production in the halophilic Archaea

Volunteer Work

08/03-06/06 Baltimore Polytechnic Institute, Baltimore, MD
Volunteer Research Practicum Mentor
- Guiding public health research practicum for high school students

08/05-12/05 Rose Street Tutoring Program, Baltimore, MD
Volunteer Tutor
- Tutoring inner-city youths at an after-school program

FUNDING

Current Department of Defense, $1,000,000
Metagenomic Analysis of Wound Microflora
- Principle Investigator

HONORS/AWARDS/ACTIVITIES

Honors

09/13/05 *Invited Speaker* – "Industrial animal production and public health" Indiana State congressional hearing on environmental concerns regarding concentrated feeding operations, Indianapolis, IN

07/07/05 *Invited Speaker* – "Public health implications of antibiotic use in industrial animal production" US congressional hearing on industrial animal production and public health, Washington, DC

Awards

2003-2005 *Predoctoral fellow Award* – the Center for a Livable Future, Johns Hopkins School of Public Health

2004 *Best Health Communication Project* – the Center for Communications Programs, Johns Hopkins School of Public Health

2000 *Outstanding Master's Thesis Award* – Department of Biological Sciences, Northern Arizona University

1996 *Sustaining Member Travel Grant* – American Society for Microbiology

Activities

Current *Member* – American Public Health Association

Current *Member* – American Society for Microbiology

2004-2005 *Representative* – Johns Hopkins School of Public Health Student Assembly

2005-2006 *Vice President* – Social and Cultural Affairs, Johns Hopkins School of Public Health Student Assembly

PUBLICATIONS

Manuscripts

Price LB, Liu CM, Melendez JH, Frankel YM, Engelthaler D, Aziz M, Bowers J, Rattray R, Ravel J, Kingsley C, Keim PS, Lazarus GS, Zenilman JM. 2009. Community analysis of chronic wound bacteria using 16S rRNA gene-based pyrosequencing: impact of diabetes and antibiotics on chronic wound microbiota. PLoS One. *In press.*

Graham JP, Evans SL, **Price LB**, Silbergeld. 2009. Fate of antimicrobial-resistant enterococci and staphylococci and resistance determinants in stored poultry litter. Environ Res. *In Press.*

Frankel YM, Melendez JH, Wang N, **Price LB**, Zenilman JM, Lazarus GS. 2009. Wound microbial flora: molecular microbiology unlocks new horizons. Arch Dermatol. *In press.*

Vogler AJ, Birdsell D, **Price LB**, Bowers JR, et al. Phylogeography of *Francisella tularensis*: Global Expansion of a Highly Fit Clone. J Bacteriol. 2009; 191:2474-84

Graham JP, **Price LB**, Evans SL, Graczyk TK and Silbergeld EK. 2009. Antibiotic resistant enterococci and staphylococci isolated from flies collected near confined poultry feeding operations. Sci. Total Environ. 2009 407:2701-10.

Graham JP, Tuchmann JL, **Price LB**, Otte JM, Pfeiffer DU, Tiensin T, and Silbergeld EK. 2008. The Animal:Human Interface and Infectious Disease in Industrial Food Animal Production: Rethinking Biosecurity and Biocontainment. Public Health Reports. 123:282-299.

Silbergeld EK, Graham J, and **Price LB.** 2008. Industrial Food Animal Production, Antimicrobial Resistance, and Human Health. Annu. Rev. Public Health. 29:151–69.

Price LB, Graham JP, Lackey L, Roess A, and Silbergeld E. 2007. Multidrug resistant *Escherichia coli* among US poultry workers. Environ Health Perspect. 115:1738-1742.

Price LB, Lackey L, Vailes R and Silbergeld E. 2007. The persistence of fluoroquinolone-resistant *Campylobacter* in poultry production. Environ Health Perspect. 115:1035–1039.

Price LB, Roess A, Graham JP, Baqar S, Vailes R, Sheikh KA, and Silbergeld E. 2007. Neurologic symptoms and neuropathologic antibodies in poultry workers exposed to *Campylobacter jejuni*. J Occ Environ Med. 49:748-55.

Chapin Sapkota AR, **Price LB**, Silbergeld EK and Schwab KJ. 2006. Arsenic Resistance in *Campylobacter* spp. Isolated from Retail Poultry Products. Appl Environ Microbiol. 72: 3069-71

Nachman, KE, Graham JP, **Price LB** and Silbergeld EK. 2005. Arsenic: a roadblock to potential animal waste management solutions. Environ Health Perspect. 113: 1123-4.

Price LB, Johnson E, Vailes R and Silbergeld E. 2005. Fluoroquinolone resistant *Campylobacter* from antibiotic-free and conventional poultry products. Environ Health Perspect. 113: 557-60.

Price LB, Vogler A, Pearson T, Busch JD, Schupp JM and Keim P. 2003. In Vitro Selection and Characterization of *Bacillus anthracis* Mutants with High-Level Resistance to Ciprofloxacin. Antimicrob. and Chemother. 47: 2362-2365.

Klevytska, AM, **Price LB**, Schupp JM, Worsham P, Wong J and Keim P. 2001. Identification and characterization of variable-number tandem repeats in the *Yersinia pestis* genome. J. Clin. Microbiol. 39:3179-3185.

Jubrias SA, PC Esselman, **LB Price**, ME Cress, Conley KE. 2001. Large Energetic adaptations of elderly muscle to resistance and endurance training. J. Appl. Physiol. 90:1663-1670.

Smith KL, DeVos V, Bryden H, **Price LB**, Hugh-Jones ME and Keim P. 2000. *Bacillus anthracis* diversity in Kruger National Park. J. Clin. Microbiol. 38:3780-3784

Price LB and Shand RF. 2000. Halocin S8: A 36 amino acid haloarchaeal microhalocin. J. Bacteriol. 182:4951-4958.

Schupp JM, Klevytska AM, **Price LB**, Zinser G and Keim P. 2000. *VrrB:* A hypervariable ORF in *Bacillus anthracis*. J. Bacteriol. 182:3989-3997.

Keim P, **Price LB**, Klevytska AM, Smith KL, Schupp JM, Okinaka R, Jackson P and Hugh-Jones ME. 2000. Multiple-Locus VNTR analysis (MLVA) reveals genetic relationships within *Bacillus anthracis*. J. Bacteriol. 182:2928-2936.

Keim P, Klevytska AM, **Price LB**, Schupp JM, Zinser G, Smith KL, Hugh-Jones ME, Okinaka R, Hill KK and Jackson PJ. 1999. Molecular diversity in *Bacillus anthracis*. J. Appl. Microbiol. 87:215-7.

Smith KL, De Vos V, Bryden HB, Hugh-Jones ME, Klevytska A, **Price LB**, Keim P and Scholl DT. 1999. Meso-scale ecology of anthrax in southern Africa: a pilot study of diversity and clustering. J. Appl. Microbiol. 87:204-7.

Schupp, JM, **Price LB,** Klevytska A and Keim P. 1999. Internal and flanking sequence from AFLP fragments using ligation-mediated suppression PCR. Biotechniques. 26:905-10.

Price LB, Hugh-Jones M, Jackson PJ and Keim P. 1999. Genetic diversity in the protective antigen gene of *Bacillus anthracis*. J Bacteriol 181:2358-62.

Porter TL, Eastman MP, Hagerman ME, **Price LB**, and Shand RF. 1998. Site-specific prebiotic oligomerization reactions of glycine on the surface of hectorite. J. Mol. Evol. 47:373-377.

Cheung J, Danna KJ, O'Connor EM, **Price LB**, and Shand RF. 1997. Isolation, sequence, and expression of the gene encoding halocin H4, a bacteriocin from the halophilic archaeon *Haloferax mediterranei* R4. J. Bacteriol. 179:548-551.

Schupp, J M, Travis SE, **Price LB**, Shand RF and Keim P. 1995. Rapid bacterial permeabilization reagent useful for enzyme assays. Biotechniques. 19:18-20.

Online Reports

Otte J, Pfieffer D, Silbergeld E, **Price L**, and Tiensin T. HPAI risk, biosecurity, and small holder adversity. FAO Policy Brief, 2006. http://www.fao.org/ag/againfo/projects/en/pplpi/hpai.html

Book chapters

Shand RF, **Price LB**, and O'Connor EM. 1999. Halocins: protein antibiotics from hypersaline environment. *In*, A. Oren and R.H. Vreeland (ed.), Microbiology and biogeochemistry of hypersaline environments. CRC Press, Inc., Boca Raton.

PRESENTATIONS

Invited oral

02/18/09 "Advanced polymicrobial genomic analysis" USAMRMC MIDRP W Wound conference. Silver Spring, MD

05/15/08 "Health Risks Associated with Antibiotic use in Food Animal Production" Women's Health and the Environment Conference: Safe Food Session. Pittsburgh, PA

11/03/07 "How Safe is Our Food Supply?" A Woman's Journey, Baltimore, MD

01/25/07 "Microbial Risks Associated with Industrial Poultry Production" Northern Arizona University Spring Seminar Series, Flagstaff, AZ

09/13/05 "Industrial animal production and public health" Indiana State congressional hearing on environmental concerns regarding concentrated feeding operations, Indianapolis, IN

07/07/05 "Public health implications of antibiotic use in industrial animal production" US congressional hearing on industrial animal production and public health, Washington, DC

04/24/05 "Potential Occupational Risks Associated With Antibiotic Use in Industrial Poultry Production" National Poultry Justice Alliance Forum, Canton, MS

10/02/04 "Antibiotics in Food Animal Production" Healthy Foods, Local Farms Conference, Louisville, KY

Oral

11/18/09 "Genomic Analysis of Complex Microbial Communities in Wounds" TATRC Product Line Review (PLR). Frederick, MD

05/11/06 "Update on research regarding Maryland's Eastern Shore—What we've done, What we're doing, and Where we're going" Community Meeting, Pokomoke City, MD

12/05/05 "Occupational Hazards associated with Industrial Food Animal Production" National Occupational Research Agenda (NORA) Town Hall Meeting, College Park, MD.

09/06/03 "Fluoroquinolone resistant *Campylobacter* from antibiotic-free and conventional poultry products" The 13th International Workshop on *Campylobacter*, *Helicobacter* and related Organisms (CHRO), Aarhus, DK.

03/30/03 "*In vitro* Selection and Characterization of High-Level Fluoroquinolone Resistance in *Bacillus anthracis*" The Third International Conference on Anthrax. Nice, France.

PROFESSIONAL MEMBERSHIPS

1994-prsnt.	American Society for Microbiology
2004-prsnt.	Alliance for the Prudent Use of Antibiotics
2003-prsnt.	American Public Health Association
2004-2006	Johns Hopkins School of Public Health Student Assembly
2009-prsnt.	American Burn Association
2009-prsnt.	Wound Healing Society

Committee on Rules
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

Your Name: Lance B. Price		
1. Are you testifying on behalf of a Federal, State, or Local Government entity?	Yes	(No)
2. Are you testifying on behalf of an entity other than a Government entity?	(Yes)	No

3. Please list any federal grants or contracts (including subgrants or subcontracts) which you have received since October 1, 2007:
W81XWH-08-1-0386
United States Army Medical Research and Materiel Command
Genomic analysis of complex microbial communities in wounds

4. Other than yourself, please list what entity or entities you are representing:

The Translational Genomics Research Institute

The Johns Hopkins Center for a Livable Future

5. If your answer to question number 2 is yes, please list any offices or elected positions held or briefly describe your representational capacity with the entities disclosed in question number 4:

I am on the research faculty at the Translational Genomic Research Institute and the director of the TGen Center for Metagenomics and Human Health. I am a Scientific Advisor for the Johns Hopkins Center for a Livable Future.

6. If your answer to question number 2 is yes, do any of the entities disclosed in question number 4 have parent organizations, subsidiaries, or partnerships to the entities for whom you are not representing?	Yes	(No)

7. If the answer to question number 2 is yes, please list any federal grants or contracts (including subgrants or subcontracts) which were received by the entities listed under question 4 since October 1, 2007, which exceed 10% of the entities revenue in the year received, including the source and amount of each grant or contract to be listed:

Signature: Lance B. Price Date: 7/10/09

Robert Price Martin
18836 Falling Star Road
Germantown, Maryland 20874
301-528-5457 (home)
301-379-9107 (cell)
Email: martinall3@aol.com

Position Sought

Senior position that will utilize my communications and leadership skills and my experience in government

Summary of Qualifications

Well organized, dedicated professional with more than 20 years of experience in progressively more responsible management positions at all levels of government and non-governmental organizations. Superior problem solving ability, including problem identification and creative solutions through consensus building. Proven success in working in fast-paced, demanding work environment.

Summary of Experience

- Recruited 16 commissioners to study public health, environmental, and animal welfare problems created by concentrated animal feeding operations as the Pew Commission on Industrial Farm Animal Production
- Recruited four full time staff and managed work flow
- Developed scope of commission work with advice from faculty and staff at Johns Hopkins Bloomberg School of the Public Health and The Pew Charitable Trusts
- Recruited authors and peer reviewers for technical reports of the commission
- Managed media, polling, and final report design consultants
- Primary spokesperson for commission with the media and all stakeholder groups
- Managed technology upgrades of U.S. Senator Tim Johnson's Washington and state offices
- Revised job descriptions for legislative staff in Washington office
- Led message team for Senator Tim Johnson
- Managed implementation of new mail processing system
- Developed operating plans, goals and objectives while directing District Offices for Congressman Dan Glickman and as Chief of Staff for Kansas Senate Democratic Leader
- Prepared and monitored office budgets as Chief of Staff for Kansas Senate Democratic Leader and as Communications Director for National Association of Insurance Commissioner
- Established office personnel policies and procedures for Kansas Senate Democratic Leader's Office and for Congressman Dan Glickman's District Offices
- Represented members of the Kansas Democratic Caucus at public meetings as Chief of Staff and Congressman Dan Glickman as his District Director
- Hired, appraised and terminated staff as Chief of Staff to the Kansas Senate Democratic Leader and as District Director for Congressman Dan Glickman

Professional Experience

Senior Officer, the Pew Environment Group

The Pew Environment Group is pursuing a public education campaign highlighting the work of the Pew Commission on Industrial Farm Animal Production.

Visiting Scholar, Johns Hopkins Bloomberg School of Public Health and Executive Director of the Pew Commission on Industrial Farm Animal Production, Washington, D.C.—October 17, 2005 to December 31, 2008

The Pew Commission on Industrial Farm Animal Production was a two-year, $3.6 million dollar study to recommend solution to the public health, environment, animal welfare, and rural community problems associated with the concentrated animal feeding operation model of food animal production. As Executive Director of the Commission, I was responsible for all phases of the development and execution of the study plan.

Special Counsel to Senate Select Committee on Ethics for U.S. Senator Tim Johnson, Washington, D.C.—February 1, 2005 to October 7, 2005

Senator Johnson was named Vice Chairman of the Senate Select Committee on Ethics in January of 2005. As special counsel, I handle all of Senator Johnson's work on the Senate Select Committee on Ethics.

Deputy Chief of Staff for U.S. Senator Tim Johnson, Washington, D.C.—March 31, 2003 to February 1, 2005

- Member of senior staff management team responsible for Washington, D.C. Senate office and three state constituent service offices
- Developed office budget, including staff compensation package
- Managed search for mail system
- Revised and developed job descriptions
- Managed technology upgrade for offices
- Revised staff salary structure
- Recruited new personnel
- Assisted Legislative Director in issue strategy
- Lead participant in message development team

Communications Director for U.S. Senator Tim Johnson, Washington, D.C. – June 20, 1999 to March 31, 2003

- Member of senior staff management team responsible for Washington, D.C. Senate office
- Developed and implemented earned media strategy for Senator
- Managed all communications for Senator

- Member of senior staff political strategy team
- Fielded all state and national media inquiries
- Implemented new accomplishments review for South Dakota media
- Advised legislative staff on strategic use of issues, when needed
- Directed activities of Deputy Communications Director and Press Assistant

Communications Manager for the National Association of Insurance Commissioners, Kansas City, Missouri—November 10, 1997 to June 17, 1999

- Developed communication division budget
- Managed all aspects of internal and external communications for the National Association of Insurance Commissioners, a professional association representing all United States insurance regulators
- Fielded all media inquiries
- Developed long-term media strategy for association
- Drafted news releases
- Planned and executed news conferences
- Managed and edited the on-line and hard copy newsletter for association
- Developed plan for association of public information officers within the association
- Planned and implemented information sharing system between association members
- Developed media plan for association, including plan for each of the annual four national meetings
- Managed and edited national meeting daily newsletter
- Conducted media training for association members
- Planned and executed national media events

Senate Press Secretary to United States Senator Tom Daschle, Washington, D.C.—August 15, 1996 to October 31, 1997

- Conducted day-to-day media relations for South Dakota media
- Drafted and implemented long-term media strategy
- Drafted news releases
- Produced radio actualities
- Planned and executed news conferences
- Assisted in national and state message development
- Initiated cable television program
- Planned and executed television satellite feeds

Chief of Staff to Kansas Senate Minority Leader, Topeka, Kansas—September 1, 1989 to August 3, 1996

- Managed all phases of Democratic Senate campaigns in 1992 and 1996
- Developed office budget
- Monitored expenses

- Managed staff of six, including hiring and firing of personnel and developing office policy and procedures manual
- Initiated and managed modernization of office computer system
- Conducted day-to-day media relations for minority leader and all Kansas Democratic senators
- Authored opinion-editorial articles for Democratic senators
- Authored news releases and weekly Senate newsletter
- Assisted in developing issue strategy for Kansas Senate Democratic Caucus
- Managed and directed full time staff of six
- Managed unsuccessful gubernatorial primary campaign of former Kansas Governor John Carlin during a leave of absence from May until August 1990

Kansas Director, Office of Fourth District Congressman Dan Glickman, Wichita, Kansas—March 1988 to August 1989

- Initiated and planned conferences and meetings for Congressman Glickman
- Developed direct mail program for office
- Managed daily operations of two Congressional District offices
- Directed casework and staff work of all district aides
- Developed district office budgets in consultation with Washington office
- Represented Congressman at public functions
- Managed upgrade of District office computer system
- Initiated and implemented constituent advisory groups

Communications Director, Office of Fourth District Congressman Dan Glickman, Washington, D.C.—June 1985 to March 1988

- Developed media strategy for Congressman
- Initiated and produced monthly public service cable television program, Window on Washington
- Authored and edited quarterly newsletter
- Conducted day-to-day media relations
- Authored news releases, opinion-editorial articles and weekly newspaper columns
- Developed direct mail program for Washington, D.C. office
- From April 2, 1986 to November 8, 1986 managed successful Congressional re-election campaign
- Oversight of all aspects of the campaign, including voter contact, fund-raising, media development and placement, get-out-the-vote plan, polling strategy and volunteer recruitment

Director of Communications and Office Manager, Kansas Farmers Union, McPherson, Kansas—January 1979 to June 1985

- Managed daily operations of state headquarters
- Conducted all media relations for non-profit organization
- Wrote, edited and produced association's monthly newsletter
- Planned agenda for annual state convention and monthly board of directors' meeting

Page 5 Robert P. Martin

- Represented members before Kansas Legislature and United States Congress
- Loaned to National Farmers Union from August 1980 to March 1981 to be assistant editor of the National Farmers Union Washington Newsletter. Edited newsletter for six weeks during medical leave of editor

Campaign Press Secretary, Daschle for Congress Committee, Sioux Falls, South Dakota—January 1978 to December 1978

- Wrote news releases, weekly columns for Congressional campaign
- Conducted daily media relations for campaign
- Assisted in formulating campaign message
- Produced radio actualities
- Planned and implemented absentee ballot program

General Assignment Reporter, Jeannette News-Dispatch, Jeannette, Pennsylvania—November 1976 to December 1977

- Reported on general assignments for daily newspaper
- Beat included two townships, two boroughs, one city and one school board
- Editorial writing as directed by publisher

Staff Assistant to Senator George McGovern, Sioux Falls, South Dakota—June 1975 to September 1976

- Escorted Senator during trips to South Dakota
- Assisted constituents with federal agency problems
- Assisted in drafting weekly columns

Education

University of South Dakota
Bachelor of Arts Degree
Major: Political Science
Minors: United States History, Sociology, and Spanish
Graduated with a 3.7 grade point average on a 4.0 scale

Honors and Awards

- Phi Beta Kappa
- Pi Sigma Alpha, National Political Science Honorary
- Who's Who Among American Colleges and Universities
- Dillon Scholarship, awarded to political science majors who excel in the communication arts
- Editor of University of South Dakota student newspaper, **The Volante**
- Former Vice President, Farmers Union Press Association
- Who's Who Registry of Rising Young Americans—1993 edition

References are available upon request

Committee on Rules
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

Your Name: Robert P. Martin

1. Are you testifying on behalf of a Federal, State, or Local Government entity?	Yes	(No)
2. Are you testifying on behalf of an entity other than a Government entity?	(Yes)	No

3. Please list any federal grants or contracts (including subgrants or subcontracts) which you have received since October 1, 2007:

4. Other than yourself, please list what entity or entities you are representing:

The Pew Environment Group

The Pew Commission on Industrial Farm Animal Production

5. If your answer to question number 2 is yes, please list any offices or elected positions held or briefly describe your representational capacity with the entities disclosed in question number 4:

I am a Senior Officer at the Pew Environment Group and previously was the executive director of the Pew Commission on Industrial Farm Animal Production

6. If your answer to question number 2 is yes, do any of the entities disclosed in question number 4 have parent organizations, subsidiaries, or partnerships to the entities for whom you are not representing? The Pew Charitable Trusts	(Yes)	No

7. If the answer to question number 2 is yes, please list any federal grants or contracts (including subgrants or subcontracts) which were received by the entities listed under question 4 since October 1, 2007, which exceed 10% of the entities revenue in the year received, including the source and amount of each grant or contract to be listed:

Signature: Robert P. Martin Date: 7-10-09

Fedele Bauccio
Co-founder and CEO, Bon Appétit Management Company

When Fedele Bauccio co-founded Bon Appétit Management Company, he set out to revolutionize the food service industry by bringing fresh, made-from-scratch food to the contract market.

Fedele began his career as a dishwasher in 1960 with Saga Corporation's Education Division while a student at the University of Portland. In 1972, he transferred to Saga's Business Food Service Division and held many positions including Divisional President, President of Saga's Specialty Foodservices Group, and President of the Stuart Anderson's restaurant chain. After over 25 years of experience, he knew institutional feeding was ready for something more.

In 1987, Bon Appétit Management Company was born. For the first time, real executive chefs were put in the kitchens of colleges, universities, corporations and cultural centers. Fedele's dream of a company committed to culinary expertise had become a reality and customers noticed, fueling quick growth for the small, San Francisco-based company.

In 1999, Fedele led his team to once again raise the bar for onsite food service by making a commitment to socially responsible food sourcing. Today, Bon Appétit spends over $55 million annually on food from within a 150-mile radius of each café, uses only sustainable seafood, sources turkey breast and chicken raised without antibiotics as a routine feed additive, features natural beef burgers, and leads the industry in using cage-free shell eggs. In 2007, the company debuted its Low Carbon Diet, the first program to make the connection between food and climate change. Bon Appétit is now a $500 million company with over 400 cafés in 28 states serving over 80 million meals a year.

Fedele was a recipient of the 1992 Restaurants & Institutions "Ivy Award," and in 1998 was presented with the Nation's Restaurant News Golden Chain Award for Excellence. In addition, Fedele was named 2008 Innovator of the Year by Nation's Restaurant News, and also received the prestigious Going Green Award by the Natural Resources Defense Council (NRDC) in 2009. He is a board member of Compass Group, North America and serves on the board of Dynamic Payment Ventures in San Francisco. Fedele is presently Chairman of the University of San Francisco Hospitality Management board and serves on the President's Advisory Council of the University of Portland. He has also served as a member of the Pew Commission on Industrial Farm Animal Production.

Fedele graduated from the University of Portland with a Master's degree in Business Administration (1966) and a Bachelor's degree in Economics (1964). He is a 1985 graduate of the Advanced Management Program of the Harvard Graduate School of Business. Fedele also holds an honorary Doctorate from the University of Portland (2004).

Committee on Rules
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

Your Name: Fedele Bauccio

1. Are you testifying on behalf of a Federal, State, or Local Government entity?	Yes	No
2. Are you testifying on behalf of an entity other than a Government entity?	Yes	No

3. Please list any federal grants or contracts (including subgrants or subcontracts) which you have received since October 1, 2007:

n/a

4. Other than yourself, please list what entity or entities you are representing:

Bon Appétit Management Company

5. If your answer to question number 2 is yes, please list any offices or elected positions held or briefly describe your representational capacity with the entities disclosed in question number 4:

Co-founder and Chief Executive Officer, Bon Appétit Management Company

6. If your answer to question number 2 is yes, do any of the entities disclosed in question number 4 have parent organizations, subsidiaries, or partnerships to the entities for whom you are not representing? Bon Appétit Management Company is a wholly-owned subsidiary of Compass Group North America.	Yes	No

7. If the answer to question number 2 is yes, please list any federal grants or contracts (including subgrants or subcontracts) which were received by the entities listed under question 4 since October 1, 2007, which exceed 10% of the entities revenue in the year received, including the source and amount of each grant or contract to be listed:

n/a

Signature: _____ Date: July 9, 2009.

Steve Ells

Founder, Chairman, Co-CEO
Chipotle Mexican Grill

When Steve Ells opened the first Chipotle in Denver in 1993, he had a novel idea: Show that food served fast didn't have to be typical fast food. Today, he and Chipotle are changing the way the world thinks about and eats fast food. With a commitment to using ingredients from more sustainable sources - including naturally raised meat, organic and locally grown produce, and dairy products made with milk from cows that are not given synthetic hormones - Ells and Chipotle are leading a revolution to make great food affordable and accessible so everyone can eat better.

Ells, a classically trained chef, has received considerable praise for his vision and leadership at Chipotle. The *New York Times* proclaimed that Chipotle provides "a chance to witness - and taste - a shift in American fast-food," and *Newsweek*, called him "an environmental champion" for his commitment to supporting sustainable agriculture.

In 2006, Chipotle's prominence as a company was recognized when it became one of the most successful initial public offerings of the year. Its leadership and success in business has prompted accolades from a new universe of sources, including the *Wall Street Journal*, which said "Chipotle has arguably become the country's most successful fast-food chain," SustainableBusiness.com, which has named Chipotle one of the world's top-20 sustainable stocks two years in a row (2007 and 2008), and the Motley Fool, which called it the "most socially responsible company" in 2008.

Ells holds a bachelor's degree in Art History from the University of Colorado, Boulder, and is a graduate of the Culinary Institute of America, Hyde Park, NY.

Committee on Rules
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

Your Name: STEVE ELLS

1. Are you testifying on behalf of a Federal, State, or Local Government entity? Yes **(No)**

2. Are you testifying on behalf of an entity other than a Government entity? **(Yes)** No

3. Please list any federal grants or contracts (including subgrants or subcontracts) which you have received since October 1, 2007: NONE.

4. Other than yourself, please list what entity or entities you are representing:

CHIPOTLE MEXICAN GRILL, INC.

5. If your answer to question number 2 is yes, please list any offices or elected positions held or briefly describe your representational capacity with the entities disclosed in question number 4:

NO ELECTED POSITIONS. CHAIRMAN + CEO OF CHIPOTLE.

6. If your answer to question number 2 is yes, do any of the entities disclosed in question number 4 have parent organizations, subsidiaries, or partnerships to the entities for whom you are not representing? Yes **(No)**

7. If the answer to question number 2 is yes, please list any federal grants or contracts (including subgrants or subcontracts) which were received by the entities listed under question 4 since October 1, 2007, which exceed 10% of the entities revenue in the year received, including the source and amount of each grant or contract to be listed: NONE.

Signature: [signature] Date: 13 JULY 09

THE LETTER FROM THE HONORABLE LEONARD BOSWELL TO CHAIRWOMAN SLAUGHTER
DATED JULY 8, 2009

LEONARD L. BOSWELL
3rd District, Iowa

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Congress of the United States
House of Representatives
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COMMITTEES:
AGRICULTURE
Chairman, Subcommittee on General Farm Commodities and Risk Management
Subcommittee on Livestock, Dairy and Poultry

TRANSPORTATION AND INFRASTRUCTURE
Subcommittee on Highways and Transit
Subcommittee on Aviation
Subcommittee on Railroads, Pipelines and Hazardous Materials

July 8, 2009

The Honorable Louise Slaughter
Chairwoman
House Committee on Rules
H-312, the Capitol
Washington, D.C. 20515

Dear Chairwoman Slaughter:

Having spent most of my life involved in animal agriculture and the responsible use of antibiotics, I understand many of the issues that affect the industry. I spent most of my youth working in livestock production, and when I retired from the Army and moved back to Iowa to begin farming, I discussed the use of antibiotics to treat sick animals and prevent future illness with my local veterinarian. From my experience with producers and veterinarians, the thoughtful use of antibiotics is not the exception but the rule.

During the 110th Congress, it was my privilege to serve as the Chairman of the Livestock, Dairy, and Poultry Subcommittee. On September 25, 2008, we held a hearing to review advances in animal health within the livestock industry, specifically focusing on antibiotic use.

For over 40 years, the U.S. animal agriculture industry has used FDA approved drugs to ensure we have healthy animals and, consequently, healthy food. Producers and veterinarians have a moral obligation to use antibiotics responsibly. Protecting human health and providing safe food are paramount concerns of America's producers. That is why we test for antibiotics residue as part of our food safety programs.

I urge caution if considering a ban on antibiotic use in livestock. We need a science-based process, one that ensures that such a ban would not have unintended consequences that put human health at risk. Denmark provides a compelling example, where the removal of antibiotics for health maintenance or growth purposes not only increased animal death and disease, but resulted in greater use of antibiotics to treat animal diseases.

Antibiotic use in livestock has been a hot topic of discussion for years. However, we are privileged in the United States to have the safest, most plentiful, most affordable food supply in the world. It is my fear that an outright ban on antibiotics for health maintenance or growth purposes would put that supply at risk.

I request that the transcript from the hearing of September 25, 2008, be submitted as part of the hearing record on H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act. I also respectfully request the opportunity to testify before your committee on July 13, 2009.

Thank you for your consideration. Should you have any questions, please feel free to contact me or Alexis Taylor on my staff at (202) 225-3806.

Sincerely,

Leonard L. Boswell
Member of Congress

Enclosures

CC: Speaker Nancy Pelosi
Majority Leader Steny Hoyer
Minority Leader John Boehner

PRINTED ON RECYCLED PAPER

STATEMENT BY BILL NIMAN AND NICOLETTE HAHN NIMAN

Comments on
The Preservation of Antibiotics for Medical Treatment Act

By Bill Niman and Nicolette Hahn Niman
Bolinas, CA
July 10, 2009

Summary of Comments

As full-time livestock ranchers and natural meat purveyors with a combined forty-four years of experience in raising farm animals, we strongly support The Preservation of Antibiotics for Medical Treatment Act. We believe that good animal husbandry makes the regular feeding of antibiotics unnecessary and that the downsides of the practice are serious and growing.

Background

Bill Niman

My life as a livestock farmer began more than 37 years ago, when I started raising chickens, goats, and pigs in Northern California. In the decades that followed, we increased the size of our pig herd and started selling pork to family members and neighbors. We added cattle, too, and began supplying beef to restaurants and retail stores. We learned how to raise livestock from our neighbors – traditional farmers and ranchers who had been farming for generations. I was involved in every aspect of meat production – from breeding and raising the livestock, to slaughter and butchering, to delivering the meat to restaurants' and retailers' backdoors.

Eventually, we stopped raising pigs and focused on cattle (because that's what does best where we live), which, along with heritage turkeys and goats, is what I still raise today. But over those decades we came to know other farmers who believed in raising cattle, pigs and sheep using natural, traditional methods. One farm at a time, Niman Ranch grew into what it is today: a network of more than 600 farms and ranches that all raise their animals according to Niman Ranch's standards.

I started my own ranch with a simple idea: Animals should be raised as naturally as possible. To me, this was just common sense. This meant using drugs only when necessary, never using hormones, and feeding only natural feeds. I also believed that animals should lead lives bearing some resemblance to how they'd live in nature; they should be given the opportunity to express their natural behaviors. In other words, pigs should be allowed to be pigs, cattle to be cattle, and sheep to be sheep.

Through my own experiences raising animals and hundreds of visits to other farms and ranches over the past three and a half decades, I have learned a lot about animals and how to raise them. What I've learned has reinforced my belief in the importance in raising animals without relying on drugs in their daily feed.

For more than a decade Niman Ranch consulted with the independent non-profit organization Animal Welfare Institute (AWI). Over ten years ago, we adopted the AWI Pig Husbandry Protocols. The standards required that pigs be given access to the outdoors or large, deeply-bedded pens with plenty of room to move about. The pigs

exercise, breathe fresh air, interact with each other and with their young, root, play, and build nests when they're ready to give birth. The standards prohibit confining animals to buildings using liquefied manure systems, which have been shown to cause serious, persistent health problems in both workers and animals. They also prohibit the feeding of antibiotics.

All of this makes for healthier and happier pigs, sparing them from needless suffering. But it also makes for better business practice and happier customers. In my three decades in the meat industry, I've become absolutely convinced that you cannot produce good meat without such high animal husbandry standards. I've always believed that if you treat an animal like a sponge, it'll taste like a sponge.

Conversely, I believe that providing an animal a good life and a swift, painless end ensure the best tasting and healthiest meat. A growing recognition of the connection between humane slaughter practices and good, safe meat has led many of the nation's meat packers to build slaughterhouses focused on the animal's subjective experience. It makes complete sense to do the same for the farm.

Over the past three decades, I've had conversations with thousands of the consumers of our meat. In these conversations I've learned that people have images in their minds' eyes about where they'd like their food to come from. Obviously, there is some diversity of opinion. But certain general themes consistently emerge: 1) animals should be living outdoors as much as possible; 2) animals should be allowed to interact normally with each other; 3) animals should be given natural, non-medicated feeds, and 4) animals should not be administered drugs unless they are sick. Likewise, certain things clearly violate the general consumer's expectation about how his or her food should be produced. Among those practices are keeping animals continually confined, adding drugs to their regular rations, and administering drugs or hormones to stimulate growth.

Nicolette Hahn Niman

For the past nine years, I have worked exclusively on issues relating to the livestock and poultry industries, first as a lawyer, then as a rancher and a writer. Much of that time has been spent researching, especially on the environmental and public health implications of different methods of animal farming. In this course of this research, I have gathered hundreds of studies from around the world.

As a result of that work, in February 2009, I published the book *Righteous Porkchop: Finding a Life and Good Food Beyond Factory Farms* (HarperCollins; see www.righteousporkchop.com), which explores the history and current state of the animal farming industry. I have also had three essays on the subject in the New York Times.[1] Over the last six years, I have also worked more than half-time on our own livestock ranch in Bolinas, California.

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[1] See: "The Unkindest Cut," March 7, 2005, at: http://www.nytimes.com/2005/03/07/opinion/07niman.html?_r=1&scp=5&sq=%22nicolette%20hahn%20niman%22&st=cse ; "A Load of Manure", March 4, 2006, at: http://www.nytimes.com/2006/03/04/opinion/04niman.html?scp=3&sq=%22nicolette%20hahn%20niman%22&st=cse ; and "Pig Out," March 14, 2007, available at: http://www.nytimes.com/2007/03/14/opinion/14niman.html .

Prior to that, I worked for nine years as a lawyer, the last two of which I was the Senior Attorney for the environmental organization Waterkeeper Alliance. In my work as a lawyer, I've been involved in litigation with the livestock and meat industry and numerous federal rulemaking processes.

In the course of my work, it has become clear that the consensus of the medical and public health literature is that the regular feeding of antibiotics to livestock and poultry is a serious public health concern. Countless studies have shown that livestock husbandry affects the safety and healthfulness of the meat. For example, a 2001 FDA study found high rates of antibiotic resistant bacteria on beef and chicken from such operations. For precisely this reason (along with concerns over the resistant bacteria entering water and air), the European Union already disallows sub-therapeutic antibiotics for livestock. As you are undoubtedly aware, the World Health Organization, Centers for Disease Control, and American Medical Association have all called for a ban on the practice. Simply put, there is plenty of evidence that feeding antibiotics to livestock is a foolhardy practice from a public health standpoint.

Moreover, it is totally unnecessary. I have also visited dozens of agricultural operations, both traditional farms and industrial operations. Without exception, the traditional farms were raising their animals ***without*** the use of subtherapeutic antibiotics. These farmers reported that they did not need to add antibiotics to their animals' feed because they rarely had illness in their herds and flocks. On those infrequent occasions when an animal would get sick, that animal would be separated from the others and treated individually with a therapeutic dose of antibiotics.

This is same practice that has always been followed here on our own ranch. Since I have been involved in this ranch, the past six years, we have had only four sick cattle (two of which were calves) and only one sick turkey. Those animals were then treated individually with a therapeutic dose of an appropriate medication. No other antibiotics are used on our ranch and never have been. Our experiences reinforce our belief that if animals are provided a good environment that includes pasture, fresh air, exercise, and healthy feeds, they are very unlikely to get sick, making the use of prophylactic antibiotics totally unnecessary.

Conclusion

The U.S. livestock and poultry industry should be restricted in its use of antibiotics. Ideally, the industries would have adopted voluntary limits. However, in spite of years of mounting evidence of the dangers of antibiotic overuse, this has not happened. Thus, it is time for Congress to act to restrict antibiotic use in animal agriculture. Specifically, Congress should adopt a law that bans the continual feeding of prophylactic antibiotics. Although we do not think it goes far enough, we support the adoption of The Preservation of Antibiotics for Medical Treatment Act as a good first step toward addressing this important public health concern.

ARTICLE BY PETER COLLIGNON, ET AL., ENTITLED "WORLD HEALTH ORGANIZATION RANKING OF ANTIMICROBIALS ACCORDING TO THEIR IMPORTANCE IN HUMAN MEDICINE: A CRITICAL STEP FOR DEVELOPING RISK MANAGEMENT STRATEGIES FOR THE USE OF ANTIMICROBIALS IN FOOD PRODUCTION ANIMALS"

FOOD SAFETY INVITED ARTICLE

Frederick J. Angulo, Section Editor

World Health Organization Ranking of Antimicrobials According to Their Importance in Human Medicine: A Critical Step for Developing Risk Management Strategies for the Use of Antimicrobials in Food Production Animals

Peter Collignon,[1,2] John H. Powers,[3,4,5] Tom M. Chiller,[6] Awa Aidara-Kane,[7] and Frank M. Aarestrup[8]

[1]Infectious Diseases Unit, Microbiology Department, The Canberra Hospital, and [2]School of Clinical Medicine, Australian National University, Woden, Australia; [3]Scientific Applications International Corporation in support of the Collaborative Clinical Research Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, and [4]University of Maryland School of Medicine, Baltimore, Maryland; [5]George Washington University School of Medicine, Washington, DC; [6]Centers for Disease Control and Prevention, Atlanta, Georgia; [7]Department Food Safety, Zoonoses, & Foodborne Diseases, World Health Organization, Geneva, Switzerland; and [8]Head Community Reference Laboratory for Antimicrobial Resistance & World Health Organization Collaborating Centre for Antimicrobial Resistance in Foodborne Pathogens, National Food Institute, Technical University of Denmark, Copenhagen, Denmark

The use of antimicrobials in food animals creates an important source of antimicrobial-resistant bacteria that can spread to humans through the food supply. Improved management of the use of antimicrobials in food animals, particularly reducing the usage of those that are "critically important" for human medicine, is an important step toward preserving the benefits of antimicrobials for people. The World Health Organization has developed and applied criteria to rank antimicrobials according to their relative importance in human medicine. Clinicians, regulatory agencies, policy makers, and other stakeholders can use this ranking when developing risk management strategies for the use of antimicrobials in food production animals. The ranking allows stakeholders to focus risk management efforts on drugs used in food animals that are the most important to human medicine and, thus, need to be addressed most urgently, such as fluoroquinolones, macrolides, and third- and fourth-generation cephalosporins.

Antimicrobials decrease morbidity and mortality associated with serious and life-threatening infections. Antimicrobial resistance decreases the effectiveness of these drugs, increasing the risk of morbidity and mortality in serious diseases and, thus, compromising human health [1–6].

Antimicrobial resistance is an inevitable consequence of antimicrobial use. Poverty; suboptimal control of the sale, quality, and use of antimicrobials; and poor sewage and water systems are factors that contribute to the emergence and spread of antimicrobial resistance. High rates of resistance have been reported, even in *Escherichia coli*, one of the most common causes of bacterial infection in people [7, 8]. Increasing levels of resistance complicate the selection of empirical and definitive antimicrobial therapy for serious bacterial infection. Some authors have recommended broad-spectrum agents, such as carbapenems, as empirical therapy [9], but the collateral damage to commensal and colonizing organisms is likely to accelerate the development of multidrug resistance through the selection and spread of bacteria that produce metallo-β-lactamases.

Food animals (e.g., chickens, cattle, turkeys, and pigs) are a source for bacterial species that cause human infections, including *Campylobacter* and *Salmonella* species. Commensal bacteria, such as *E. coli* and *Enterococcus*, and the resistance genes they carry, are transmitted to people via the food chain or by direct exposure to animals [10–14]. The administration of antimicrobials occurs in higher volumes among food animals, compared with people [14, 15]. The amount of antimicrobial-resistant bacteria that develop are proportionate to

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The content of this article does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government.

World Health Organization meeting participants are listed at the end of text.

Reprints or correspondence: Dr. Peter Collignon, Infectious Diseases Unit and Microbiology Dept., The Canberra Hospital, School of Clinical Medicine, Australian National University, P.O. Box 11, Woden, ACT, 2607 Australia (peter.collignon@act.gov.au).

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the total volume of antimicrobials used, and the development of resistance is affected by the ways in which the drugs are used. In many countries, antimicrobial use in food animals occurs in situations with little or no associated economic or health benefits (e.g., growth promotion) while contributing to the risk of antimicrobial resistance [16].

Antibiotic usage in food animals leads to the development and spread of organisms that are resistant to fluoroquinolones, third- and fourth-generation cephalosporins, and vancomycin, among others. The relative contribution of foodborne transmission to antimicrobial resistance in humans remains unknown, but it is not zero and is likely more substantial than is currently appreciated [10–14]. Humans are exposed to antimicrobial-resistant bacteria and resistance genes that are present in the food chain. Some studies have suggested that the majority of antibiotic-resistant *E. coli* carried by people may have originated in food animals, especially chickens [12].

Mitigating the risks of antimicrobial resistance to human health requires risk management strategies for the use of antimicrobials in animals. To decrease the development and spread of antimicrobial-resistant foodborne bacteria, we must reduce the use of antibiotics in food animals and decrease the injudicious use of antimicrobials in human medicine. These issues are of great importance for drugs that are critical to human medicine.

The World Health Organization (WHO) has developed criteria to rank antimicrobials according to their importance in human medicine [17, 18]. These lists will be a component of risk management strategies to mitigate the human health risks associated with antimicrobial use in food animals. The WHO lists help to prioritize resources that address the use in food animals of the most critical antibiotics for humans. These lists will help regulators and stakeholders determine which types of antimicrobials could be used in food animal production and determine how these antibiotics might be managed (e.g., single animal therapy or mass treatment via water, prohibiting extra-label use, etc.). The use of these lists will help preserve the effectiveness of currently available antimicrobials. We present the development, criteria, and content of these lists in this paper.

WHAT ARE THE BACTERIA AND ANTIMICROBIAL-RESISTANCE TRAITS OF MOST CONCERN FROM FOOD ANIMALS?

Campylobacter *and* Salmonella. *Campylobacter* and non-typhoid *Salmonella* species spread from animals to people via food and water, particularly in developed countries. When antimicrobials are indicated for treatment of *Salmonella* infection (e.g., bloodstream infections), clinicians often treat with fluoroquinolones and third-generation cephalosporins [19]. However, these same classes of antimicrobial agents are also administered to food animals, which leads to the inevitable development of resistant bacteria [20–26].

An increasing prevalence of *Campylobacter* that are resistant to fluoroquinolones is associated with the use of this class of drugs in food animals [20–26]. In countries where fluoroquinolones are banned or used sparingly in food animals (e.g., Sweden, Norway, and Australia), studies demonstrate a low prevalence of fluoroquinolone-resistant *Campylobacter* [21, 25], despite the use of fluoroquinolones in human medicine for >20 years. In countries where fluoroquinolones are or were frequently used in food animals (e.g., Spain, China, and the United States), higher rates of resistance are observed among isolates from both food animals and humans [20–26]. In these latter countries, high resistance rates developed very rapidly, but did so only after the introduction of fluoroquinolones in food animals.

Staphylococcus aureus. *S. aureus* causes infections in many animals, including poultry, pigs, and cattle. In Europe, the United States, and Canada, methicillin-resistant *S. aureus* isolates have spread from food animals [27–30] and companion animals to people [31, 32]. Although it currently represents a low proportion of the total methicillin-resistant *S. aureus* infections that occur in people, there are an increasing number of reports of animal-derived methicillin-resistant *S. aureus*, especially from pigs, causing community-onset infection in people.

E. coli. Antimicrobial resistance in *E. coli* is an increasing problem [7, 8, 33–42], particularly in developing countries (e.g., China and Mexico) [7, 33] where strains that cause blood stream infections are frequently multidrug resistant. The main reservoir for *E. coli* is the gastrointestinal tract, where there is a large turnover of *E. coli* each day [41]. Food is an important vector for these organisms [10, 12, 13, 38, 39]. Food animals likely contribute a substantial proportion of the *E. coli* in the human gastrointestinal tract, including drug-resistant strains. Although most strains of *E. coli* are relatively host specific, various studies have demonstrated that drug-resistant strains of animal origin (e.g., fluoroquinolone-resistant *E. coli* from chickens) can either colonize or cause infection in humans [12, 13, 36, 38]. Human infections with bacteria that are resistant to third-generation cephalosporins, fluoroquinolones, and/or aminoglycosides are now widespread, and the number of such infections is rapidly increasing in many countries [3].

Studies report an increasing frequency of community-acquired infections due to extended-spectrum β-lactamase–producing *E. coli* strains, despite the relatively infrequent use of third- and fourth-generation injectable cephalosporins for treating people in the community [33, 34, 37, 38]. Increasing numbers of community-acquired, extended-spectrum β-lactamase–producing *E. coli* are carried in the population. Researchers have reported increasing frequencies of drug-resistant

isolates in foods around the world. In Spain [38], studies found similar bacteria in humans, food, animal farms, and sewage. The use of third- and fourth-generation cephalosporins in food animals select for undesired drug-resistance phenotypes in animal bacteria, including selection of extended-spectrum β-lactamase–producing strains [40–43]. Worldwide spread of these highly drug-resistant bacteria and their genes (genes that encode CTX-M and CMY β-lactamases are transferable among bacteria) is occurring.

Enterococcus. *Enterococcus* species, in particular *Enterococcus faecium*, are intrinsically resistant to a number of antimicrobials, which limits treatment options for infection due to these pathogens. The emergence of genetic determinants that confer resistance to vancomycin can limit treatment options still further [43].

WHO CLASSIFICATION ON THE CRITICAL IMPORTANCE OF ANTIMICROBIALS USED IN HUMAN MEDICINE

The Canberra meeting, 2005. In 2005, the WHO organized a consultation in Canberra, Australia, to develop a list of critically important antimicrobial agents in human medicine [17]. This list was generated in an effort to provide a tool for developing risk-management strategies and focusing resources to address antimicrobial use in agriculture and veterinary medicine. Until that time, there had been no international consensus on the classification of different groups of antibiotics in relation to their importance to human medicine [3, 14, 15, 25, 26].

In developing the list, the consultants did not consider any antimicrobial or class of antimicrobials used in human medicine to be unimportant. Therefore, to categorize the relative importance of these drugs in human medicine, they defined 3 categories of antimicrobials: *critically important* (table 1), *highly important* (table 2), and *important* (table 3). The consultants included comments in the tables in recognition of regional factors that might affect the rankings, but these comments were not meant to be exhaustive, and other regional factors may be relevant. The purpose of the comments was to increase, not decrease, the importance of drugs on the list on the basis of these regional factors. An antimicrobial class is defined as a group of agents with a similar mechanism of action, regardless of chemical structure.

Each antimicrobial agent (or class) was assigned to 1 of the 3 categories of importance on the basis of 2 criteria: (1) the agent or class is the sole therapy or one of few alternatives to treat serious human disease; and (2) the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases caused by organisms that may acquire resistance genes from nonhuman sources. *Critically important* antimicrobials are those that meet both criteria. *Highly important* antimicrobials are those that meet 1 of 2 criteria. *Important* antimicrobials are those that do not meet either criteria.

The consultants considered it important to set ranking criteria first to categorize drugs in a fair and impartial manner. The consultants arrived at these criteria through discussion and consensus. These criteria are based on sound scientific reasoning. For criterion 1, it is obvious that antimicrobials that are one of few alternatives for treatment of serious diseases have a critical place in human medicine. Criterion 2 grants greater importance to antimicrobial agents that are used to treat diseases caused by bacteria that can be transmitted from nonhuman sources to humans. The panel did not suggest that the transmission of such organisms or their genes must be proven, but only that there is the potential for such transmission to occur.

Tables 1, 2, and 3 outline the rankings of antimicrobials. The tables list only the generic drug names of antimicrobials used in humans. The tables show examples of members in each class, but the list is not inclusive of all drugs. In most groups, similar drugs are used in animals, for example, both enrofloxacin (a fluoroquinolone) and tylosin (a macrolide) are used in food animals (table 4). If resistance develops to 1 member of a class, generally, all other members of that group are affected because of cross-resistance. The WHO classification should be considered to be a core list of the most critical antimicrobial agents globally [17, 18]. However, considerations such as cost and availability of antimicrobials in various geographic areas and local resistance rates could increase the ranking of some drugs. For instance, an antimicrobial agent that is ranked *highly important* may become *critically important* in a particular region, because that agent may be the sole agent available in that area.

The Copenhagen meeting, 2007. The WHO convened a second meeting in Copenhagen, Denmark, in 2007 to re-evaluate the classification of antimicrobials and update the list on the basis of recent developments [18]. Relatively few changes were needed. The panel recommended the following changes:

- 1. Tigecycline (a new tetracycline-derivative with activity against multidrug-resistant *S. aureus* and gram-negative bacteria) became available in 2005 and was categorized as *critically important*.
- 2. All penicillins (except for penicillins active against staphylococcal organisms) were grouped together as a single class and remained *critically important*.
- 3. The penicillins active against staphylococcal organisms were moved from the *important* to the *highly important* category, because there is now more evidence of the potential transfer of *S. aureus*, including methicillin-resistant *S. aureus*, from animals to humans.
- 4. Because of the evidence of transfer of *flo* genes and chloramphenicol-resistant *Salmonella* species from animals to hu-

Table 1. ***Critically important*** **antimicrobials that are used in human medicine.**

Antimicrobial class	Antimicrobial(s)	Criterion 1[a]	Criterion 2[b]	Comment(s)
Aminoglycosides	Amikacin and arbekacin; gentamicin, netilmicin, and tobramycin; and streptomycin	Yes	Yes	Limited therapy as part of treatment of enterococcal endocarditis and MDR tuberculosis Potential transmission of *Enterococcus* species, Enterobacteriaceae (including *Escherichia coli*), and *Mycobacterium* species from nonhuman sources.
Ansamycins	Rifabutin, rifampin, and rifaximin	Yes	Yes	Limited therapy as part of therapy of mycobacterial diseases including tuberculosis and single drug therapy may select for resistance Potential transmission of *Mycobacterium* species from nonhuman sources
Carbapenems and other penems	Ertapenem, faropenem, imipenem, and meropenem	Yes	Yes	Limited therapy as part of treatment of disease due to MDR gram-negative bacteria Potential transmission of Enterobacteriaceae, including *E. coli* and *Salmonella* sprecies, from nonhuman sources
Cephalosporins, third and fourth generation	Cefixime, cefotaxime, cefpodoxime, ceftazidime, ceftizoxime, cefoperazone, cefoperazone-sulbactam, and ceftriaxone; cefepime, cefpirome, and cefoselis	Yes	Yes	Limited therapy for acute bacterial meningitis and disease due to *Salmonella* in children Fourth-generation cephalosporins provide limited therapy for empirical treatment of neutropenic patients with persistent fever Potential transmission of Enterobacteriaceae, including *E. coli* and *Salmonella* species, from nonhuman sources
Glycopeptides	Teicoplanin and vancomycin	Yes	Yes	Limited therapy for infection due to MDR *Staphylococcus aureus* and *Enterococcus* species Potential transmission of *Enterococcus* species and MDR *S. aureus* from nonhuman sources
Lipopeptides	Daptomycin	Yes	Yes	Limited therapy for infection due to MDR *S. aureus* Potential transmission of *Enterococcus* species and MDR *S. aureus* from nonhuman sources
Macrolides, including 14-, 15-, and 16-membered compounds, and ketolides	Azithromycin, clarithromycin, erythromycin, midecamycin, roxithromycin, spiramycin, and telithromycin	Yes	Yes	Limited therapy for infection due to *Legionella*, *Campylobacter*, and MDR *Salmonella* species Potential transmission of *Campylobacter* species from nonhuman sources
Oxazolidinones	Linezolid	Yes	Yes	Limited therapy for infection due to MDR *S. aureus* and *Enterococcus* species Potential transmission of *Enterococcus* species and MDR *S. aureus* from nonhuman sources
Penicillins, including natural penicillins, aminopenicillins, and antipseudomonals	Penicillin G, penicillin V, ampicillin, ampicillin-sulbactam, amoxicillin, amoxicillin-clavulanate, piperacillin, piperacillin-tazobactam, azlocillin, carbenicillin, mezlocillin, ticarcillin, and ticarcillin-clavulanate	Yes	Yes	Limited therapy for syphilis (natural penicillins), *Listeria* and *Enterococcus* species (aminopenicillins), and MDR *Pseudomonas* species (antipseudomonals) Potential transmission of *Enterococcus* species, Enterobacteriaceae (including *E. coli*), and *Pseudomonas aeruginosa* from nonhuman sources
Quinolones	Cinoxacin, nalidixic acid, and pipemidic acid; ciprofloxacin, enoxacin, gatifloxacin, gemifloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, and sparfloxacin	Yes	Yes	Limited therapy for *Campylobacter* species, invasive disease due to *Salmonella* species, and MDR *Shigella* species infection Potential transmission of *Campylobacter* species and Enterobacteriaceae, including *E. coli* and *Salmonella* species, from nonhuman sources
Streptogramins	quinupristin-dalfopristin and pristinamycin	Yes	Yes	Limited therapy for MDR *Enterococcus faecium* and *S. aureus* infection Potential transmission of *Enterococcus* species and MDR *S. aureus* from nonhuman sources
Tetracyclines and glycylcyclines	Tigecycline	Yes	Yes	Limited therapy for infection due to MDR *S. aureus*

Table 1. ***(Continued.)***

Antimicrobial class	Antimicrobial(s)	Criterion 1[a]	Criterion 2[b]	Comment(s)
Drugs used solely to treat tuberculosis or other mycobacterial diseases	Cycloserine, ethambutol, ethionamide, isoniazid, para-aminosalicylic acid, and pyrazinamide	Yes	Yes	Limited therapy for tuberculosis and other disease due to *Mycobacterium* species For many of these drugs, single drug therapy may select for resistance Potential transmission of *Mycobacterium* species from nonhuman sources

NOTE. From the World Health Organization meeting in Copenhagen, Denmark [18]. Both of the 2 criteria were met for classification as a *highly important* antimicrobial. MDR, multidrug-resistant.

[a] Criterion 1: the agent or class is the sole therapy or one of few alternatives to treat serious human disease.

[b] Criterion 2: the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases causes by organisms that may acquire resistance genes from nonhuman sources.

mans, the amphenicols were moved from the *important* to the *highly important* category.

- 5. Because of differing resistance mechanisms, the aminoglycosides were divided into 2 groups. As a result, 2 aminoglycosides (kanamycin and neomycin) were moved from the *critically important* to the *highly important* category.
- 6. Third- and fourth-generation cephalosporins were combined in the tables, because the mechanisms of action and antimicrobial resistance are similar.. The first- and second-generation cephalosporins were also combined.

PRIORITIZATION WITHIN THE *CRITICALLY IMPORTANT* CATEGORY

The WHO asked the consultants in Copenhagen to prioritize agents within the *critically important* category, to assist the allocation of resources toward agents for which risk management of antimicrobial resistance is needed most urgently. The consultants considered drugs to be of greatest priority if: (1) there are relatively large absolute numbers of people affected by diseases for which the drug is the sole alternative or one of few alternative therapies; (2) the overall frequency of use of the drugs in human medicine for any reason (whether appropriate or inappropriate) is relatively large; and (3) the drug is used to treat disease due to pathogens for which there is evidence regarding transmission of bacteria or their genes from nonhuman sources to humans (i.e., *E. coli*, *Campylobacter* species, and *Salmonella* species).

This prioritization resulted in the designation of quinolones, third- and fourth-generation cephalosporins, and macrolides as the classes for which risk-management strategies are needed most urgently. In the future, the WHO might consider convening a meeting of stakeholders to discuss the progress of various government agencies in addressing risk-management strategies for the use of these antimicrobials. In addition, there should be reliable, unbiased measures of the impact on resistance of any prudent-use guidelines or principles that are adopted by veterinary medical associations or animal production groups.

The expert panel emphasized that prioritization of these 3 classes of drugs should not minimize the importance of other drugs that are categorized as *critically important* on the list. Furthermore, any use of the ranking should consider regional differences, as noted above. Therefore, drugs that are not considered to be *critically important* in the list might be *critically important* in some developing countries (e.g., the importance of chloramphenicol might be increased because of a lack of access to cephalosporins).

Comments on the WHO classification of antimicrobial agents. The WHO criteria were developed with regard only to the importance of these antimicrobials in human medicine. Drug classes that are not used in humans and that are currently used only in animal medicine include arsenicals, bambermycins, ionophores, orthosomycins, quinoxalines, and others. The Office International des Épizooties (now known as the World Organisation for Animal Health) has undertaken a similar initiative to define critically important antimicrobial agents in veterinary medicine.

The classification in 2005 by the WHO was the first international attempt to classify antimicrobial agents on the basis of their importance in human medicine. The conclusions by the WHO panel in 2005 were unanimous on all drug classifications, with 1 exception [17]. There was significant discussion regarding the classification of natural penicillins and aminopenicillins. After thorough discussion, the consensus was that clinicians use both types of drugs as therapy when there are few other options for serious human disease, such as in the case of invasive enterococcal infection. This view was reinforced at the second WHO meeting in Copenhagen [18].

The purpose of the WHO classification is to serve as a factor in guiding decisions regarding risk management strategies for antimicrobial use in food animals and agriculture. Cost was not a primary consideration in developing the list of *critically important* antimicrobial agents, because there is little choice regarding cost when an antimicrobial agent is the sole alternative or one of few available alternatives to treat a disease.

The list will need to be updated regularly as new information becomes available, including data on resistance patterns, new and emerging diseases, and new drug development. It is also

Table 2. *Highly important* antimicrobials that are used in human medicine.

Antimicrobial class	Antimicrobial(s)	Criterion 1[a]	Criterion 2[b]	Comment(s)
Amidinopenicillins	Mecillinam	No[c]	Yes	Potential transmission of Enterobacteriaceae, including *Escherichia coli*, from nonhuman sources MDR *Shigella* species infections may be a regional problem
Aminoglycosides, other	Kanamycin, neomycin, and spectinomycin	No	Yes	Potential transmission of gram-negative bacteria that are cross-resistant to streptomycin from nonhuman sources
Amphenicols	Chloramphenicol and thiamphenicol	No[c]	Yes	May be 1 of limited therapies for acute bacterial meningitis, typhoid fever, and respiratory infections in certain geographic areas
Cephalosporins, first and second generation	Cefazolin, cephalexin, cephalothin, and cephradine	No	Yes	Potential transmission of Enterobacteriaceae, including *E. coli*, from nonhuman sources
Cephalosporins, second generation	Cefaclor, cefamandole, cefuroxime, and loracarbef	No	Yes	Potential transmission of Enterobacteriaceae, including *E. coli*, from non-human sources
Cephamycins	Cefotetan and cefoxitin	No	Yes	Potential transmission of Enterobacteriaceae, including *E. coli*, from nonhuman sources
Clofazimine	Clofazimine	Yes	No	Limited therapy for leprosy
Monobactams	Aztreonam	No	Yes	Potential transmission of Enterobacteriaceae, including *E. coli*, from nonhuman sources
Penicillins, antistaphylococcals	Cloxacillin, dicloxacillin, flucloxacillin, oxacillin, and nafcillin	No	Yes	*Staphylococcus aureus*, including methicillin-resistant *S. aureus*, has been transferred to humans from animals
Polymyxins	Colistin and polymyxin B	Yes	No	Polymyxins may be the only available therapy for some infections due to gram-negative bacteria (e.g., infection due to *Acinetobacter* species and *Pseudomonas aeruginosa*)
Sulfonamides, dihydrofolate reductase inhibitors, and combinations	Para-aminobenzoic acid, pyrimethamine, sulfadiazine, sulfamethoxazole, sulfapyridine, sulfisoxazole, and trimethoprim	No[c]	Yes	Potential transmission of Enterobacteriaceae, including *E. coli*, from nonhuman sources May be 1 of limited therapies for acute bacterial meningitis and other infections in certain geographic areas
Sulfones	Dapsone	Yes	No	Limited therapy for leprosy
Tetracyclines	Chlortetracycline, doxycycline, minocycline, oxytetracycline, and tetracycline	Yes	No	Limited therapy for infection due to *Chlamydia* species and *Rickettsia* species

NOTE. From the World Health Organization meeting in Copenhagen, Denmark [18]. One of the 2 following criteria were met for classification as a *highly important* antimicrobial: (1) the agent or class is the sole therapy or one of few alternatives to treat serious human disease; and (2) the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases causes by organisms that may acquire resistance genes from nonhuman sources. MDR, multidrug-resistant.

[a] Criterion 1: the agent or class is the sole therapy or one of few alternatives to treat serious human disease.

[b] Criterion 2: the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases causes by organisms that may acquire resistance genes from nonhuman sources.

[c] The importance of the class or antimicrobial may change on the basis of regional differences.

Table 3. *Important* antimicrobials that are used in human medicine.

Antimicrobial class	Antimicrobial(s)	Criterion 1[a]	Criterion 2[b]	Comment(s)
Cyclic polypeptides	Bacitracin	No	No	...
Fosfomycin	Fosfomycin	No[c]	No	May be 1 of limited therapies for Shiga toxin–producing *Escherichia coli* O157 in certain geographic areas
Fusidic acid	Fusidic acid	No[c]	No	May be 1 of limited therapies to treat multidrug-resistant *Staphylococcus aureus* infection in certain geographic areas
Lincosamides	Clindamycin and lincomycin	No	No	...
Mupirocin	Mupirocin	No	No	...
Nitrofurantoins	Furazolidone and nitrofurantoin	No	No	...
Nitroimidazoles	Metronidazole and tinidazole	No[c]	No	Criterion 1 was evaluated on the basis of antibacterial properties only May be 1 of limited therapies for some anaerobic infections, including *Clostridium difficile* infection, in certain geographic areas

NOTE. From the World Health Organization meeting in Copenhagen, Denmark [18]. Neither of the 2 following criteria were met for classification as an *important* antimicrobial: (1) the agent or class is the sole therapy or one of few alternatives to treat serious human disease; and (2) the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases causes by organisms that may acquire resistance genes from nonhuman sources.

[a] Criterion 1: the agent or class is the sole therapy or one of few alternatives to treat serious human disease.

[b] Criterion 2: the antimicrobial agent or class is used to treat diseases caused by organisms that may be transmitted via nonhuman sources or diseases causes by organisms that may acquire resistance genes from nonhuman sources.

[c] The importance of the class or antimicrobial may change on the basis of regional differences.

important to take into account that antimicrobial resistance may also develop slowly after a long period of usage. As an example, investigators first detected vancomycin resistance in *Enterococcus* after >40 years of vancomycin usage. Thus, even if resistance has not yet developed among particular groups of bacteria, it does not mean that it will not develop in the future.

CONCLUSION

The WHO lists are the first attempt to develop an international consensus on the relative importance of classes of antibacterial agents to human medicine to help guide risk management strategies for use of similar agents in food animal production and agriculture. Reducing the use of *critically important* antimicrobials in food animals will reduce the amount of resistant bacteria that can develop and spread. This will help mitigate a threat to human health and decrease morbidity and mortality in humans, by preserving effective treatments for use in the case of serious disease caused by these bacteria. We should strive to reduce the use of antimicrobials everywhere (and thus reduce resistance everywhere), including reduction of inappropriate use in humans for treatment of viral and fungal diseases, as well as for treatment of diseases in which the benefit of antibacterials is unclear (e.g., sinusitis and bronchitis). However, these lists allow us to focus initially on those agents that are *critically important* to human medicine.

The US Food and Drug Administration (FDA) has been particularly concerned about the extra-label use of cephalosporins (e.g., ceftiofur) in food animals, especially poultry [46]. The extra-label use of cephalosporins in food animals has contributed to emerging cephalosporin-resistant zoonotic foodborne bacteria. The FDA determined that extra-label use in animals presents a risk to the public health and, therefore, proposed a rule to prohibit the extra-label use of cephalosporins in food animals [46]. The rule was scheduled to take effect in November 2008, but the FDA has delayed implementation of the final rule to review comments by various stakeholders. However, there does not appear to be new scientific data to alter the risks and benefits to human health with respect to the use of cephalosporins in food-producing animals.

The same principles that were used in deriving this WHO antibacterial ranking apply for other pathogens and the drugs used to treat them, such as fungal diseases and antifungal agents. It is also critical to acknowledge that most research has involved organisms that directly cause disease, focusing less on important contributions by commensal bacteria, which carry antimicrobial resistance genes. Although these organisms generally do not cause disease in immunocompetent people, they can transfer resistance genes to other bacteria. It is possible that this phenomenon has occurred with some pathogenic bacteria, including *S. aureus*. The gene encoding methicillin resistance *(mecA)* may have originated from less-virulent coagulase-negative staphylococci. Horizontal transfer may occur relatively infrequently, but once the gene is established in a successful virulent clone, the clone and the carried gene can spread in individual countries and worldwide, such as in the case of multidrug-resistant *S. aureus* and pneumococci.

Table 4. Antimicrobial agents approved for use in human and veterinary medicine.

Category, antimicrobial class	Example(s) of antimicrobials used in human medicine	Example(s) of antimicrobials used in veterinary medicine or as growth promoters
Critically important		
Aminoglycosides	Amikacin, arbekacin, gentamicin, kanamycin, netilmicin, neomycin, tobramycin, and streptomycin	Amikacin, apramycin, gentamicin, neomycin, streptomycin, dihydrostreptomycin, kanamycin, framycetin, and paromomycin (aminosidine)
Ansamycins	Rifabutin, rifampin, and rifaximin	Rifampicin
Carbapenems and other penems	Ertapenem, faropenem, imipenem, meropenem, and doripenem	None approved or known to be used
Cephalosporins, third generation	Cefixime, cefotaxime, cefpodoxime, ceftazidime, ceftizoxime, cefoperazone, cefoperazone-sulbactam, and ceftriaxone	Cefpodoxime, ceftiofur, cefoperazone, and cefovecin
Cephalosporins, fourth generation	Cefipime, cefpirome, and cefoselis	Cefquinome
Lipopeptides	Daptomycin	None approved or known to be used
Glycopeptides	Teicoplanin and vancomycin	Avoparcin[a]
Macrolides, including 14-, 15-, and 16-membered compounds, and ketolides	Azithromycin, clarithromycin, erythromycin, midecamycin, roxithromycin, spiramycin, and telithromycin	Erythromycin, pirlimycin, spiramycin, tylosin, tulathromycin, kitasamycin, oleandomycin, tilmicosin, and jasamycin
Oxazolidinones	Linezolid	None approved or known to be used
Penicillins, aminopenicillins	Ampicillin-amoxicillin, ampicillin-sulbactam, amoxicillin-clavulanate, piperacillin, and piperacillin-tazobactam	Ampicillin-amoxicillin, ampicillin-sulbactam, and amoxicillin-clavulanate
Penicillins, natural	Penicillin G and penicillin V	Penicillin G and penicillin V
Quinolones	Cinoxacin, nalidixic acid, pipedemic acid, ciprofloxacin, enoxacin, gatifloxacin, gemifloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, and sparfloxacin	Nalidixic acid, oxolinic acid, flumequin, pipemidic acid, danofloxacin, difloxacin, enrofloxacin, ibafloxacin, marbofloxacin, sarafloxacin, orbifloxacin, and moxifloxacin
Streptogramins	Quinupristin-dalfopristin and pristinamycin	Virginiamycin[b]
Drugs used solely to treat tuberculosis or other mycobacterial disease	Cycloserine, ethambutol, ethionamide, isoniazid, para-aminosalicylic acid, and pyrazinamide	None approved or known to be used
Highly important		
Cephalosporins, first generation	Cefazolin, cephalexin, cephalothin, and cephradine	Cephalothin, cephalonium, cephalexin, cefadroxil, and cefazolin
Cephalosporins, second generation	Cefaclor, cefamandole, cefuroxime, and loracarbef	Cefuroxime
Cephamycins	Cefotetan and cefoxitin	None approved or known to be used
Clofazimine	Clofazimine	None approved or known to be used
Monobactams	Aztreonam	None approved or known to be used
Penicillins, aminopenicillins	Mecillinam	None approved or known to be used
Penicillins, antipseudomonals[c]	Azlocillin, carbenicillin, mezlocillin, ticarcillin, and ticarcillin-clavulanate	None approved or known to be used
Polymyxins	Polymyxin B and colistin	Polymyxin B and colistin
Spectinomycin	Spectinomycin	Spectinomycin
Sulfonamides, dihydrofolate reductase inhibitors, and combinations	Para-aminobenzoic acid, pyrimethamine, sulfadiazine, sulfamethoxazole, sulfapyridine, sulfisoxazole, and trimethoprim	Sulfadiazine, sulfadimidime, sulfadimethoxine, trimethoprim, and baquiloprim
Sulfones	dapsone (for treatment of leprosy)	None approved or known to be used
Tetracyclines	Chlortetracycline, doxycycline, minocycline, oxytetracycline, and tetracycline	Chlortetracycline, doxycycline, oxytetracycline, and tetracycline
Important		
Amphenicols	Chloramphenicol and thiophenicol	Chloramphenicol, florfenicol, and thiamphenicol
Cyclic polypeptides	Bacitracin	Bacitracin
Fosfomycin	Fosfomycin	Fosfomycin
Fusidic acid	Fusidic acid	Fusidic acid
Lincosamides	Clindamycin and lincomycin	Clindamycin and lincomycin
Mupirocin	Mupirocin	Mupirosin
Nitrofurans	Furazolidone, nitrofurantoin, and nitrofurazone	Furazolidone, nitrofurantoin, and nitrofurazone
Nitroimidazoles	Metronidazole and tinidazole	Metronidazole and dimetridazole
Penicillins, antistaphylococcals	Cloxacillin, dicloxacillin, flucloxacillin, methicillin, nafcillin, and oxacillin	Cloxacillin, nafcillin, methicillin, oxacillin, and dicloxacillin
Classes not used for human treatment		
Bambermycin	None approved or known to be used	Flavomycin

Table 4. ***(Continued.)***

Category, antimicrobial class	Example(s) of antimicrobials used in human medicine	Example(s) of antimicrobials used in veterinary medicine or as growth promoters
Novobiocin	Might be some use for humans in some countries	Novobiocin
Orthosomycins	None approved or known to be used	Avilamycin
Quinoxaline	None approved or known to be used	Olaquindox and carbadox
Pleuromutilins	None approved or known to be used	Tiamulin and valnemulin
Polyethers	None approved or known to be used	Monensin, salinomycin, lasalocid, and narasin[c]

NOTE. This table mainly includes antimicrobials approved for veterinary use in Australia, Europe, and the United States [14, 44, 45]; thus, it is not a complete list of antimicrobials used in all countries. Extra-label use of human drugs in food animal production is also a possibility. This table was reproduced from [13] with permission from the publisher.

[a] Until 2000, avoparcin was extensively used around the world (except in North America) as a growth promoter.

[b] Until 2000, virginiamycin was extensively used as a growth promoter in Europe. It is still used extensively in North America, Australia, and many other parts of the world.

[c] Extensively used for growth promotion and/or control of coccidiosis around the world.

Antimicrobial resistance, whether attributable to animal or human use, poses a threat to human health. The food animal reservoir is an important source of antimicrobial resistance, even though it might be difficult to quantify the exact burden, compared with human use. However, to ensure the future effectiveness of antimicrobials in therapy for human disease, the time to act is now. Protecting human health requires immediate development and implementation of risk-management strategies by government authorities for the use of fluoroquinolones, third- and fourth-generation cephalosporins, and macrolides in food-producing animals. The rankings provided by the WHO can assist the risk management process so that stakeholders can take appropriate actions that are urgently needed.

LIST OF WHO MEETING PARTICIPANTS

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LETTER FROM DR. ANNE A. GERSHON, M.D., WITH INFECTIOUS DISEASES SOCIETY OF AMERICA TO CHAIRWOMAN SLAUGHTER, DATED JULY 10, 2009

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July 10, 2009

The Honorable Representative Louise Slaughter
United States House of Representatives
2469 Rayburn House Office Building
Washington, DC 20510

Dear Representative Slaughter:

The Infectious Diseases Society of America is pleased to endorse H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act of 2009. As an organization that represents more than 8,600 infectious diseases physicians and scientists, our ultimate goal is to ensure that patients suffering from serious infections have access to effective anti-infective therapies.

The development of antimicrobial agents to treat life-threatening infections has been one of the most notable medical achievements of the past century. However, there is growing concern among infectious diseases specialists that antimicrobial agents' effectiveness in treating infections is becoming compromised by increasing bacterial resistance. Infectious diseases physicians care for patients with serious infections, including HIV/AIDS, meningitis, heart valve infections, severe bone, joint or wound infections, and those with cancer or transplants who have life-threatening infections caused by unusual organisms. Antimicrobial resistance can complicate the treatment of patients suffering from these infections, sometimes leading to serious disability or death.

Many factors contribute to the risk of antibiotic resistant infections, and the relationship between antimicrobial use in animals and the development of antibiotic resistant infections in humans is complex. However, there is a growing body of scientific evidence which demonstrates that antimicrobial use in livestock contributes to the spread of resistant bacteria to humans. This includes the direct acquisition of resistant pathogens through the food supply as well as the transfer of resistance genes to human bacterial populations. Despite uncertainties regarding the frequency and mechanisms of antibiotic resistance acquired from food animals, it is reasonable and prudent to conclude that the use of antimicrobials in food animals poses a threat to human health. For example, it is well-documented that fluoroquinolone use in poultry was a major source of fluoroquinolone-resistant Campylobacter infections in humans. The European Union recognized this threat in 2002 and decided to withdraw the use of antimicrobial growth promoters in food animals by 2006. In Denmark, where the use of antimicrobial growth promoters has been largely banned since 1998, the impact on poultry and swine production has been negligible.

The Preservation of Antibiotics for Medical Treatment Act of 2009 will help preserve the effectiveness of lifesaving antimicrobial drugs by phasing out their non-therapeutic use in U.S. food animals. Another important provision will automatically restrict the non-therapeutic use of antimicrobial agents that are currently approved only for use in animals, but which later may become important for human therapeutic use. Your bill represents sound public policy that will benefit patients and the public, while continuing to allow food producers to use antimicrobial agents to treat infectious diseases in animals.

Once again, IDSA applauds you for introducing the Preservation of Antibiotics for Medical Treatment Act of 2009. Antimicrobial agents are critical tools used by infectious diseases physicians and other physicians to treat life-threatening infections, and their continued effectiveness in combating these diseases must be protected. The Society and its members look forward to working with you to enact this important legislation. It is our hope that this letter will be of assistance in advancing the national dialogue on the issue of antimicrobial resistance.

Sincerely,

Anne A. Gershon, MD, FIDSA
President

PREPARED STATEMENT OF DR. FRANK MOLLER AARESTRUP AND DR. HENRIK WEGENER OF THE NATIONAL FOOD INSTITUTE, TECHNICAL UNIVERSITY OF DENMARK

Testimony of Dr. Frank Møller Aarestrup and Dr. Henrik Wegener
National Food Institute
Technical University of Denmark
Søborg, Denmark

For the U.S. House of Representatives Committee on Rules

Hearing on H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act of 2009
Submitted for the Record

July 13, 2009
Washington, D.C.

Thank you for the opportunity to submit written testimony on this important issue. As scientists working for the National Food Institute at the Technical University of Denmark, we have long studied the looming public health threat of antibiotic resistance (our curriculum vitae are attached at the conclusion of this testimony). We work closely with the U.S. Centers for Disease Control and Prevention, World Health Organization, the European Union and other individual countries to track and study the growing crisis due to the overuse of antibiotics in humans and animal agriculture. This testimony focuses on a study we recently concluded on what has become known as the "Danish experience" – a ban by the government of Denmark on the nontherapeutic use of antibiotics in the feed and water of swine.

The U.S. uses more antibiotics on a per pound basis in the production of meat and poultry, than any other developed country (see Figure 1). We believe you will find our research findings to be particularly helpful as your Congress and new Administration deliberate how to stem the rising tide of antibiotic resistance. As you may be aware, representatives of organizations funded by U.S. agri-business have criticized and mis-represented the facts on the Danish ban of antibiotics since its inception. Our goal is to set the record straight by presenting our key findings in this testimony. The data have been publicly available in the English reports of our national monitoring reports of drug usage and animal health. Furthermore, we have recently compiled the data for a more extensive publication in a scientific journal in the near future.

As way of background, soon after their discovery in 1928, antibiotics were introduced in veterinary medicine to treat sick farm animals and later to promote their growth. Since the 1950s, antibiotics have been an integral part of industrial food animal production. However, due to rising concerns over antibiotic-resistant bacteria transmitting from animals to humans, efforts to promote prudent use of antibiotics in food animal production were launched in many countries in the 1990s. Both Denmark and the European Union (EU) have taken regulatory actions on the non-therapeutic use of antibiotics in food animals. It is important to note here that while both the Danish and EU bans prohibit the inclusion of non-therapeutic antibiotics in animal feed , the full arsenal of antibiotics remains available to veterinarians to treat sick animals and herds. The

other important aspect is that this use requires a veterinarians prescription, the bulk of the drugs are sold by the pharmacy, not the prescribing vet (to limit financial incentives to prescribe), and that flouroquinolones, which are particularly important for human medicine, only can be administered by injection, not by feed or water.

Denmark is a major provider of pork in the world, producing more than 26 million swine and exporting 90 percent of the production each year. In 1998, the Danish government instituted a voluntary ban on the non-therapeutic use of antimicrobials in pork production at the finishing stage. Faced with a tax of $2.00 per pig if they did not comply with the voluntary ban, most producers did stop using antibiotics at the finishing stage. On January 1, 2000, Denmark banned non-therapeutic antimicrobials at both the weaning and finishing stages.

Key Findings:

- Total antibiotic usage for kg of pork decreased by more than 50 percent from 1992-2007 while overall swine productivity has significantly improved in total Danish pig production has increased by 43 percent (from 18.4 to 26.3 million pigs produced) and the average number of pigs produced per sow per year increased from 21 to 25 (an important indicator of swine health and welfare). (See Figure 2)
- The highest consumption of antimicrobials for swine occurred in 1992 (100 mg antimicrobial/kg pig produced) and the lowest in 1999 (31 mg/kg). Since then, the use has gradually increased to 47 mg/kg in 2007, in part due to the emergence and spread of a number of new infectious diseases. However, by way of comparison, the U.S. uses 250-300 mg/kg. (See Figure 1)
- Weaner mortality increased gradually from 1993 to 2003, but has reduced to pre-ban numbers. In addition, weaner average daily weight gain decreased slightly from 1992 to 2000, where after it has increased. Finisher mortality has been slowly increasing from 1993 to 2007. Finisher daily gain seems to be unaffected by the changes in drug usage. (See Figure 2)
- Although year-to-year variations in productivity of swine make it difficult to determine short-term impacts, it is clear that over the long-term, swine productivity has increased even as antimicrobial use has decreased.

These facts suggest that the discontinuation of non-therapeutic antibiotic use has not negatively impacted long-term swine productivity in Denmark. The facts outlined show that long-term swine production in Denmark has not been negatively impacted by the ban on non-therapeutic antibiotic use.

Please feel free to contact Professor Frank Møller Aarestrup, National Food Institute, Bülowsvej 27, DK-1790 Copenhagen V, Denmark for background materials or other information you may need.

Figure 1: Comparison of antimicrobial use on a pound per pound basis among top meat producing countries. On the U.S. line, the black bar is the estimate of 70 percent calculated by the Union of Concerned Scientists and the grey bar is the estimate calculated by the Animal Health Institute.

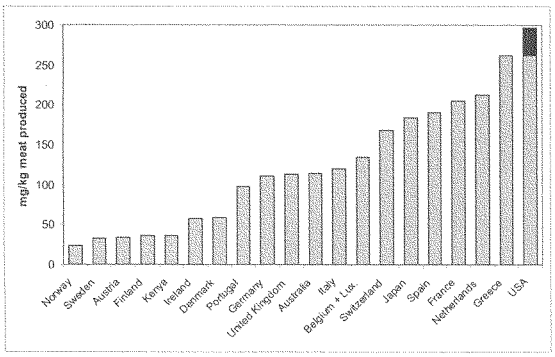
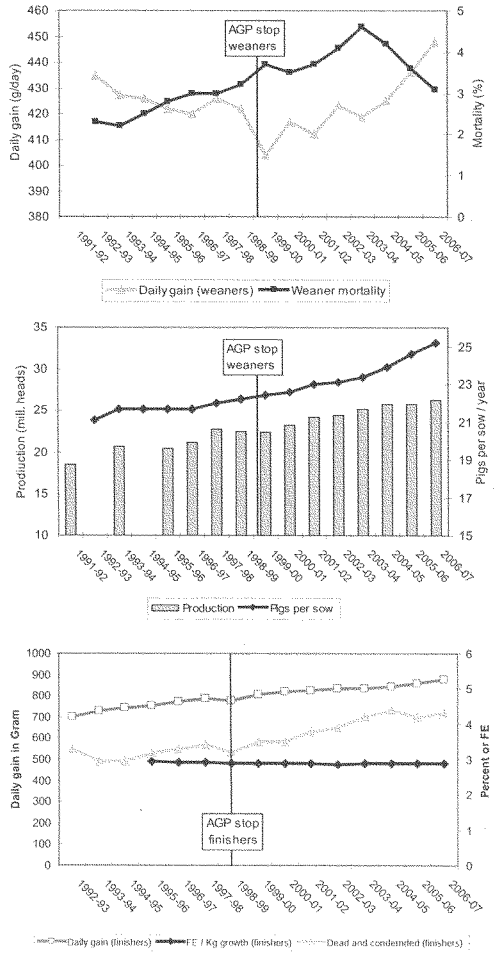


Figure 2: Selected productivity data from the Danish pig industry (http://www.dansksvineproduktion.dk) from October 1992 to October 2007. Each year indicated is from October to October, except the total production, which is the calendar year. Thus, the production for 1992 is given under 1991-92. The ban for finishers was April 1, 1998, and the ban for weaners was January 1st 2000. FE: feed units per kg produced meat.



TRANSCRIPT FROM THE SUBCOMMITTEE ON LIVESTOCK, DAIRY, AND POULTRY, COMMITTEE ON AGRICULTURE HEARING TO REVIEW THE ADVANCES OF ANIMAL HEALTH WITHIN THE LIVESTOCK INDUSTRY, THURSDAY, SEPTEMBER 25, 2008 *

* Previously printed by GPO, Serial No. 110–48 and can be accessed on the Committee of Agriculture's Website at http://agriculture.house.gov/testimony/110/110-48.pdf

KEEP ANTIBIOTICS WORKING FACT SHEET AND LETTER TO DR. JOSHUA SHARFSTEIN, MD, DEPUTY COMMISSIONER OF FDA FROM MR. RICHARD R. WOOD, CHAIR OF KEEP ANTIBIOTICS WORKING STEERING COMMITTEE

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The Campaign to End Antibiotic Overuse

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Safe Tables Our Priority (S.T.O.P.)

Sierra Club

Union of Concerned Scientists

Waterkeeper Alliance

FACT SHEET

Antibiotic Resistant Foodborne Pathogens - Intensifying the Food Safety Crisis

- Foodborne bacteria originating from the production of food animals cause severe and often life-threatening illnesses in the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 1.4 million people are infected with *Salmonella* each year and that there are 2.4 million *Campylobacter* infections. The USDA estimates that the cost of illness and death from *Salmonella* alone is 2.5 billion dollars each year.

- Increasingly, these foodborne infections are resistant to one or more antibiotics. CDC data shows that roughly one in five *Salmonella* infections is drug-resistant. Nearly 100,000 of these infections would resist treatment with at least five antibiotics. Roughly one-half of *Campylobacter* infections, or 1.2 million per year, are drug-resistant. Of these, 326,000 cases are resistant to two or more antibiotics

- Many other resistant, disease-causing bacteria are also found on farms and in food, including disease-causing *Escherichia coli*, *Enterococci*, Methicillin-resistant *Staphylococcus aureus* (MRSA), and *Clostridium difficile*. Bacteria made resistant on the farm can transfer resistance traits to other bacteria, including disease- causing bacteria found in the human body.

- Resistance increases the already high cost of foodborne disease. The hundreds of thousands of cases of resistant foodborne illness are more severe and lead to higher rates of hospitalization than ordinary contamination, which adds significantly to the nation's spiraling healthcare costs. Based on experience with MRSA, resistant infections can increase the cost of illness by 40 to 50 percent.

- Foodborne bacteria carry high levels of resistance traits because large amount of antibiotics are given to food producing animals often in feed and water for growth promotion and other non-therapeutic purposes. Studies have consistently shown that feeding low doses of antibiotics to large numbers of food animals over long periods of time leads to resistance.

- Antimicrobial resistance is a global problem and imported foods can also be a source of resistant pathogens. In 2007 the FDA imposed import controls on Chinese seafood because of concerns about antibiotic resistance. Chinese fish farmers often use antibiotics, like fluouroquinolones, that are prohibited for use in the U.S.

- The federal government needs to act on this serious food safety problem. FDA's food safety initiative should review the safety of antibiotics used in animal feeds in light of the threat of antimicrobial resistance and remove from the market any products that are unsafe. Imports should be monitored for the presence of resistant bacteria.

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Natural Resources Defense Council

Physicians for Social Responsibility

Safe Tables Our Priority (S.T.O.P.)

Sierra Club

Union of Concerned Scientists

Waterkeeper Alliance

April 2, 2009

Joshua Sharfstein, MD
Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Dear Deputy Commissioner Sharfstein:

On behalf of the undersigned groups and Keep Antibiotics Working (KAW), a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups working to protect the efficacy of antibiotics in both human and veterinary medicine, we ask that you take quick action to respond to the growing crisis of antimicrobial resistance related to veterinary drug use in the United States.

As you are aware, the overuse and misuse of antibiotics in both human and animal medicine is responsible for the crisis of antibiotic resistance: drug treatments that no longer work, more severe and debilitating disease, and escalating medical costs. This crisis demands a comprehensive response from the FDA.

Despite a long recognition of the problem, the FDA has delayed taking actions that are necessary to protect public health. In particular, the FDA has failed to protect the public from the rapid growth of resistance to cephalosporins in food-producing animals and has failed to complete and act on reviews of the resistance implications of existing veterinary drug approvals.

The undersigned groups ask that you immediately take the following three steps:

First, formally reject the application to approve 4th generation cephalosporins for use in food-producing animals.

Second, reissue the ban on the extra-label use of cephalosporins in food-producing animals.

Third, make public the findings of FDA's review of penicillin and other veterinary drugs currently on the market, and take appropriate action on any drugs shown to be unsafe.

In taking these steps, you would help protect the efficacy of antimicrobials vital for treatment of human and animal diseases. Prompt action is urgently needed on the cephalosporin class of drugs, which are critically important for the treatment of serious infections in children, including those caused by *Salmonella* (Shea, 2004). The ongoing outbreak of *Salmonella* Typhimurium in peanut products that has resulted in over 100 hospitalizations, and a likely 9 deaths, illustrates the importance of this class of drugs. One in five of the patients affected by the contaminated peanuts were children under the age of 5 (CDC, 2009). Fortunately, in this case the *Salmonella* strain was susceptible to drugs used for treatment, but next time we may not be so lucky.

Resistance to cephalosporins in human and animal Salmonella isolates is on the rise and numerous studies connect the increase to the use of cephalosporin drugs in food-producing animals. It is urgent that you address the inappropriate use of cephalosporins in food-producing animals.

Reject the application to approve 4th generation cephalosporins

In September 2006, the FDA Veterinary Medicine Advisory Committee (VMAC) met to consider the application for the approval of the first fourth generation cephalosporin, cefquinome, to be used for disease treatment in food-producing animals, specifically bovine respiratory disease in beef cattle. The major medical organizations American Medical Association, Infectious Disease Society of America, and the American Academy of Pediatrics all opposed its approval because of concerns about losing cephalosporins for treatment of serious human illness. The U.S. Center for Disease Control (CDC) also raised concerns about the approval of this drug. At the end of the meeting, a majority of the committee members voted that the sponsor had failed to show cefquinome was safe with respect to antimicrobial resistance. The FDA has yet to formally reject the application.

KAW also opposed the application. Bovine respiratory disease is common in cattle and cefquinome, if approved, would be widely used in feedlots, where it could select for cephalosporin-resistant bacteria with an easy path back to human populations. KAW was particularly concerned about the potential for widespread cefquinome use leading to the spread of a specific class of enzymes, CTX-M extended spectrum beta-lactamases. The CTX-M class of enzymes is capable of destroying 4th generation cephalosporins and other newer cephalosporin drugs. These resistance enzymes have not been detected in food-producing animals in the U.S., but have been detected on farms and in food in other countries where cefquinome is used. KAW was concerned cefquinome's approval would promote the rise of CTX-M class enzymes in the United States.

In the intervening 2 years, new evidence has come to light documenting a new and more immediate resistance concern. In the U.S., resistance to 3rd generation cephalosporins, which are approved for use in food-producing animals in the U.S., has been conferred mainly by two different enzymes, TEM and AmpC beta-lactamases (Frye, 2008). Until recently, it was believed that these enzymes were incapable of breaking down cefquinome and related cephalosporins, but there is new evidence that mutations in

genes conferring these types of resistance are threatening the 4th generation cephalosporins (Ahmed and Shimamoto, 2008; Gniadkowski, 2008; Kim et al, 2006; Mammeri et al., 2007; Mammeri et al, 2008a; Wachino et al., 2006). The new versions of AmpC beta-lactamases also put at risk non-cephalosporin drugs such as carbapenems (Mammeri et al., 2008b).

We are concerned that the approval of cefquinome for use in the U.S. food animal environment where there are already high levels of bacteria with genes producing AmpC and TEM enzymes could create an ideal situation for spreading the new mutants. The same conditions also encourage the rise of the CTX-M resistance genes. Either way, the continued efficacy of cephalosporins is at risk. To preserve the valuable cephalosporin class of drugs, KAW and the undersigned groups ask that you formally reject the approval of cefquinome for use in food-producing animals, especially in light of the new studies on AmpC and TEM enzymes.

Reissue the order prohibiting the extra-label use of cephalosporins

Cephalosporins, like many drugs, are used for purposes other than those indicated on labels. This use is legal unless the FDA specifically prohibits it. The FDA did just that in an order published July 3, 2008 in the *Federal Register*, which determined that the extra-label use of cephalosporins in food-producing animals presents a risk to human health and should be prohibited. The CDC, in a letter to CVM Director Dunham dated November 7, 2008, agreed with the FDA's assessment and supported the decision. As KAW noted in comments on the notice of the ban (attached), the evidence from both the National Antimicrobial Resistance Monitoring System (NARMS) plus additional evidence from Canada (not cited by FDA) provide strong evidence that extralabel use of cephalosporins in poultry hatcheries has led to the increase in serious resistant *Salmonella* infections in humans.

On November 28, 2008 the FDA revoked the order prohibiting the extra-label use of cephalosporins in food-producing animals. The FDA did not provide reasons for withdrawing the order beyond stating that they had received many comments on the order. KAW has reviewed the comments submitted to the FDA on the order (Docket Number FDA-2008-N-0326) and found nothing in them that warrants FDA's withdrawal of the prohibition. The most cogent of the arguments in the comments against the order were objections that FDA has not shown that every individual extra-label use of cephalosporins creates a risk, so therefore FDA should only take action on specific identified risks. In our view, FDA's determination in its initial decision that it would not select among different classes of cephalosporin drugs was wise. It is reasonable to assume that each use of this class of drugs creates an incremental risk without obtaining specific data on the risks of each possible extra-label use. Collecting the data on all possible or even likely uses would cause unreasonable delay and waste resources if it is even doable given FDA's lack of ability to collect data on how approved antimicrobials are used.

We are aware that veterinarians have been using large amounts of cephalosporins drugs for extra-label purposes. As noted above, such use is legal and it is understandable that veterinarians would prefer to have at hand as large an arsenal as possible. But in this case, the drug class at issue, the cephalosporins, is simply too valuable to human and veterinary medicine to continue to allow extra-label uses in the face of data showing that those uses are leading to resistant disease in humans.

In addition, KAW's review of the comments did not identify any extra-label veterinary indications for which there are not currently alternative drugs. Despite FDA providing an extra month for comments, the major producer organizations did not provide a single peer reviewed article supporting the claim that extra-label cephalosporin use is essential for animal health. Where research articles supporting the claim were mentioned in comments, we found evidence of alternative treatments for the identified indications in the cited articles. For example, the American Association of Bovine Practitioners (AABP) comments cite a review of studies on antimicrobial therapies for the treatment of keratoconjunctivitis in cattle (O'Connor, 2006). The review noted cephalosporins were effective, but also identified 6 other antimicrobial treatments for this indication including the antimicrobial oxytetracycline, a drug with far less significance for human medicine than cephalosporins.

There is no valid scientific reason to withdraw the order. It should be reissued immediately.

Publish reviews of existing veterinary drug approvals

In October 2003, the 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* describing a new qualitative method to be used to assess the safety of drugs with respect to antimicrobial resistance. At that time, FDA stated in public meetings the intention was to apply the Guidance #152 to existing as well as new approvals starting with uses of penicillins and tetracyclines in feed. The 2004 FDA Center for Veterinary Medicine (CVM) annual report stated that reviews of the uses of penicillins based on Guidance #152 were completed and that reviews of tetracyclines had been started. Letters were sent in 2004 to sponsors of penicillin stating that FDA had found that certain feed uses of penicillins were inappropriate. The 2005 CVM annual report once again mentioned the review of penicillin and tetracycline stating the penicillin review was completed and tetracycline reviews were ongoing. The 2006 and 2007 annual reports, however, fail to mention reviews of any existing approvals and no action has been taken to limit or cancel approvals for either class of drug.

KAW and the undersigned groups ask that FDA make public its findings on the safety of these approved drugs. If justified by the findings, we ask you to initiate appropriate action on any approved antimicrobial drugs that have been shown to be unsafe.

Addressing drugs already on the market, in particular the penicillins and tetracyclines, also has implications for the spread of cephalosporin resistance. Because cephalosporins

are chemically related to penicillins, bacteria resistant to cephalosporins are often also resistant to penicillin. Recent studies suggest that repeated exposure of bacterial populations to different beta-lactam antibiotics including both penicillins and cephalosporins may lead to bacteria developing resistance to a wider range of beta-lactam drugs than would occur with exposure to either penicillin or cephalosporins alone (Blazquez et al., 2000).

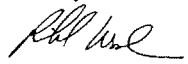
In addition, cephalosporin resistance in food-producing animals in the United States is often carried on mobile genetic elements that include determinants conferring resistance to tetracycline (Lynne et al., 2008). Since the selection of any of one of determinants on the mobile element will select for all of them, it is likely that the ongoing use of both penicillins and tetracycline is contributing to the selection and dissemination of cephalosporin resistance on farms. NARMS data support that concern. In 2005, NARMS found that 68.3% of human and 81.7% of cattle isolates of *Salmonella* resistant to ceftiofur were also resistant to tetracycline as well as a number of other drugs (FDA, 2009). The role of the ongoing uses of already approved drugs in driving resistance to newer, often chemically unrelated, drugs through linked multidrug resistance elements underscores the urgency of reviewing the safety implications of already approved drugs.

Summary

KAW and the undersigned groups ask that you act quickly to address the risks to human and animal health resulting from the inappropriate use of antimicrobial drugs in food-producing animals by: 1) making a final decision against the approval of cefquinome for use in food-producing animals, 2) reissuing the prohibition against extra-label use of cephalosporins in food-producing animals, and 3) making public findings of the reviews of penicillin and taking appropriate action on any uses of penicillin shown to be unsafe.

Thank you for considering our views.

Sincerely,



Richard R Wood
Chair, Keep Antibiotics Working Steering Committee,
and the following organizations:

American Academy of Pediatrics
Consumer Federation of America
Center for Food Safety
Center for Science in the Public Interest
Environmental Defense Fund
Food Animal Concerns Trust
Humane Society of the United States
Institute for Agriculture and Trade Policy

Safe Tables Our Priority
Union of Concerned Scientists

cc: Dr. Bernadette Dunham
Director, FDA Center for Veterinary Medicine

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ARTICLE BY LANCE B. PRICE, ET AL., ENTITLED "FLOUROQUINOLONE-RESISTANT CAMPYLOBACTER ISOLATES FROM CONVENTIONAL AND ANTIBIOTIC-FREE CHICKEN PRODUCTS

Fluoroquinolone-Resistant *Campylobacter* Isolates from Conventional and Antibiotic-Free Chicken Products

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The use of fluoroquinolones (FQs) in poultry production is an important issue in public health today. In February 2002, two prominent U.S. poultry companies pledged to stop using FQs for flock-wide treatment. One year later, we began a survey of *Campylobacter* isolates on chicken products from these two companies and from two producers claiming total abstention from antibiotic use. Using both standard isolation methods and new methods modified to enhance detection of FQ-resistant *Campylobacter*, we compared rates of FQ-resistant *Campylobacter* among these products. Four major findings were drawn from this study: *a*) antibiotic-free brands were not more likely to be contaminated with *Campylobacter*; *b*) a high percentage of products from the two conventional brands were contaminated with FQ-resistant *Campylobacter* (43 and 96%); *c*) these conventional brands had significantly higher odds of carrying resistant strains compared with antibiotic-free products; and *d*) supplementing media with FQs increased the sensitivity of detecting FQ-resistant strains among mixed populations of *Campylobacter*, thus reducing a bias toward underestimating the prevalence of FQ-resistant *Campylobacter* on samples. These results suggest that FQ resistance may persist in the commercial poultry environment in the absence of FQ-selective pressure and that these strains contaminate a larger proportion of foods than reported previously. *Key words:* bacterial, *Campylobacter*, chickens, drug resistance, drugs, fluoroquinolones, food microbiology, methods, poultry, veterinary. *Environ Health Perspect* 113:557–560 (2005). doi:10.1289/ehp.7647 available via *http://dx.doi.org/* [Online 2 February 2005]

Microbiologic and epidemiologic investigations have begun to elucidate the major sources of fluoroquinolone (FQ)-resistant *Campylobacter* infections in the United States. Major findings include the following: *a*) an increasing proportion of isolates collected in the United States from human *Campylobacter* infections are resistant to FQs [Allos 2001; Centers for Disease Control and Prevention (CDC) 2003; Nachamkin et al. 2002]; *b*) studies of human stool samples taken before FQ therapy indicate that most of the infections were resistant before treatment (Gaunt and Piddock 1996; Smith et al. 1999); *c*) epidemiologic studies indicate that fresh poultry products are the major sources of *Campylobacter* infections in humans (Harris et al. 1986; Neimann et al. 2003); *d*) FQ-resistant *Campylobacter* populations develop quickly in *Campylobacter*-infected chickens that are treated with FQs (McDermott et al. 2002); and *e*) in the United States, consumer-ready fresh poultry products are commonly contaminated with FQ-resistant strains of *Campylobacter* (Ge et al. 2003). It has been inferred from these findings that a large number of FQ-resistant *Campylobacter* infections in humans are the result of FQ use in the poultry house. Some of the strongest evidence to support this connection comes from a recent study of human campylobacteriosis in Australia, where despite regular clinical use of FQs and normal rates of *Campylobacter* infection, there are no confirmed cases of domestically acquired FQ-resistant campylobacteriosis (Unicomb et al. 2003). The authors concluded that this dramatic phenomenon is likely related to Australia's prohibition of FQ use in poultry production.

FQs, Sara Flox WSP (sarafloxacin water-soluble powder; Abbott Laboratories, North Chicago, IL) and Baytril (enrofloxacin; Bayer Corporation, Shawnee Mission, KS), have been approved for use in the United States to control *Escherichia coli* infections in broiler chickens since 1995 and 1996, respectively [Food and Drug Administration (FDA) 1995, 1996]. In October 2000, the FDA's Center for Veterinary Medicine announced that it intended to withdraw approval for FQs in poultry production because new evidence had shown that it may not be safe for human health (FDA 2000a). In March 2004, the FDA's regulation was upheld in court, but Bayer has appealed this decision. Although this battle continues, Baytril continues to be marketed for use as a drinking water additive for flock-wide application in broiler production. The exact number of birds treated with Baytril annually is not publicly available, but Bayer estimated that < 1% of the American poultry flock was treated with the drug in 2001 (Bayer Healthcare 2004). Given the enormous scale of the American poultry flock (~ 8.4 billion in 2001), this estimate indicates that up to 84 million birds may be treated with Baytril annually [U.S. Department of Agriculture (USDA) 2002]. In February 2002, in response to public concerns regarding FQ use in poultry production, two major U.S. producers, Tyson and Perdue, separately announced that they would stop using FQs in drinking water to treat poultry flocks (Perdue Farms 2002; Tyson Foods 2002).

A recent survey of *Campylobacter* from raw poultry products indicated that 35% of isolates were resistant to ciprofloxacin (CIP) (Ge et al. 2003). Ge et al. (2003) used standard FDA methodologies in which *Campylobacter* colonies were isolated on *Campylobacter* media and a small sample of colonies (typically no more than three) was tested for susceptibility to FQs. Because poultry products are often contaminated with mixed populations of *Campylobacter* strains with differing FQ susceptibilities, this assay has questionable sensitivity, and the 35% figure reported previously is considered to underestimate the actual prevalence of FQ-resistant strains (FDA 2000b).

In the present study, we performed a survey of fresh poultry products from two of the countries largest conventional producers, Tyson Foods and Perdue Farms, and two "antibiotic-free" producers, Bell & Evans and Eberly. *Campylobacter* strains were isolated using standard FDA methodology and also by a modified method that included FQ-supplemented agar medium to identify resistant strains among a mix of susceptible and resistant strains. We analyzed our results comparing FQ-resistant *Campylobacter* carriage among the two "antibiotic-free" and the two conventional brands and tested the increased sensitivity gained by using FQ-supplemented agar.

Materials and Methods

Sampling and enrichment. Fresh chicken products from two antibiotic-free producers, Bell & Evans (Fredericksburg, PA; A) and Eberly Poultry (Stevens, PA; B), and two conventional producers, Perdue Farms (Salisbury, MD; C), and Tyson Foods (Springdale, AR; D), were purchased seven to eight times from grocery stores in the Baltimore, Maryland, area over the course of 10 weeks (from 25 February to 13 May 2003; Table 1). All samples were purchased in packaging applied

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at the processing plant, and all products were "bone-in" and "skin-on" (i.e., not skinless boneless products). On most occasions, three separate packages from the four producers were purchased each time; all three samples were purchased from the same grocer on a given date and were typically from the same production lot. Packages were refrigerated at 4°C until they were sampled (within 48 hr of purchase).

A single piece of chicken was sampled from each package. The package was wiped with 70% ethanol and cut open with a new disposable razor blade, and the plastic cover was removed and photocopied for record keeping. Sterile forceps were used to transfer a single piece of chicken to a stomacher bag containing 200 mL sterile Bolton broth supplemented with laked horse blood (Oxoid, Ogdensburg, NY; Quad Five, Ryegate, MT). Samples were then shaken by hand for 2 min. Chicken was removed using forceps, and the bag was sealed 1–2 cm above the top of the broth. Enrichments were incubated at 42°C for 22–26 hr.

Isolation. Ten microliters of the enrichment [~ 10^6 colony forming units (CFU)] was streaked onto Abeyta-Hunt agar (Hunt et al. 2000) with and without 4 µg/mL CIP (U.S. Biological, Swampscott, MA) and incubated for 22–26 hr at 42°C. A single typical *Campylobacter* colony from each of the two media was streaked for isolated colonies on *Campylobacter* blood agar (Fisher Scientific, Hampton, NH). A single purified colony was then streaked for confluent growth on *Campylobacter* blood agar and incubated for 22–26 hr. A 10-µL loopful of cellular material was transferred to *Campylobacter* freezing medium (Hunt et al. 2000).

DNA isolation. DNA was isolated from a second loopful of material using the DNeasy tissue kit (Qiagen, Valencia, CA).

Species confirmation. Presumptive *Campylobacter* isolates were confirmed and the species identified using a polymerase chain reaction (PCR) amplification/restriction digest protocol described previously (Engvall et al. 2002). Briefly, THERM1 and THERM4 PCR primers were used to amplify a region of DNA specific to thermophilic members of the genus *Campylobacter*. This PCR product was then digested in two separate reactions using the restriction endonucleases *Alu*I and *Tsp*509I. The species-specific restriction patterns produced from this digestion enabled us to identify the species of each isolate.

Susceptibility. Susceptibility to CIP was determined using standard Clinical and Laboratory Standards Institute and *Campylobacter*-specific methods described previously (McDermott and Walker 2003). Briefly, *Campylobacter* isolates were grown overnight on *Campylobacter* blood agar (Fisher) under microaerophilic conditions. Colonies were suspended to approximately 0.5 McFarland standard in Mueller-Hinton broth and inoculated onto Mueller-Hinton agar supplemented with 5% sheep blood and CIP (U.S. Biological) ranging from 0.12 to 32 µg/mL. Plates were grown 22–26 hr at 42°C under microaerophilic conditions. The reference strain used was *Campylobacter jejuni* ATCC 33560 (American Type Culture Collection, Rockville, MD). Strains were designated resistant if their minimum inhibitory concentration was > 4 µg/mL.

gyrA QRDR sequence analysis. The nucleotide sequence of the quinolone-resistance–determining region (QRDR) of *gyrA* was sequenced from isolates using the following primer pair designed from the *Campylobacter* whole-genome DNA sequence (Parkhill et al. 2000): Cj gyrA QRDR F, GCC TGA CGC AAG AGA TGG TTT A; and Cj gyrA QRDR R, TAT GAG GCG GGA TGT TTG TCG. Multilocus sequence typing analysis was used to further characterize some isolates as described previously (Dingle et al. 2001).

Statistical analysis. We performed statistical analyses using Stata 8.0 (StataCorp, College Station, TX). We used Fisher's exact tests to compare the rates of undifferentiated *Campylobacter* (susceptible and resistant) carriage and FQ-resistant *Campylobacter* carriage across the brands. Odds ratios (ORs) of undifferentiated and FQ-resistant *Campylobacter* carriage with corresponding exact 95% confidence intervals (CIs) were computed for all pair-wise comparisons across the brands.

Results

Overall, *Campylobacter* was detected on 84% of the chicken tested, and FQ-resistant strains were detected on 17% using unsupplemented media and on 40% using agar supplemented with 4 µg/mL CIP (Table 2). When the two methods resulted in the isolation of strain pairs of different FQ susceptibilities, analysis of the *gyrA*, *aspA*, *glnA*, *gltA*, *glyA*, *pgm*, and *tkt* genes from the two isolates revealed that most of these pairs (19 of 21) also differed at two or more nucleotides (data not shown). That is to say, 19 of the 21 resistant isolates were shown to be genetically unique from their susceptible counterparts and would have been missed using standard isolation techniques (i.e., unsupplemented media). In contrast, only two strains were found to be within a single polymorphism (among the seven genes examined) of their susceptible counterparts. Therefore, as potential sporadic mutants isolated by chance, these two strains represent the maximum potential loss in assay specificity.

DNA sequence analysis of the *gyrA* gene revealed that all resistant strains isolated in this survey had a Thr86→Ile substitution, as reported previously by Wang et al. (1993).

Using Fisher's exact test, we were able to reject the null hypothesis that the rates of undifferentiated *Campylobacter* (susceptible and resistant) carriage are the same for all the brands ($p < 0.001$). Table 3 displays the pair-wise odds ratios of undifferentiated *Campylobacter* carriage and exact 95% CIs among the brands. We found that brand A (antibiotic-free) had significantly lower carriage rates compared with the other producers.

Given the robustness of the selective assay data, all comparative statistical analyses were performed using the data resulting from the CIP-supplemented media. We found statistically significant differences in the rates of FQ-resistant *Campylobacter* carriage across the brands (Fisher's exact test, $p < 0.001$). The pair-wise analysis of FQ-resistant *Campylobacter* carriage among the brands is presented in Table 4. Brand D (conventional) had a 96% carriage rate for FQ-resistant *Campylobacter* and significantly higher odds of carrying these

Table 1. Summary of dates and samples tested.

	Purchase dates							
Brand	25 Feb	4 Mar	11 Mar	25 Mar	1 Apr	22 Apr	29 Apr	13 May
A	T	T	T	T	T	T	T	T
B[a]	N	W	W	W	W	D	D	L
C	T	T	T	T	T	N	T	T
D	T	T	T	T	T	T	T	T

Abbreviations: D, drumstick; L, leg; N, no sample; T, thigh; W, whole chicken.
[a]Thighs from antibiotic-free brand B were not available in the Baltimore area at the time of the sampling.

Table 2. Percentage (*n*) of samples testing positive for *Campylobacter* and FQ-resistant *Campylobacter* carriage, by brand and medium.

	Brand (no. of samples)	Undifferentiated *Campylobacter*	Nonselective medium, CIP-resistant *Campylobacter*	Selective medium, CIP-resistant *Campylobacter*
Antibiotic-free	A (24)	54 (13)	13 (3)	13 (3)
	B (21)	95 (20)	0 (0)	5 (1)
Conventional	C (21)	90 (19)	19 (4)	43 (9)
	D (24)	100 (24)	33 (8)	96 (23)
Total	All (90)	84 (76)	17 (15)	40 (36)

strains than did each of the other brands. The biggest difference in odds of FQ-resistant *Campylobacter* carriage was observed when comparing brand D with brand B (antibiotic-free). Specifically, we estimated that the odds of FQ-resistant carriage in brand D was 460 times greater than the odds of FQ-resistant carriage in brand B (95% CI, 21.7–19766.8). There was no significant difference between the two antibiotic-free brands when compared with one another.

Discussion

Limitations of the study. The present study has three primary limitations. First, the study was limited in the number of stores sampled and its geographical region. However, this was not likely to reduce the generalizability of the results because we used products that are widely distributed in the United States. Moreover, we carefully selected packages that were sealed at the processing facility by the producer so that store-related factors would not affect the prevalence of FQ-resistant *Campylobacter*. Second, the sampling period (25 February to 13 May 2003) was relatively short. Because of this, we could not detect any potential seasonal variation in carriage rates. Finally, we were not able to test the same cut (e.g., thigh) each time from each producer, which would have been ideal. This was because thighs were not available for brand B during the testing period. However, given that we measured the presence or absence of *Campylobacter* on chicken products, rather than the quantity of *Campylobacter* on a given sample, this variation likely did not affect the overall outcome of the study.

Table 3. Pair-wise comparisons of the odds of undifferentiated *Campylobacter* (susceptible and resistant) carriage among brands.

Reference brand	Comparison brand	OR[a] (95% CI)[b]	*p*-Value[c]
A	B	16.9 (1.9–763.8)	< 0.01
	C	8.0 (1.3–85.6)	0.01
	D	40.6 (4.8–∞)	< 0.01
B	C	0.5 (0.01–10.0)	> 0.99
	D	2.4 (0.0–∞)	0.47
C	D	5.0 (0.61–∞)	0.21

[a]Zero counts were replaced with 0.5 in order to estimate ORs for comparisons with D. [b]95% CIs are based on exact methods; upper bounds of the 95% CI were not estimable for comparisons with D. [c]Based on Fisher's exact test for each pair-wise comparison.

***Lingering FQ-resistant* Campylobacter.** On 18 February 2002, Tyson announced that it planned to discontinue FQ use and estimated use in previous years to be approximately 0.2% (Tyson Foods 2002). Shortly thereafter, on 25 February 2002, Perdue announced that they would immediately stop using FQ and also claimed FQs had not been used within the previous year (Perdue Farms 2002). However, 1 year later, we found significant proportions of products from both of these companies that carried FQ-resistant strains of *Campylobacter*. Accepting the veracity of these announcements, our data suggest that past FQ use may have persistent effects on *Campylobacter* populations in poultry houses. This is consistent with reports from Denmark indicating that vancomycin-resistant enterococci could be isolated from broiler flocks 5 years after avoparcin was banned for use in broilers in that country (Heuer et al. 2002). These studies challenge the notion that resistant populations will quickly revert to a susceptible state once antimicrobial pressure is removed. Indeed, models indicate that microbes may be more likely to develop compensatory mutations that ease the metabolic costs of resistance determinants rather than simply revert back to a susceptible phenotype (Levin et al. 2000).

Inadequate hygiene. If what we observed is an indication of lingering resistance, it may be important to improve cleaning and disinfection between flocks. Biofilms in water distribution systems have been identified as potential sources of *Campylobacter* infection in poultry houses (Trachoo et al. 2002). Baytril is administered through poultry drinking water systems; therefore, this could be an important reservoir of FQ-resistant *Campylobacter*. Studies using molecular fingerprinting techniques have provided mixed indications of the importance of insufficient floor sanitation to the carryover of *Campylobacter* isolates, and it is clear that some strains do persist from flock to flock (Petersen and Wedderkopp 2001; Shreeve et al. 2002). This problem may be magnified in the United States, where many poultry houses are built with dirt floors and are typically cleaned only every 2–3 years (Hayes et al. 2000). This practice may support a long-term reservoir for FQ-resistant *Campylobacter* infections of subsequent flocks.

Table 4. Pair-wise comparisons of the odds of FQ-resistant *Campylobacter* carriage among brands.

Reference brand	Comparison brand	OR (95% CI)	*p*-Value
A	B	0.4 (0.01–4.9)	0.61
	C	5.3 (1.0–34.7)	0.04
	D	161.0 (13.5–6924.0)	< 0.01
B	C	15.0 (1.6–689.3)	< 0.01
	D	460.0 (21.7–19766.8)	< 0.01
C	D	30.7 (3.3–1365.6)	< 0.01
"Antibiotic-free"	Conventional	25.2 (6.8–111.4)	< 0.01

Cross-contamination. The microbes on fresh poultry products may reflect the cecal contents of the individual bird at harvest as well as conditions in the processing plant. Modern plants can process > 200,000 broilers/day, and *Campylobacter* strains found on poultry carcasses after processing can be significantly different from those found in the flock before slaughter (Newell et al. 2001). Therefore, the presence of antimicrobial-resistant *Campylobacter* on a particular broiler carcass may result from contamination of the slaughter equipment by a broiler flock processed previously. This issue is particularly relevant to the antibiotic-free producers whose broiler products may become contaminated with antimicrobial-resistant bacteria in abattoirs that process both antibiotic-free and conventional flocks. Both of the antibiotic-free producers included in this study process their broilers in facilities that are also used for antimicrobial-treated flocks. However, no FQ-treated flocks are said to be processed in the brand A abattoir (Ranck S, personal communication). Such a claim could not be made for the brand B abattoir (Carson E, personal communication).

Enhancing the sensitivity of detecting antibiotic resistance in food isolates. The sensitivity of antibiotic resistance surveys can be significantly enhanced by including a selective step in the isolation procedure. The *Campylobacter* isolation methodology recommended by the FDA and used in the National Antibiotic Resistance Monitoring Service (NARMS) does not include a selective isolation step. Without such a step, this method is likely to underestimate the presence of resistant strains when they exist among a group of mixed susceptibility strains. The results of the present study indicate that the risk of underestimation using nonselective media likely outweighs the risk of potential false positives due to sporadic mutation during enrichment. We observed no difference between the numbers of resistant isolates determined by the two methods on the brand A (antibiotic-free) samples. Furthermore, despite the fact that most brand B (antibiotic-free) samples were positive for *Campylobacter* (20 of 21), only one sample gave conflicting results using the two different assays. DNA sequence analysis revealed that the two strains isolated from this sample were genetically distinct (i.e., differed by more than one polymorphism).

Campylobacter strains have been shown to develop quinolone resistance at an average rate of 5×10^{-9} (Taylor et al. 1985; Wang et al. 1993; Wang and Taylor 1990), with a few strains reported to develop at rates as high as 5×10^{-7} (Bachoual et al. 2001; Payot et al. 2002; Wang et al. 1993). Using the standard FDA protocol, approximately 10^6 CFU are transferred to a plate from enrichment

(assuming a 10-μL calibrated loop and an overnight *Campylobacter* culture grown in Bolton broth). Therefore, on average, one would expect to isolate a random mutant with a frequency of approximately 1 in 200 assays. In the present study, sequence typing analysis was used to examine the genetic background of strains isolated using the two different methods. In 19 of 21 cases, the strains differed at multiple nucleotides unrelated to resistance. The most parsimonious explanation for the observed difference in strains isolated by the two methods is that these poultry samples were contaminated with mixed populations of FQ-susceptible and FQ-resistant strains. Under such conditions, the likelihood of isolating resistant strains using nonselective conditions is dependent upon variables such as relative starting concentration and doubling time of individual strains in the enrichment broth. Using the selective method minimized potential masking of the effects of such variables.

Implications for public health. Despite high incidence rates, mortality due to *Campylobacter* infections is rare in the United States. Most healthy individuals are thought to pass infections without the aid of antimicrobial therapy within 7–10 days. In contrast, antimicrobial therapy can be critical for the treatment of *Campylobacter* infections in the elderly and the immunocompromised (Djuretic et al. 1996; Manfredi et al. 1999; Tee and Mijch 1998). CIP is a commonly prescribed antimicrobial for campylobacteriosis (Nachamkin et al. 2002), and the emergence of FQ-resistant *Campylobacter* strains magnifies the threat to at-risk populations (Anderson et al. 2003). Therefore, it is critical to accurately measure the prevalence of FQ-resistant *Campylobacter* in the food supply and to identify the factors contributing to their presence.

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ARTICLE BY LANCE B. PRICE, ET AL., ENTITLED "THE PERSISTENCE OF FLUOROQUINOLONE-RESISTANT CAMPYLOBACTER IN POULTRY PRODUCTION"

The Persistence of Fluoroquinolone-Resistant *Campylobacter* in Poultry Production

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BACKGROUND: The use of antibiotics in food animal production has been associated with antibiotic-resistant infections in humans. In 2005, the Food and Drug Administration (FDA) banned fluoroquinolone use in U.S. poultry production in order to reduce the prevalence of fluoroquinolone-resistant *Campylobacter*. Little is known about the potential efficacy of this policy.

OBJECTIVES: Our primary objective was to follow temporal changes in the prevalence of fluoroquinolone-resistant *Campylobacter* among poultry products from two conventional producers who announced their cessation of fluoroquinolone use in 2002 (3 years before the FDA's ban). Our secondary objective was to compare, over time, the prevalence of fluoroquinolone-resistant *Campylobacter* in conventional poultry products to those from producers who claim to use no antibiotics.

METHODS: We collected poultry samples from two conventional producers and three antibiotic-free producers over the course of 20 weeks in 2004 (n = 198) and 15 weeks in 2006 (n = 210). We compared the rates of fluoroquinolone resistance among *Campylobacter* isolates from the different producers.

RESULTS: We found no significant change in the proportion of fluoroquinolone-resistant *Campylobacter* isolates from the two conventional producers over the study period. In addition, *Campylobacter* strains from the two conventional producers were significantly more likely to be fluoroquinolone resistant than those from the antibiotic-free producers.

CONCLUSIONS: The results from this study indicate that fluoroquinolone-resistant *Campylobacter* may be persistent contaminants of poultry products even after on-farm fluoroquinolone use has ceased. The FDA's ban on fluoroquinolones in poultry production may be insufficient to reduce resistant *Campylobacter* in poultry products.

KEY WORDS: antibiotic, antimicrobial, *Campylobacter*, chickens, ciprofloxacin, fluoroquinolones, food microbiology, poultry, resistance, veterinary. *Environ Health Perspect* 115:1035–1039 (2007). doi:10.1289/ehp.10050 available via *http://dx.doi.org/* [Online 19 March 2007]

Resistance to antimicrobials is a growing crisis in clinical medicine, and it is generally recognized that misuse and overuse in any sector contributes to this burden. Antimicrobial use in food animal production is an area of concern because the on-farm selection of antimicrobial-resistant zoonotic pathogens can lead to human exposure and infection via various pathways, including meat and poultry products. Fluoroquinolone use in poultry production selects for fluoroquinolone-resistant *Campylobacter* populations and is associated with an increase in fluoroquinolone-resistant *Campylobacter* infections in humans via poultry exposure (Gupta et al. 2004, 2005).

Campylobacter is an important foodborne zoonotic pathogen causing enteritis and diarrhea (campylobacteriosis). *Campylobacter* infection is also associated with a number of rare neuropathologic sequelae, including Guillain-Barré syndrome (Hughes et al. 1999). In the United States, *Campylobacter* is the most common cause of bacterial diarrhea, with over a million people estimated to be affected annually [Centers for Disease Control and Prevention (CDC) 2005]. Campylobacteriosis is typically self-limiting, with symptoms rarely lasting more than 10 days (Butzler 2004; CDC 2005); however, it can be fatal in more vulnerable populations (Djuretic et al. 1996; Manfredi et al. 1999; Tee and Mijch 1998).

Indeed, antimicrobial therapy is essential for elderly, pregnant, and immunocompromised patients for whom hydration and electrolyte maintenance may be insufficient (Allos 2001). Until recently, fluoroquinolones were regularly prescribed for those requiring antimicrobial therapy. However, a sharp increase in the prevalence of fluoroquinolone-resistant *Campylobacter*, shown to occur in parallel with the use of fluoroquinolones in U.S. poultry production, has limited fluroquinolones' effectiveness in the clinical setting (Allos 2001; Collignon 2005; Gupta et al. 2004). Immunocompromised patients with *Campylobacter* bacteremia often require a prolonged course of multiantimicrobial therapy (Tee and Mijch 1998); therefore, the loss of fluoroquinolones as an effective therapeutic has become a threat to these patients.

Based on a risk assessment of the contribution of fluoroquinolone use in poultry production to fluoroquinolone-resistant *Campylobacter* infections in humans, the Food and Drug Administration (FDA) suspended all fluoroquinolone use in poultry production as of 12 September 2005 (FDA 2000). The goal of this policy is to eliminate on-farm selection of fluoroquinolone-resistant *Campylobacter* and thereby reduce human exposure via food to these organisms. However, this policy's efficacy may be limited by stable reservoirs of fluoroquinolone-resistant *Campylobacter* strains in and around poultry production facilities. These reservoirs can serve to sustain resistant *Campylobacter* in poultry environments, even after the cessation of on-farm fluoroquinolone use (Bull et al. 2006; Moore et al. 2006). Furthermore, some studies indicate that fluoroquinolone-resistant *Campylobacter* isolates may actually be more fit than the wild-type with respect to poultry colonization (Zhang et al. 2006). Therefore, to better assess this policy's efficacy, it is essential to monitor the prevalence of resistant strains in poultry flocks, production facilities, consumer poultry products, and human infections. If resistant strains continue to persist in spite of the fluoroquinolone ban, it may be necessary to implement other measures in order to reduce fluoroquinolone-resistant *Campylobacter* populations.

Previously, we reported that poultry products from two conventional producers were more likely to be contaminated with fluoroquinolone-resistant *Campylobacter* than products from producers who claimed to use no antibiotics (Price et al. 2005), even though both conventional producers had announced discontinuation of fluoroquinolone use 1 year before the study. Because of the relatively short period of time between this announcement and our analysis, we undertook the current study of products for an additional 3 years (i.e., 4 years beyond the point at which these two companies committed to stop using fluoroquinolones).

Methods

Poultry producers. We included products from five different poultry producers in the present study: A) Bell & Evans (Fredericksburg, PA);

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B) Murray's (South Fallsburg, NY); C) Eberly (Stevens, PA); D) Perdue (Salisbury, MD); and E) Tyson (Springdale, AR). Producers A–C claim that their chickens are raised without any antibiotics, including fluoroquinolones. We refer to these producers and their products as "antibiotic-free." Producers D and E do not claim general prohibitions on antibiotics; we refer to these producers and their products as "conventional." A critical caveat to this designation is that each of the conventional producers announced separately in February 2002 that they had adopted company policies prohibiting the use of fluoroquinolones. In the same announcement, producer D claimed that no fluoroquinolones had been used in the year before the announcement. Finally, all producers except producer C claimed to exclusively slaughter their own flocks in their processing plants. Representatives from producer C acknowledged that "custom flocks," including those treated with antibiotics, were occasionally processed in their facilities during the study period.

Sampling and enrichment. We purchased fresh chicken products from grocery stores in the Baltimore, Maryland, area on a weekly basis from 19 January 2004 to 7 June 2004 and from 20 February 2006 to 5 June 2006. Two to three packages from each of the five producers were purchased each time (except when availability was limited). Thighs and legs (bone-in and skin-on) were the default cuts for the study. However, these cuts were not consistently available for all producers; in those cases, we tested alternative cuts, including breasts, quarters, and whole chickens. Packages were refrigerated at 4°C until they were sampled (within 48 hr of purchase). A single piece of chicken was sampled from each package as follows. First, each package was wiped with 70% ethanol and cut open with a new disposable razor blade; the plastic cover was then removed and photocopied for our records. We used sterile forceps to transfer the entire piece of chicken to a stomacher bag containing 200 mL sterile Bolton broth (Oxoid, Hampshire UK) supplemented with laked horse blood (Quad Five, Ryegate, MT); samples were shaken by hand for 2 min, the chicken was removed using forceps, and the bag was sealed 1–2 cm above the top of the broth. Enrichments were incubated at 42°C for 22–26 hr (Hunt 2000; Price et al. 2005).

Isolation. Ten microliters of the enrichment (~ 10^6 colony forming units) was streaked onto CCDA (blood-free *Campylobacter* medium; Oxoid) and incubated for 22–26 hr at 42°C. A single typical *Campylobacter* colony was transferred to a fresh CCDA plate and streaked for isolated colonies (this process was repeated once to insure the isolation of a single strain). A single purified colony was then streaked for confluent growth on CCDA and incubated for 22–26 hr. A 10-µL loop-full of cellular material was transferred to *Campylobacter* freezing medium (Hunt 2000), frozen on dry ice, and stored at –80°C.

DNA isolation. DNA was isolated using a rapid freeze–thaw method. Briefly, one 10-µL loop-full of cellular material was transferred to 150 µL Tris-EDTA in a 200-µL capacity polymerase chain reaction (PCR) tube or 96-well PCR plate. Cellular suspensions were covered and placed in a chilled aluminum block on dry ice for 2 min. Frozen cellular suspensions were then heated in a 95°C aluminum block for 2 min. This process was repeated three times, ending with a final denaturing step of 95°C for 10 min. Cellular debris was pelleted by centrifugation, and 100 µL supernatant was transferred to a fresh PCR tube or 96-well PCR plate.

Species confirmation. Presumptive *Campylobacter* isolates were confirmed and the species identified using a PCR amplification/restriction digest described previously (Engvall et al. 2002). Briefly, THERM1 and THERM4 PCR primers were used to amplify a region of DNA specific to thermophilic members of the genus *Campylobacter*. This PCR product was then digested in two separate reactions using the restriction endonucleases, *Alu*I and *Tsp*5091 (New England Biolabs, Ipswich, MA). The restriction patterns produced from this digestion are distinctive among the thermophilic *Campylobacter* species (Engvall et al. 2002).

Susceptibility. Susceptibility to fluoroquinolone was determined using standard Clinical and Laboratory Standards Institute methods and *Campylobacter*-specific methods described previously by McDermott and Walker (2003). Briefly, *Campylobacter* isolates were grown overnight on CCDA under microaerophilic conditions. Colonies were suspended to approximately 0.5 McFarland standard in Mueller-Hinton broth and inoculated onto Mueller-Hinton agar supplemented with 5% sheep blood and ciprofloxacin (USBiological, Swampscott, MA) at concentrations of 0.12–32 µg/mL. Plates were grown 22–26 hr at 42°C under microaerophilic conditions. The reference strain used was *Campylobacter jejuni* (ATCC 33560; American Type Culture Collection, Manassas, VA). Strains were designated resistant if their minimal inhibitory concentration was ≥ 4 µg/mL.

Statistical analysis. We performed statistical analyses using Stata 8.0 (StataCorp, College Station, TX). Chi-square analysis was used to compare the proportions of samples testing positive for *Campylobacter* and those positive for *Campylobacter* resistant to fluoroquinolones. Relative proportions with corresponding 95% confidence intervals (CIs) were computed for all pair-wise comparisons of producers. We detected no fluoroquinolone-resistant *Campylobacter* isolates from two producers in 2006 (Table 1); zeros were replaced with ones for relative proportion calculations involving these producers. We used univariate analysis to examine the association between species and fluoroquinolone resistance.

Results

Fluoroquinolone resistance. Overall, 13% of *Campylobacter* isolates were resistant to fluoroquinolones in 2004 and 21% in 2006 (a nonsignificant increase; $p = 0.06$) (Table 1). The proportion of *Campylobacter* isolates resistant to fluoroquinolones did not change significantly between the two test periods for any particular producer (Table 1). The proportion of resistant isolates from the two conventional producers was consistent with those collected in 2003 (Price et al. 2005).

Pair-wise comparisons revealed significant differences in the proportion of fluoroquinolone-resistant *Campylobacter* among the different producers. Without exception, *Campylobacter* from conventional products were more likely to be fluoroquinolone resistant than *Campylobacter* isolated from antibiotic-free products (Table 2). Fluoroquinolone resistance was significantly more prevalent among isolates from conventional products compared with antibiotic-free products (Table 2). These

Table 1. Prevalence of *Campylobacter* and fluoroquinolone-resistant *Campylobacter* among producers in 2004 and 2006.

	2004			2006		
Producer	No. of samples	Percent (no.) *Campylobacter*[a]	Percent (no.) FQ-resistant *Campylobacter*[b]	No. of samples	Percent (no.) *Campylobacter*[a]	Percent (no.) FQ-resistant *Campylobacter*[b]
Antibiotic-free						
A	40	67.5 (27)	3.7 (1)	45	66.7 (30)	0.0 (0)
B	38	63.2 (24)	4.2 (1)	33	90.9 (30)[c]	0.0 (0)
C	40	92.5 (37)	2.7 (1)	42	95.2 (40)	15.0 (6)
Conventional						
D	40	62.5 (25)	24.0 (6)	45	77.8 (35)	37.1 (13)
E	40	97.5 (39)	28.2 (11)	45	93.3 (42)	42.9 (18)
Total	198	76.8 (152)	13.2 (20)	210	84.3 (177)	20.9 (37)

FQ, fluoroquinolone.
[a]Percentage of samples contaminated with *Campylobacter* (susceptible or resistant). [b]Percentage of *Campylobacter* isolates resistant to fluoroquinolone. [c]Significant increase over the 2004 proportion ($p < 0.05$).

data were consistent with previous product surveys (Cui et al. 2005; Price et al. 2005), as well as with an on-farm study that showed conventionally raised poultry are more likely to be colonized with fluoroquinolone-resistant *Campylobacter* compared with those raised under the U.S. Department of Agriculture (USDA) organic label guidelines (Luangtongkum et al. 2006).

Campylobacter *contamination.* *Campylobacter* (undifferentiated by fluoroquinolone resistance) was detected on 77% and 84% of all the chicken products tested in 2004 and 2006, respectively (Table 1), again consistent with previous studies (Cui et al. 2005; Price et al. 2005). Among the five producers, only producer B (antibiotic-free) was significantly more contaminated in 2006 than in 2004 ($p = 0.006$). The reason for this increase is not known, but the increase may reflect changes in production methods that are beyond the scope of this article.

In our pair-wise analysis, significant differences in the prevalence of *Campylobacter* contamination were shown both among the three antibiotic-free producers and between the two conventional producers. We also found significant differences in the prevalence of *Campylobacter* contamination between specific antibiotic-free and conventional producers, but there was no overall difference between the two groups (conventional vs. antibiotic-free) in either year (Table 3).

Of the isolates, 92% were identified as either *Campylobacter coli* (36%) or *C. jejuni* (56%). One isolate was identified as being *Campylobacter lari*, and the remaining isolates were identified as *Campylobacter* spp., based on standard phenotypic analysis. We found no significant difference in the prevalence of fluoroquinolone resistance between the *C. coli, C. jejuni, or Campylobacter* spp. collected in this study (*C. lari* was too rare to contribute significantly to this assessment).

Discussion

This is the first published study reporting the temporal trends in fluoroquinolone-resistant *Campylobacter* on poultry products from two major U.S. broiler producers after they voluntarily ceased using fluoroquinolones for broiler production. The results of this study indicate that fluoroquinolone-resistant *Campylobacter* may be persistent contaminants of poultry products for years after on-farm fluoroquinolone use has ended.

Sustained resistance. Poor hygiene practices and insufficient biosecurity measures may play critical roles in sustaining fluoroquinolone-resistant *Campylobacter* populations (Moore et al. 2006; Newell and Fearnley 2003). In the United States, protocols for cleaning broiler chicken houses range from removing the upper layer of litter between every flock to reusing litter for multiple flocks before removal (Morison C, personal communication). Complete *Campylobacter* decontamination is probably rare under any standard practice, and contaminated litter can be a significant source of *Campylobacter* carryover and colonization in poultry houses (Petersen and Wedderkopp 2001). *Campylobacter* in poultry house water distribution systems is another potential reservoir of resistant strains. Although individual *Campylobacter* cells are sensitive to many common disinfectants, they can form disinfectant-resistant biofilms in the water distribution systems of poultry houses (Trachoo and Frank 2002; Trachoo et al. 2002). *Campylobacter* can also reside in protozoa that contaminate water distribution systems, thereby increasing their resistance to chemical disinfectants (Snelling et al. 2005).

Colonization with fluoroquinolone-resistant *Campylobacter* is not limited to *Campylobacter* sources within the broiler facility; the immediate external environment has also been shown to be an important source of *Campylobacter* for colonization. Once a flock becomes colonized with fluoroquinolone-resistant *Campylobacter*, these resistant organisms can be pumped into the environment via tunnel ventilation systems. *Campylobacter* has been detected in the air up to 30 m downwind of facilities housing colonized flocks (Bull et al. 2006). In addition, wild birds and surface waters can also become colonized or contaminated with fluoroquinolone-resistant *Campylobacter*, thereby becoming reservoirs for subsequent flocks (Bull et al. 2006; Chuma et al. 2000; Waldenstrom et al. 2005). Finally, recent studies have demonstrated that houseflies can carry *Campylobacter* and that these flies are undeterred by conventional biosecurity measures, with as many as 30,000 entering a facility during a single flock rotation (Hald et al. 2004). The combination of environmental, animal, and insect reservoirs and potential carriers provide significant challenges to poultry producers who wish to eliminate the fluoroquinolone-resistant *Campylobacter* colonizing their flocks.

The continued presence of fluoroquinolone-resistant *Campylobacter* on poultry products may be a result of more than contamination in and around farms. Controlled physiology experiments indicate that fluoroquinolone-resistant strains may be more fit than wild-type *Campylobacter* in their ability to

Table 2. Relative proportions of fluoroquinolone-resistant *Campylobacter* among producers.

Reference producer	Comparison producer	2004 Relative proportion resistant (95% CI)	2004 *p*-Value	2006 Relative proportion resistant (95% CI)	2006 *p*-Value
A[a]	B	1.1 (0.1–17.0)	0.932	> 1.0 (0.1–15.3)	1.000
	C	0.7 (0.0–11.2)	0.820	> 4.5 (0.6–35.4)	0.107
	D	6.5 (0.8–50.1)	0.032	> 11.1 (1.5–80.3)	0.001
	E	7.6 (1.0–55.6)	0.011	> 12.9 (1.8–91.1)	0.000
B[a]	C	0.6 (0.0–9.9)	0.754	> 4.5 (0.6–35.4)	0.107
	D	5.8 (0.7–44.4)	0.047	> 11.1 (1.5–80.3)	0.001
	E	6.8 (0.9–49.2)	0.018	> 12.9 (1.8–91.1)	0.000
C	D	8.9 (1.1–69.3)	0.009	2.5 (1.1–5.8)	0.028
	E	10.4 (1.4–76.9)	0.002	2.9 (1.3–6.5)	0.006
D	E	1.2 (0.5–2.8)	0.710	1.2 (0.7–2.0)	0.611
Antibiotic-free	Conventional	7.8 (2.4–25.5)	0.000	5.0 (2.5–10.3)	0.000

The relative proportion resistant is the proportion of fluoroquinolone-resistant *Campylobacter* from the comparison producer divided by the proportion of fluoroquinolone-resistant *Campylobacter* from the reference producer. Each producer was compared with every other producer in a pair-wise fashion.

[a]Zero counts were replaced with 1 in order to estimate relative proportions; ">" indicates that the replacement of zero values results in an underestimate of the actual relative proportions.

Table 3. Relative proportions of *Campylobacter* contamination (susceptible and resistant) among producers.

Reference producer	Comparison producer	2004 Relative proportion contaminated (95% CI)	2004 *p*-Value	2006 Relative proportion contaminated (95% CI)	2006 *p*-Value
A	B	0.9 (0.7–1.3)	0.687	1.4 (1.1–1.7)	0.012
	C	1.4 (1.1–1.7)	0.005	1.4 (1.1–1.8)	0.001
	D	0.9 (0.7–1.3)	0.639	1.2 (0.9–1.5)	0.239
	E	1.4 (1.2–1.8)	0.000	1.4 (1.1–1.7)	0.002
B	C	1.5 (1.1–1.9)	0.002	1.0 (0.9–1.2)	0.456
	D	1.0 (0.7–1.4)	0.952	0.9 (0.7–1.0)	0.124
	E	1.5 (0.2–0.5)	0.000	1.0 (0.9–1.2)	0.691
C	D	0.7 (0.5–0.9)	0.001	0.8 (0.7–1.0)	0.018
	E	1.1 (1.0–1.2)	0.305	1.0 (0.9–1.1)	0.703
D	E	1.6 (1.2–2.0)	0.000	1.2 (1.0–1.4)	0.036
Antibiotic-free	Conventional	1.1 (0.9–1.2)	0.375	1.0 (0.9–1.2)	0.662

The relative proportion contaminated is the proportion of products contaminated with *Campylobacter* from the comparison producer divided by the proportion of products contaminated with *Campylobacter* from the reference producer. Each producer was compared with every other producer in a pair-wise fashion.

both colonize and persist in the gut of chickens (Zhang et al. 2006). If these findings hold true in the setting of real-world poultry facilities, merely removing the fluoroquinolones from production may be insufficient to reduce the prevalence of resistant strains.

Although the present study does not include samples from before the voluntary cessation of fluoroquinolone use by two conventional producers, it clearly shows that the prevalence of fluoroquinolone-resistant *Campylobacter* is not decreasing on their products in the years following cessation and has not decreased to the level found on the products of antibiotic-free producers who claim no history of fluoroquinolone use. On the other hand, this study also shows that the resistance is not increasing significantly. In Spain, where fluoroquinolones were used heavily in poultry production, approximately 99% of poultry-associated *Campylobacter* isolates were fluoroquinolone resistant in the late 1990s (Garau et al. 1999; Saenz et al. 2000). Compared with this, holding the proportion of *Campylobacter* resistant to fluoroquinolones < 50% may be considered, by some, to be a victory.

Antibiotic-free versus conventional products. Consistent with our previous study (Price et al. 2005), *Campylobacter* isolates from antibiotic-free products were significantly less likely to be fluoroquinolone resistant than those from conventional producers. The substantial, although not statistically significant, increase from 2004 to 2006 in fluoroquinolone-resistant strains among *Campylobacter* isolated from the antibiotic-free producer C may be due to cross-contamination from processing equipment previously used to slaughter conventional flocks. Producer C was the only antibiotic-free producer that processed both antibiotic-free and conventional flocks in their processing facilities during the time of the study.

Such cross-contamination may take place in conventional processing facilities as well. For example, it is feasible that some growers who raise chickens under contract with conventional producers have no history of on-farm fluoroquinolone use. These growers may raise flocks that become cross-contaminated by slaughter equipment in conventional slaughter facilities. Previous studies have shown that cross-contamination is a regular occurrence in processing plants (Newell et al. 2001). However, it should be emphasized that antibiotic use on the farm is generally dictated by the producers who control the processing plants and with whom growers contract.

Campylobacter *contamination.* The prevalence of *Campylobacter* (susceptible and resistant) in poultry products varied significantly among producers; however, there was no consistent pattern with regard to antibiotic-use group. These findings are consistent with those from Denmark, where *Campylobacter* contamination on poultry products did not change significantly after antimicrobials were removed as feed additives (Evans and Wegener 2003). On-farm and processing plant practices, such as between-flock cleaning and decontamination of slaughter equipment, likely outweigh any impact from antimicrobial use on general *Campylobacter* contamination.

Limitations of the study. The present study had four primary limitations. First, the study was limited in geographic region; however, despite this limitation, the results are probably generalizable because integrator-defined production methods vary little from region to region. Moreover, broiler production has become regionally concentrated in the southeastern United States, and products from this region are distributed widely throughout the United States. Second, the study was limited in the number of producers included in the study. We focused on conventional producers D and E because they announced that they had ceased using fluoroquinolones in 2002. The three antibiotic-free producers were the only three with branded products consistently available in the Baltimore area. Third, we could not test the same cut each time from each producer. Thighs and legs (bone-in, skin-on) were the default cuts for the study; however, because these cuts were not consistently available for some producers, alternative cuts were tested occasionally. However, because products were tested for the presence or absence of *Campylobacter* rather than by quantifying colony forming units, the choice of cut probably had little, if any, impact on the outcome of the study. Finally, actual use of fluoroquinolones during the test period could not be determined because information on drug use in food animals is considered proprietary and not subject to mandatory disclosure to regulatory bodies (National Research Council 1999).

Public health implications. Fluoroquinolone-resistant *Campylobacter* strains pose a significant public health threat in the United States. In response to growing concerns over the contribution of agricultural antimicrobial use to resistant human infections, the FDA banned the use of fluoroquinolones in U.S. poultry production (FDA 2000). The results from the present study indicate that fluoroquinolone-resistant *Campylobacter* may be persistent contaminants of poultry products even after on-farm fluoroquinolone use has ceased. Thus, the FDA's policy alone may be insufficient to reduce consumer exposures to fluoroquinolone-resistant *Campylobacter*. Without additional interventions, fluoroquinolone-resistant *Campylobacter* may continue to be a public health burden for years after the FDA's ban.

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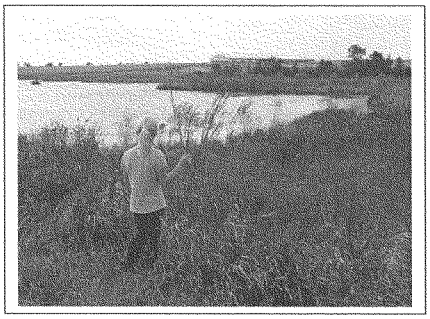
ARTICLE BY JAYNE CLAMPITT, ENTITLED "LIVING BY LARGE ANIMAL CONFINEMENTS PARADISE LOST: ONE COUNTRY FAMILY'S STORY"

Living by Large Animal Confinements
Paradise Lost: One Country Family's Story

by Jayne Clampitt
Buchanan, County Iowa



Hog confinement near conservation pond in Crumbacher Wildlife Area.

Each day I find myself waking up on my small farm wondering which way the wind is blowing and hoping I will not be down wind from the newest hog confinement that was recently built a half-mile away from my home. There are now (16) confinements. We do not own any of them. Living in the country was not always like this. Hog confinements have dramatically changed the quality of my life, and they have brought much harm to the environment around our area.

I have lived in the country most all of my life and I come from generations of farmers on both sides of my family. This is where my passion for farming and respect for our earth originated. I have cared for a variety of animals and worked in the farm fields, baling hay, detasseling corn, and even cleaned stockyards. This was my world growing up and I choose to continue to raise my children with the same work ethics, morals, and passion.

It is not my intention to stop progress or to shut down corporations who provide food for many people. But in order to make wise decisions, we must be willing to listen to people like myself who have grown up in agriculture and are experiencing the negative changes from large agriculture with corporate mentality. We need to open our eyes to the harmful pollution these confinements are causing to the environment, consider the safety of the hogs raised in these confinements for human consumption, and hold them accountable for the harm they are doing.

It is not possible to have the same quality of life that I have known since my childhood. Large hog confinements have been so devastating to me and my Iowa family that we are actively planning on moving. This topic is easy to ignore when you do not live by a confinement. However, if you have ever shut off your car vents when a load of hogs are in front of you on a semi truck, or you speed by a confinement because the stench overwhelms your car and the smell repulses you, then you have experienced a second of what I live in daily.

When people do not have to see how the hogs live or deal with their care and slaughter, somehow it is easy to ignore how that pork chop arrived in the grocery store or on their plate. It is easy to pass judgment on people who are living by the laws to produce the food we consume when those making the laws and the people who consume the food do not have a clue on what it takes to provide it. However, most of our laws only protect corporate agriculture and there are fewer laws to protect our environment.

Fortunately, our country is now awakening to these things. Many people choose to know where their food comes from and care about the quality of life of food they consume because they realize it directly affects their life. We all need to greatly consider what the future holds for other living creatures, our health, sustainability of farming for our nation, and for future generations to come. I can not live in my home because of the pollution from these confinements, so I know we can not have both worlds. Progress is good but not at the expense of destroying neighbors quality of life, polluting our water and air, and producing a cheap product that could be making us sick. Only a few people are profiting from these large confinements, but many people are losing the very things that we should be protecting.

Living In Iowa

Farming has changed in Buchanan County, Iowa, in the 15 years since we moved here. I can remember the first time we saw our home in 1993. We fell in love with it immediately. It was one of the original homesteads in our county over 160 years old. A typical square white farm house sitting near a gravel road with out buildings, a large yard, and many old trees.

What was also very appealing to us was the beautiful 360-acre wildlife area (Crumbacher Wildlife Area) that held a diverse range of ecosystems waiting to be explored across the road. It provided the space and opportunities in which we desired to raise a family. It seemed like paradise to us.

My husband and I had graduated from our universities, and he accepted a job from a large company in Waterloo, Iowa. After living in dorms or renting houses and paying back our student loans, we were thrilled to own our first home. Our baby boy was recently born and we thought we had found a safe and beautiful place to raise our child.

Over the next 15 years, we worked hard and managed every penny to turn our country home into a small working farm raising three children. We desired to start raising cattle, so we slowly bought more land, built a barn, put up fencing, sowed hay fields, and purchased used farm equipment. We built a seven-row shelterbelt for the area wildlife and to block the strong northwest winds. We peeled up the sod by hand to form a large vegetable garden and planted berries and fruit trees. Our families live in another state so we were not able to borrow equipment or tools. Everything we needed we acquired from hard work and being responsible with or money. We were living the American Dream.

I have enjoyed watching my children grow up in the country. They love to climb trees, ride bikes, catch fireflies, and play with their animals on our farm. Eating fresh vegetables from the garden, flying kites, building snow caves, dancing in the rain, seeing a rainbow, watch an amazing sunset, or looking up into the night's sky and find the constellations in the stars were things that we enjoyed doing around our home. Each fall the Monarch butterflies migrate by our home and rest overnight in our trees.

As the children grew, they learned to enjoy and appreciate nature. We went for long walks in the wildlife area across the street of our home, exploring all of its wonderful natural resources and animals. We rolled up our pants and waded in the shallow sand-bottomed creek and hiked around the park falling in love with the wildlife and experiencing nature. Often we walked in the woods, picked wild flowers and berries and mushrooms, watched the deer having their babies, found the trees where hawks built nests or where the turkeys roost at night. Sometimes we caught tadpoles in the ponds, followed beavers in the creek to their huts and dams, discovered many insects and plant species, and listened to the songs of the birds in the tall grass prairie.

Even though my husband and I had other jobs and volunteered in our community, we also worked hard maintaining our small farm to provide food for us and our animals to be self-sufficient. It was important for us to instill in our children the values and responsibilities of a farmer's way of life. We enjoyed being outside and our families, neighbors, and friends loved coming over to visit and having cookouts.

We worked hard and were making memories enjoying our home. It felt like we were living in paradise, but then things changed.

The Change

When we first moved here, there was only one family farm a mile east of us with around 2,000 hogs. Now they have 20,000 hogs in (14) large confinements. Over time, the smell from their buildings began to permeate the air to the point that it was unbearable to be outside parts of some days. But we adjusted our lifestyle because we liked our neighbors and it was infrequent. Eventually they needed more land to support the increasing number of hogs they were raising, so they contracted the land around our home, that another farmer owned, and started spreading the waste on the fields in the fall. Now there were days and weeks when it was unbearable to be outside.

Since then, more confinement facilities have been built in the area. There are now over 30,000 hogs raised annually within a mile of my home and the much loved wildlife area. The hogs are housed in 16-large confinements and produce over three million gallons of manure that is spread within a two-mile radius. Buchanan County has gone from being the 13th to the 5th largest hog-producing county of the (99) counties in Iowa. In my county township, there are now 161,000 hogs raised annually in large confinement facilities, producing 14,000,000 gallons of manure that are spread over 4,000 acres. Most of these fields are located around Lime Creek.

Now, for a moment, imagine 30,000 people moving in next to you. Imagine these people being forced to live together by the hundreds living above their waste, with the smell propelled by large fans out into the air you breathe - because they would die in minutes because of the toxic fumes. Then imagine that waste being removed from the buildings in the spring or fall and being spread on the fields around your home. Stench so overpowering that it overwhelms the air that you breathe and causes you to run inside and shut all of the windows in your house, or wakes you up from a deep sleep at night because your body knows there is something wrong with the air you are breathing. This is what I live with. Sounds like a third world country, not paradise.

For months, the liquid waste remains in the large cement pits below the confinement until it is drawn out by manure spreaders and sprayed on the fields in the fall. It will be there until May when the farmers start to plant their fields and where it would be beneficial to the crops they plant. However, when it rains or when the snow melts during those months, the waste washes down through the tiled fields and then into the creek. This liquid waste flows into the nearby creek, Lime Creek, that is 50 yards away from the shallow well your family uses for drinking water.

Fertilizer

Farmers need some form a fertilizer to put on their fields to produce a healthy crop. In the past, small farmers used their own animal manure because they did not have many acres. Later, anhydrous was used to fertilize more acres. Hog manure became popular as anhydrous companies became fewer and prices increased. There is a huge difference between liquid and bedding manure and how it decomposes and stays in the soil for plants to utilize. However, most of the Iowa fields have been tiled for better farming practices that have allowed the liquid manure to drain easily through the soil, to the tiles, and into our waters. Iowa now has some of the worst water in the nation. Our creeks and rivers are not our sewer system and can not support the large quantities from fields after fields of liquid manure being applied from these large confinements. It is the only industry that does not have a waste-treatment program to protect our waters.

Farmers can contain the majority of waste in the large pits under the confinements, but there are few regulations once they remove and apply the waste on their fields. We are simply relying on farmers to be good stewards, but recently we are dealing with companies spreading the manure and care little about the land or overapplying. Most small hog farmers in Iowa are required to have a two hour training course at their local extension office each year to be certified to apply their manure, but Extension is restructuring in Iowa and it is now uncertain how this training will be provided to farmers.

Little research has been done to see if the manure pits are leaking into our groundwater, or what bacteria, viruses, antibiotics, or other harmful organisms are forming in the manure that brews for eleven months. Pits are suppose to be inspect and air quality reports are required but are rarely done.

Large confinements are required to have a manure management plan and meet with Natural Resource Conservation Service (NRCS) to know the correct amounts to apply on their fields, but it is only a guideline. There are not enough state Department of Natural Resources (DNR) personnel to ensure that these plans and laws are being adhered to, and minor penalties are enforced when manure spills or fish kills happen. Iowa Legislation cut funding to DNR so there are even fewer employees to handle the increasing number of large confinement problems throughout the state, so most of these large confinements go unregulated.

Confinement Operation

Most farmers do not own or build these confinements themselves. They are owned by investors or large corporations who do not live in the area. There are large feed companies that haul feed, another large confinement supplies the pigs, and another to take them to the locker, and then another large outfit will spread the manure. The local farmer benefit from the manure on his fields and has little care or involvement with the confinement. The biggest profits go to the investors. All are supported by the Pork Producers and the Farm Bureau who lobby in the state capitol to protect their interest. The smaller farmer can not compete with this organized industry.

Most confinements are monitored electronically and services contracted out, so there is little human/animal interaction to monitor the living conditions of the hogs. There are no pets in confinements, like on small farms. They are seen only as a food source and business profit/loss factor instead of a living creature. Dead hogs are simply pulled outside and stacked in open cement holding unit until a rendering truck picks them up within the week.

Concerns with the Newest Confinement

In the Summer of 2007, we learned of another farmer building a confinement a half mile southwest of our home and 500-feet away from the wildlife area. This is the newest confinement that I have been referring to. The farmer who owns this confinement represents a different mentality of American farmers that have moved from traditional family farms to factory farms.

From the moment that I heard about the construction of the confinement I began doing intense research to understand the policies and laws that govern them. I have talked to many local and state organizations and officials, legislation, professors, veterinarians, doctors, and people across Iowa and this country. I started trying to find ways to better protect my home, my children, the wildlife area, the county wetlands and Lime Creek, but through my research I realized that there are few and limited laws/people/organizations that have the ability to protect any of those things.

The permit for the newest confinement operation was approved in April 2007 but we did not find out about it until late-June when construction began. Because of the size of the confinement, it was not large enough to be categorized as a Confined Animal Feeding Operation (CAFO). Therefore, the farmer did not have to notify neighbors or advertise in the area papers before construction. There is a one month time period after a permit has been signed by your supervisors that people can challenge the location. After that, there is nothing that you can do to prevent it by Iowa laws...as long as they meet the simple matrix standards. If the county does not have a matrix, there are less laws that govern hog confinements.

The county supervisors say they are not allowed to deny a confinement as there is no place on the confinement applications permit to deny one as long as the farmer meets the matrix requirements. Supervisors can be contacted by confinement owners at any time to sign the permit, then the manure plan goes to the regional DNR for approval. If the Supervisors do not indicate there is a local concern, then the regional DNR approves the permit. Rarely do they go on site to review or inspect confinement locations. If the confinement is smaller than 2,500 head of hog holding capacity, it will not be filed as a Confined Animal Feeding Operation (CAFO) and it is not required to meet more strenuous stewardship requirements. That is why most confinements are not CAFO units across the state.

The newest confinement was built near a (360) acre wildlife area, but the local supervisors, NRCS and DNR departments were not required to contact the park director, so they did not. Now there are confinements on three sides of the wildlife area within 500ft. It did not matter how close the confinement was being built, that school children have field trips there, that the public from many counties and states enjoys this wildlife area throughout the year, or that public money support its maintenance, or that precious ecosystems would be put in jeopardy. All the requirements for the permit were met by the current state laws so the confinement was allowed to be built.

This finishing-house confinement became operational in October 2007. It holds 2,400 head of hogs that will house three sets of hogs being raised to full weight producing over 7,200 head of hogs per year and one million gallons of manure to be spread on an estimated (250) acres near the confinement.

The farmer who is responsible for the newest confinement owns the farm ground around this confinement, but he will not live next to it or any of his other confinements around the county. He lives three miles west of us on 76-acres and chose not to apply the manure on the field around his home.

This newest confinement is built on a sand ridge with a limestone base. The manure pit beneath the confinement is the length of a football field and will contain a million gallons of manure. When they were pouring cement for the manure pit, it rained seven inches, but no one was required to inspect it to ensure that it would not leak into our aquifers. When the regional DNR was contacted, they said that they are not required to inspect the manure pit and it is good for it to get wet as the cement cures better.

County Wetlands

The confinement was built only 500 feet away from the wildlife area with county wetlands. State and Federal wetlands are protected to where a confinement can not be built within 2,500 feet, but the word "county" was not listed on the original law. When the regional DNR was contacted, they indicated that they believe confinements do well around wetlands because they feel that wetlands help filter out the toxins before it goes into the other water sources. This mentality is shocking and reveals the detachment our local organizations are to environment protection.

There are more county wetlands in Iowa than state and federal wetlands, but county wetlands are still not protected by Iowa laws. I lobbied for a bill in 2008 in our state capitol to have county wetland protected under the same law, but it did not pass from the Iowa House Agriculture Committee. It was approved by the Iowa House Environmental Committee, but the Agriculture Committee chairperson killed the bill without any committee discussion. We will have to wait a year to begin the whole process over. There are powerful organizations in our state that has huge influence on our legislation. Only a couple of laws have passed in Iowa for over (10) years to protect the environment in fear of limiting the corporate farmers or hindering farmers from traditional farming practices. Every year our environmental conditions worsen.

The driveway to the newest confinement facility needed to be built up over five feet high as it went through a wetland area in the farmer's field. The large tiles from the waterways drain directly into the conservation pond and county wetlands. All the runoff from manure applied to the additional 334 acres contracted from this confinement facility surrounding the wildlife area will flow directly into these waters. There is no way these precious ecosystems can manage the waste that will flow into them this fall or if there is a manure spill.

Manure on Frozen Ground

The manure from the newest confinement was spread in early December on frozen ground after an ice and snow storm. After two months of snow cover and abnormally cold temperatures we had our first thaw. My daughters and I took a walk in the wildlife area and discovered large amounts of hog manure running into the county wetlands and conservation pond, which overflowed into Lime Creek. The park director contacted the EPA (Environmental Protection Agency) and the DNR came two days later to test the water. They found nothing wrong.

The DNR representative had a meeting with the hog farmers who owned the land and spread the manure. They denied spreading on frozen ground, misrepresented their manure management plan, and threatened to reroute their waterway to not support the wildlife area. The DNR only emailed me and the park director with a report. They were not concerned with the pollution damage that obviously came from their facility and proceeded to drive by our house park on the road to intimidate us until we called the police.

Lime Creek

The creek that I mentioned is in its third year in a watershed program being monitored by Iowa State University, Coe College, and the Buchanan County Extension Services for being in the top (20) percentile of contaminated streams in Iowa showing high levels of phosphates and nitrates. The DNR is doing another independent study as the mussels and small organisms are disappearing and the oxygen levels are decreasing.

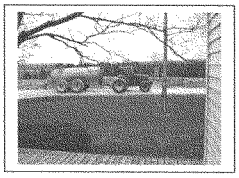
A fish kill happened in the summer of 2008, but the DNR was unable to find a source. Campers in one of the two parks along this creek discovered the dead fish. It is categorized as "Hazardous for children to play" and since it is maintained by the county, no signs are required to be posted to protect the people. One report per year is required to be printed in the paper. Taxpayer money is being used to encourage farmers to have better farming practices but after three years there has been little improvement in water quality.

More hog confinement facilities have been built near this contaminated creek in the past two years even being governed under a watershed program. It is not considered under the matrix rules. Three miles south of our home, a 114,000 capacity CAFO was approved in 2008. Over seven million gallons a hog manure will be spread around the fields next to Lime Creek. It was built 100-feet next to a contributory of Lime Creek.

You can see the foam and feces floating in the water, so we no longer explore the creek anymore, ice-skate or explore the pond, and we have our well tested frequently. My parents remember drinking from their creeks, now my children can not play in them.

Secondary Road

The gravel road is so busy now with large feed trucks, trailers transporting the hogs, and semis supporting these large confinement operations every day. They damage the roads and produce walls of gravel dust that mount higher than our two-story house. The large 10,000-gallon manure tankers that transport the manure from the facilities weigh more than semis on hard roads. They are damaging our secondary roads.



The noise is distracting and we have no privacy in our country home. It is not safe to be on the narrow roads or breathe the dust. We spend over $300 each year for dust control and we rarely open our windows anymore.

Breakdown in Farming Communities

I tried to talk to our neighbors about what I see happening around our home. Most of them raise hogs and have responded in threatening and intimidating mannerisms. They do not want us to report things to the media and have tried to prevent us from voicing our concerns in our platform meetings for our area caucus. Local control is not the answer, because hog farmers permeate the local, regional, and state governments to protect their own interests.

One neighbor said to me, "If you can't stand the smell, then move out of the country." The country that I grew up in did not smell like hog manure. Even when I worked on farms or cleaned the local stockyards in my teen years, it never smelled anything like the foul aroma that comes from these large confinements. I did not worry about my air or my water being contaminated because there were not large confinements that raised large number of animals or produced the large amount of liquid waste. There is something wrong when people, like us, who have lived in the country most all of our lives, now find it a nauseating place to live. Needless to say, friends and family do not like to visit our country home anymore and frequently comment on how we can endure.

What disturbs us the most is realizing that the neighbors we have known for 15-years have little compassion for our wellbeing and how disrespectful they have chosen to act toward us. It only proves the breakdown in the farming communities to that of corporate mentality.

Decreased Home Value

Statistics show that our home will depreciate 12-25%; this approximately $50,000. There are no laws to protect the local property owner's investments.

Fewer Small Farms

Hog confinements dot the Iowa landscape and take the place of small farms. Over 60% of 4-H members are residential, not rural. Extension in Iowa is restructuring to continue limiting the resources for sustainable agriculture. Even if laws were changed in Iowa, the hog industry would simply move to another state – like it did from North Carolina to Iowa. These concerns are needed federally to monitor the sustainability of agriculture and protect our environment because the states are influenced by corporations.

Health Hazards

There is scientific proof that there are real health hazards living near large confinement facilities - these are reported in the Pew Charitable Trust and Johns Hopkins Bloomberg School of Public Health executive summary report on Industrial Farm Animal Production. Looking back over our medical records, I have noticed that my family has endured many illnesses like nasal surgeries, walking pneumonia, strange rashes, and staph infections.

We have even lost animals to things like chronic obstructive pulmonary disease (COPD) and Salmonella. Ironically it coincides with the same times that the area farmers spread their waste around our home in the fall. Our health problems could be a result of the dust from the gravel roads, from the hydrogen-sulfide and ammonia radiating from the confinements, or the bacteria and viruses that are in the manure pits under the confinements fermenting for months and then spread on the land to go in the air we breathe and water we drink. Living in the country now seems like a health hazard, not a place of paradise.

Animal Welfare

I enjoy animals and feel strongly that we are stewards of them, but I also understand that humans consume animals and it is the delicate food chain that balances this earth. These animals did not ask to be born into these confinements and sadly will never know the difference, so it remains with humans to care enough to see them as living creatures that can bless us in life and in their deaths if we are careful not to abuse our power. At least we should educate ourselves how our food is raised and consider if it is healthy for us or not.

Hogs being raised in confinements now are nothing like how hogs lived on my grandfather's farm. These large confinements are impressive and efficient, but it is easy to see the differences. Personally, I find it appalling to know how these animals are forced to live in these crowded confinements—living above their own waste, spending

their whole lives on concrete and metal, and never feeling the sun, breathing fresh air, or knowing the joy of living on the earth. I know because I have seen and the difference and the meat taste very different.

The hogs that live in these confinements have been genetically altered for leanness and conformity so they could not live outside and survive Iowa winters. The sows are put in stanches where they can only stand and lay down and continually bred until they are unproductive. When the piglets are weaned we send them to another crowded confinement that requires the use of antibiotics to keep them healthy. We raise these animals like an assembly-line factory, and seem to overlook the fact that they are living creatures.

Understand that this is the food we all consume. The USDA purchased $50 million of this large confinement pork in 2008 for the national school lunch program, the school breakfast program, the summer food service program, the food distribution program on Indian reservations, the nutrition program for the elderly, the commodity supplemental food program and the emergency food assistance program distributed by the Food and Nutrition Service.

Conclusion

There is a need for large confinements to feed the world but there are some real problems with them that we need to immediately address as a state and nation. There are alternative farmers who are raising animals differently than the large factory farmers but it is difficult for them to compete. The important thing to remember is that farmers will produce food to meet the demands of the people. Larger farmers/corporations can provide a quantity of produce that stores and restaurants can function, and produce more to ensure lower costs in spite of the taste and quality differences. This allows the larger investors and corporations to take over our food supply and for our country to be less sustainable.

The answer is dictated by the choices that each one of us makes every day in the products we purchase, and deciding whether or not to raise our own food. We choose jobs that mandate our time and sell our land that prevents us from being self sufficient. We do not educate ourselves to understand how our food systems work and how laws are made assuming that other people have our best interests in mind.

Information is needed for people to understand the value of agriculture. It would empower them to make better decisions and become more self-sufficient in raising their own food. There are a vast number of people who no longer know what it takes to raise the animals and the foods that they consume. They do not want to deal with the work required or the life and death inconveniencies of raising animals. However, these same people expect the product to be in their local stores and demand low prices. It is easy to realize this is happening by noticing the decline of animals on farms across the country. Most people do not know how their food is being raised or where it comes from as long as it is cheap and convenient.

I believe that there should be laws that protect my home and my family, the quality of our lives, the air we breathe, and the water we drink. I took these precious things for granted and believed that these unalienable rights would always be there for everyone. Not just for my family, but for everyone and future generations to come. Not just in Iowa, but across this country. We all seek places of nature for our vacations or weekend get-a-ways or retirement. There should be no question that laws are needed to better protect our precious natural resources and make sure that no one or any corporation can take those precious things away from us.

We cannot live without fresh water. Iowa waters are now polluted beyond safe standard levels for human consumption across the state. Our polluted water does not stay within the boarders of Iowa but flows into other states and water sources. Iowa has many amazing natural resources that are not being protected but are being destroyed by large animal confinement waste and pollution. It is great to be the top hog and egg-producing state that helps feed the world, but when we can no longer live in the areas that produce the food we eat, I think we need to make immediate changes.

Farming in Iowa was not always like this, and farmers are not the only ones polluting our land and water. An enormous quantity of raw sewage from numerous towns across Iowa was released into the rivers from the recent flooding. Unregulated chemicals are sold to consumers without proper training who overuse them or dump them down the drains, which go into our waters. Golf courses, lawn fertilizers/chemicals, road-side spraying are all big contributors to water pollution.

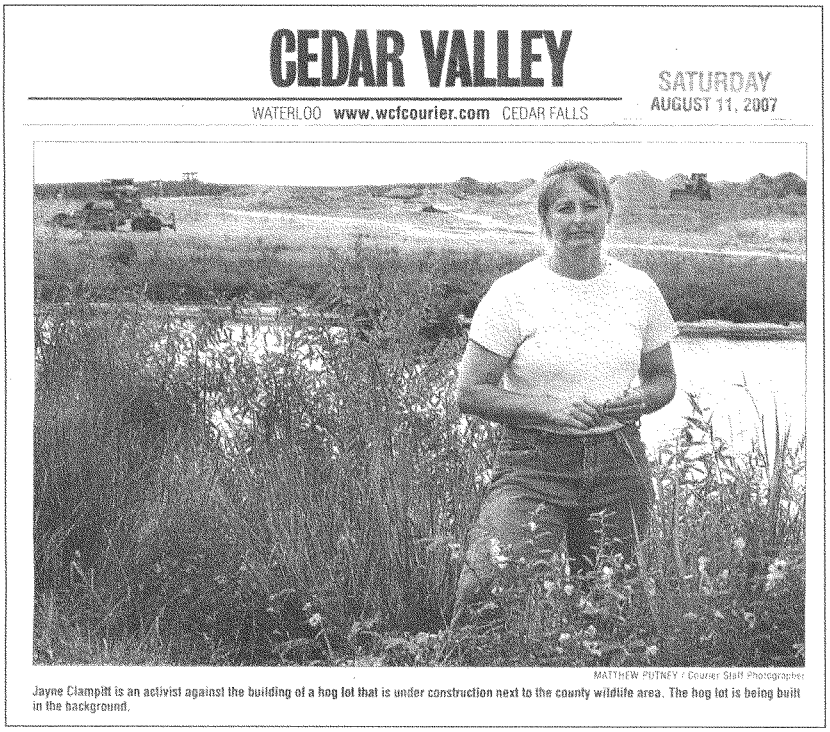
We all must consider greatly how we live and choose to be better stewards to our earth, our neighbors, and to the animals. Chief Seattle stated many years ago, "What we do to each other, we do to ourselves...we are all connected." There is no better wisdom to explain things than this.

Our paradise is lost. There is nothing to reward our respect for the earth, our hard work, being responsible with our money, raising children who are resourceful and responsible that respect their animals, neighbors, and earth. The way of life that we have cherished is disappearing before my eyes. There are fewer and fewer small farms in Iowa or young families taking over family farms or have knowledge to be self-sufficient. There are no laws to protect our farm, our air, our water, the county wetlands, the wildlife area, Lime Creek, the wildlife.

This is my story that is also happening to many people across this state. It can easily happen to you someday because we are all connected and we are allowing these corporate farming practices to continue and not holding them accountable for the large amount of pollution they are causing. The pollution I now live in affects us all and will continue if we do not speak up for change and laws to protect the things we hold precious. Perhaps cheap pork is more important to people rather than clean waters, fresh air, small farms, good neighbors, healthy food, and nature.

One thing I do know is if we do not protect these things as a nation, it is only a matter of time before we all will wake each morning wondering which way the wind is blowing and realize that all of your rights are gone…like mine. Then you will understand, but it will be too late.

Jayne Clampitt
Buchanan County, Iowa
July 4, 2009



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MATTHEW PUTNEY / Courier Staff Photographer

Jayne Clampitt is an activist against the building of a hog lot that is under construction next to the county wildlife area. The hog lot is being built in the background.