Working Group on Antibiotic Use in Food Animals
(as of May 2013 – 51 organizations)

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics*
American Association of Critical Care Nurses
American College of Preventive Medicine
American Medical Association
American Nurses Association
American Osteopathic Association
American Public Health Association
American Society of Health-System Pharmacists
Association for Professionals in Infection Control and Epidemiology
Dignity West (formerly Catholic Healthcare West)
Center for a Livable Future (Johns Hopkins, Bloomberg School of Public Health)
Center for Food Safety
Center for Foodborne Illness Research & Prevention
Center for Science in the Public Interest
Children's Environmental Health Network
Consumers Union
Credo Action
Environmental Working Group
FamilyFarmed.org
First Focus
Food & Water Watch
Food Animal Concerns Trust
Food Democracy Now
Government Accountability Project
Health Care Without Harm
Humane Society of the United States
Humane Society Veterinary Medical Association
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Institute for a Sustainable Future
Keep Antibiotics Working*
LULAC
March of Dimes
Michigan Antibiotic Resistance Reduction Coalition
National Catholic Rural Life Conference
National Consumers League
National Foundation for Infectious Diseases
National Research Center for Women & Families
National Sustainable Agriculture Coalition
Natural Resources Defense Council
Organic Consumers Association
Pediatric Infectious Diseases Society
The Pew Charitable Trusts*
Physicians for Social Responsibility
School Food FOCUS
Society of Infectious Diseases Pharmacists
STOP Foodborne Illness
Trust for America's Health
Union of Concerned Scientists
Waterkeeper Alliance

* Conveners of working group

Photo Credit: David Harp

10 Facts About Superbugs, Antibiotics, and Food Animal Production

- **29.9 million**—pounds of antibiotics sold for use in food animal production in 2011.[1]
- **7.7 million**—pounds of antibiotics sold to treat sick people in 2011.[2]
- **$26 billion**—the annual cost of antibiotic-resistant infections to U.S. healthcare.[3]
- **8 million**—extra days that patients stay in hospitals every year because of antibiotic-resistant infections.[4]
- **19,000**—people who died from a staph superbug known as MRSA in 2005, which was more than those who died from AIDS, emphysema, or homicide that year.[5]
- **13**—new classes of antibiotics introduced between 1935 and 1968.[6]
- **2**—new classes of antibiotics introduced since 1968.[7]
- **450**—health, agriculture, environment, consumer, faith-based, labor, and other groups that support the Preservation of Antibiotics for Medical Treatment Act, legislation that would eliminate the overuse of medically important antibiotics in healthy food animals.[8]
- **36**—years since the U.S. Food and Drug Administration first acknowledged that antibiotic overuse on industrial farms poses a threat to human health.[9]
- **0**—requirements that FDA has implemented to restrict the use of antibiotics to make animals grow faster and to compensate for unsanitary and overcrowded conditions.

Margaret Chan, the World Health Organization's director-general, warns we are approaching a "post-antibiotic era," which means "an end to modern medicine as we know it." Chan says that "things as common as strep throat or a child's scratched knee could once again kill."[10]

Why are our antibiotics becoming less effective while bacteria grow stronger?

Antibiotic overuse on industrial farms is a big part of the problem. The largest U.S. meat and poultry producers feed antibiotics to healthy animals over much of their lives to make them grow faster and to compensate for the overcrowded and unsanitary conditions in which they are raised and slaughtered. Hundreds of studies published over the past four decades demonstrate that these practices breed superbugs that end up in our air and water, our food, and ultimately our bodies.[11] When they infect us, antibiotic-resistant bacteria are more difficult and costly to fight and more likely to cause death.

The Pew Charitable Trusts is working to preserve the effectiveness of antibiotics by eliminating the overuse and misuse of drugs in food animal production. We work with public health and food industry leaders, veterinarians, agricultural interests, academics, and citizen groups who share our objective of protecting human and animal health.

For further information, please visit:

saveantibiotics.org

Endnotes

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A brief from THE PEW CHARITABLE TRUSTS | July 2013

Data Collection on Antibiotic Use in Food Animals

Shedding Light on a Public Health Crisis

Background

Passed in 2003, the Animal Drug User Fee Act, or ADUFA, authorizes the Food and Drug Administration to collect fees from animal drug companies in order to fund safety reviews of new applications for animal drugs. In response to the growing threat of antibiotic-resistant bacteria and their link to the nontherapeutic use of such drugs in livestock, Congress amended ADUFA in 2008 to require that drugmakers report annual sales of antibiotics destined for use in food animal production.

What ADUFA Section 105 does

Section 105 of the law requires drug companies to report annually to FDA each class of antibiotic sold or distributed for use in food animals by container size, strength, and dosage form. The law also requires reporting on the quantity of antibiotics distributed domestically and internationally, and listing the animals and indications approved for use on the product label. FDA must publish summaries of this information each year.

Section 105 of the law requires drug companies to report annually to FDA each class of antibiotic sold or distributed for use in food animals by container size, strength, and dosage form.

What FDA has done to comply with the law

To date, FDA's public summaries have only listed the total volume of antibiotics sold domestically and internationally each year by drug class. The summaries do not include any information on intended use, the species or production classes targeted, or the route of administration (by injection or in feed or water). One reporting category, "Not Independently Reported," combines antibiotic classes manufactured by fewer than three companies, thereby protecting confidential business information.

The case for more data

The most recent antibiotic sales report, published by FDA on February 6, 2013, shows that nearly 30 million pounds of antibiotics were sold for use in livestock and poultry in 2011—almost four times the amount for treating sick people. Most of the antibiotics used in meat production are used in human medicine.[1]

While this information is helpful in illustrating the scope of antibiotic use in animal agriculture, it is insufficient for understanding and responding to the public health risks posed by nontherapeutic antibiotic use in food animals. Likewise, current data do not provide a sufficient means for evaluating the success of FDA's voluntary guidance strategy to address injudicious uses of antibiotics in animal agriculture.

Even FDA agrees. "Having additional information that provides a better understanding of the extent of use of medically important antimicrobial drugs in food-producing animals will support the implementation of the agency's strategy announced April 11, 2012," the agency said in a subsequent request for comment.[2]

Which data are most needed

To increase transparency and utility, ADUFA public reports must be improved. Congress missed the opportunity to improve data reporting during the law's reauthorization in 2013. But the agency itself can take steps to require that more meaningful data is collected. FDA should propose a rule and invite public comment on ways to enhance transparency regarding sales and use of antibiotics in animal agriculture. At a minimum and within existing authority, FDA should:

- Publish annual reports by a reasonable deadline and in a consistent format to enable year-to-year analysis of trends.
- Immediately include the route of antibiotic administration (or dosage form), sales data by state or region, and listings of approved species and uses within each drug class.
- Divide data protected by business confidentiality into two categories—drugs used in humans versus drugs not used in humans.
- Allow for easy comparison and analysis of data on antibiotic sales and use in humans and food animals.
- Require that drug companies estimate the amount of each drug class sold by species and, where possible, species production class (a subset of production based on animal age or stage of development).
- Require drug companies to report sales by marketing category (over-the-counter, prescription, or veterinary feed directive).

FDA also should explore taking additional steps to increase transparency within the authority of the Food, Drug, and Cosmetic Act, such as:

- Require reporting by large feed mills of the quantity and type of antibiotics mixed into animal feed by key animal species and production class, where possible, and category of intended use (growth promotion, disease control, disease prevention, or disease treatment).[3]
- Set up future reporting of veterinary feed directive data on the frequency and manner in which antibiotics are mixed into animal feed.

For further information, please visit:

saveantibiotics.org

Endnotes

1 U.S. Food and Drug Administration, FDA Annual Report on Antimicrobials Sold or Distributed for Food-Producing Animals in 2011. Feb. 5, 2013, www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm338178.htm.

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August 22, 2013

The Washington Post

The threat from antibiotic use on the farm

By Donald Kennedy

Donald Kennedy was commissioner of the U.S. Food and Drug Administration from 1977 to 1979. He is professor emeritus of environmental science at Stanford University.

When I was commissioner of the U.S. Food and Drug Administration (FDA), the agency's national advisory committee recommended in 1977 that we eliminate an agricultural practice that threatened human health. Routinely feeding low doses of antibiotics to healthy livestock, our scientific advisory committee warned, was breeding drug-resistant bacteria that could infect people. We scheduled hearings to begin the process of curtailing the use of penicillin and other antibiotics for this purpose, but Congress halted the effort before it started.

Today, the science is even clearer that antibiotic overuse in agriculture is dangerous — yet the same risks persist. Fortunately, the FDA appears poised to act by instituting a measure known as Guidance 213. This voluntary policy instructs pharmaceutical companies to stop marketing certain antibiotics for animal production purposes. Some public health advocates want the agency to make the restrictions mandatory, but voluntary guidance can work — if it is finalized. The agency issued a draft version of its policy in April 2012 and received public comments, as required, but the comment period closed about a year ago. Drugmakers have been left awaiting further instruction.

The new guidelines cannot come soon enough. More antibiotics were sold for use in food animal production in 2011, the last year for which complete data are available, than in any prior year. The FDA annually examines bacteria on retail meat and poultry, and each year the bugs show more resistance to antibiotics. Moreover, several new studies using genetic analysis demonstrate with great precision the evolution and transmission of resistant pathogens not traditionally linked to food. Methicillin-resistant Staphylococcus is a troublesome new source of livestock-associated infections, and the E. coli that cause drug-resistant urinary tract infections can also be transmitted to people via food.

Representatives of the livestock and drug industries try to dismiss part of the problem by saying that overuse of antibiotics in hospitals is responsible for the evolution of

superbugs. Medical overprescribing is surely one piece of the puzzle. But those concerned with human health cannot dismiss or ignore the overwhelming evidence that agricultural practices also contribute to the problem.

About 80 percent of the antibiotics sold in this country are intended for food animals, not people. Consumers and the public health community would like to know more but, unfortunately, the FDA is not authorized to collect data from pharmaceutical manufacturers, feed mills or livestock producers to demonstrate exactly how many antibiotics are being used and for what specific purpose. Until it has the data, the agency cannot be certain that its voluntary approach can be effective. FDA officials have initiated a process to obtain that information, but whether it will work, and how long it will take to complete, is not certain.

In 2012, during his reelection campaign, President Obama said that his "administration is taking steps to limit antibiotic use for livestock. This will help ensure that antibiotics are used only [to] address diseases and health problems, and not for enhancing growth and other production purposes."

The Obama administration isn't the first to be concerned. Those of us at the FDA in Jimmy Carter's day were worried, too. But "production purposes" introduce a more complex note that the FDA should clearly define. Many animals are raised in conditions that pose a constant threat to their health — a symptom of a sick system.

Agricultural businesses should be able to treat animals in ways that promote efficiency and profit, which includes giving the drugs to livestock that are actually infected. But the FDA should not allow extensive uses of antibiotics in confined animals for prophylactic protection; doing so threatens to undermine those same drugs that are critical to human medicine.

A far better solution would be to improve the crowding and poor sanitation that make food animals susceptible to disease in the first place. Action by the FDA would be the initial step to encourage companies to make such changes and stop relying on massive overuse of antibiotics.

The FDA should finalize Guidance 213, tell the public how data will be collected to ensure that its voluntary strategy is working and then, if antibiotic misuse continues unabated, apply the full force of regulation. It has been 36 years since the agency moved to restrict injudicious antibiotic practices that threatened the public's health. It should not wait any longer to finish the job.

The New York Times

March 27, 2013

Antibiotics and the Meat We Eat

By DAVID A. KESSLER

San Francisco

SCIENTISTS at the Food and Drug Administration systematically monitor the meat and poultry sold in supermarkets around the country for the presence of disease-causing bacteria that are resistant to antibiotics. These food products are bellwethers that tell us how bad the crisis of antibiotic resistance is getting. And they're telling us it's getting worse.

But this is only part of the story. While the F.D.A. can see what kinds of antibiotic-resistant bacteria are coming out of livestock facilities, the agency doesn't know enough about the antibiotics that are being fed to these animals. This is a major public health problem, because giving healthy livestock these drugs breeds superbugs that can infect people. We need to know more about the use of antibiotics in the production of our meat and poultry. The results could be a matter of life and death.

In 2011, drugmakers sold nearly 30 million pounds of antibiotics for livestock — the largest amount yet recorded and about 80 percent of all reported antibiotic sales that year. The rest was for human health care. We don't know much more except that, rather than healing sick animals, these drugs are often fed to animals at low levels to make them grow faster and to suppress diseases that arise because they live in dangerously close quarters on top of one another's waste.

It may sound counterintuitive, but feeding antibiotics to livestock at low levels may do the most harm. When he accepted the Nobel Prize in 1945 for his discovery of penicillin, Alexander Fleming warned that "there is the danger that the ignorant man may easily underdose himself and by exposing his microbes to nonlethal quantities of the drug make them resistant." He probably could not have imagined that, one day, we would be doing this to billions of animals in factorylike facilities.

The F.D.A. started testing retail meat and poultry for antibiotic-resistant bacteria in 1996, shortly before my term as commissioner ended. The agency's most recent report on superbugs in our meat, released in February and covering retail purchases in 2011, was 82 pages long and broke down its results by four different kinds of meat and poultry products and dozens of species and strains of bacteria.

It was not until 2008, however, that Congress required companies to tell the F.D.A. the quantity of antibiotics they sold for use in agriculture. The agency's latest report, on 2011 sales and also released in February, was just four pages long — including the cover and two pages of boilerplate. There was no information on how these drugs were administered or to which animals and why.

We have more than enough scientific evidence to justify curbing the rampant use of antibiotics for livestock, yet the food and drug industries are not only fighting proposed legislation to reduce these practices, they also oppose collecting the data. Unfortunately, the Senate Committee on Health, Education, Labor and Pensions, as well as the F.D.A., is aiding and abetting them.

The Senate committee recently approved the Animal Drug User Fee Act, a bill that would authorize the F.D.A. to collect fees from veterinary-drug makers to finance the agency's review of their products. Public health experts had urged the committee to require drug companies to provide more detailed antibiotic sales data to the agency. Yet the F.D.A. stood by silently as the committee declined to act, rejecting a modest proposal from Senators Kirsten E. Gillibrand of New York and Dianne Feinstein of California, both Democrats, that required the agency to report data it already collects but does not disclose.

In the House, Representatives Henry A. Waxman of California and Louise M. Slaughter of New York, also Democrats, have introduced a more comprehensive measure. It would not only authorize the F.D.A. to collect more detailed data from drug companies, but would also require food producers to disclose how often they fed antibiotics to animals at low levels to make them grow faster and to offset poor conditions.

This information would be particularly valuable to the F.D.A., which asked drugmakers last April to voluntarily stop selling antibiotics for these purposes. The agency has said it would mandate such action if those practices persisted, but it has no data to determine whether the voluntary policy is working. The House bill would remedy this situation, though there are no Republican sponsors.

Combating resistance requires monitoring both the prevalence of antibiotic-resistant bacteria in our food, as well as the use of antibiotics on livestock. In human medicine, hospitals increasingly track resistance rates *and* antibiotic prescription rates to understand how the use of these drugs affects resistance. We need to cover both sides of this equation in agriculture, too.

I appreciate that not every lawmaker is as convinced as I am that feeding low-dose antibiotics to animals is a recipe for disaster. But most, if not all of them, recognize that we are facing an antibiotic resistance crisis, as evidenced by last year's bipartisan passage of a measure aimed at fighting superbugs by stimulating the development of new antibiotics that treat serious infections. Why are lawmakers so reluctant to find out how 80 percent of our antibiotics are used?

We cannot avoid tough questions because we're afraid of the answers. Lawmakers must let the public know how the drugs they need to stay well are being used to produce cheaper meat.

David A. Kessler was commissioner of the Food and Drug Administration from 1990 to 1997.

July 29, 2013

The New York Times

Tracing Germs Through the Aisles

By SABRINA TAVERNISE

Twice a month for a year, Lance Price, a microbiologist at George Washington University, sent his researchers out to buy every brand of chicken, turkey and pork on sale in each of the major grocery stores in Flagstaff, Ariz. As scientists pushed carts heaped with meat through the aisles, curious shoppers sometimes asked if they were on the Atkins diet.

In fact, Professor Price and his team are trying to answer worrisome questions about the spread of antibiotic-resistant germs to people from animals raised on industrial farms. Specifically, they are trying to figure out how many people in one American city are getting urinary infections from meat from the grocery store.

Professor Price describes himself as something of a hoarder. His own freezer is packed with a hodgepodge of samples swabbed from people's sinuses and inner ears, and even water from a hookah pipe. But the thousands of containers of broth from the meat collected in Flagstaff, where his nonprofit research institute is based, are all neatly packed into freezers there, marked with bar codes to identify them.

He is now using the power of genetic sequencing in an ambitious attempt to precisely match germs in the meat with those in women with urinary infections. One recent day, he was down on his hands and knees in his university office in Washington, studying a family tree of germs from some of the meat samples, a printout of more than 25 pages that unfurled like a roll of paper towels. Its lines and numbers offered early clues to Professor Price's central question: How many women in Flagstaff get urinary infections from grocery store meat? He expects preliminary answers this fall.

Researchers have been warning for years that antibiotics — miracle drugs that changed the course of human health in the 20th century — are losing their power. Some warn that if the trend isn't halted, there could be a return to the time before antibiotics when people died from ordinary infections and children did not survive strep throat. Currently, drug resistant bacteria cause about 100,000 deaths a year, but mostly among patients with weakened immune systems, children and the elderly.

There is broad consensus that overuse of antibiotics has caused growing resistance to the medicines. Many scientists say evidence is mounting that heavy use of antibiotics to promote faster growth in farm animals is a major culprit, creating a reservoir of drug resistant bugs that are finding their way into communities. More than 70 percent of all the antibiotics used in the United States are given to animals.

Agribusiness groups disagree and say the main problem is overuse of antibiotic treatments for people. Bugs rarely migrate from animals to people, and even when they do, the risk they pose to human health is negligible, the industry contends.

Scientists say genetic sequencing will bring greater certainty to the debate. They will be able to trace germs in people to their origins, be it from a farm

animal or other patients in a hospital. Representative Louise Slaughter, a Democrat from New York who has pushed for legislation to control antibiotic use on farms, said such evidence would be the "smoking gun" that would settle the issue.

Professor Price is seeking to quantify how extensively drug-resistant bugs in animals are infecting people. He is trying to do that by analyzing the full genetic makeup of germs collected from both grocery store meat and people in Flagstaff last year. The plummeting cost of genomic sequencing has made his research possible.

He is comparing the genetic sequences of E. coli germs resistant to multiple antibiotics found in the meat samples to the ones that have caused urinary tract infections in people (mostly women).

Urinary infections were chosen because they are so common. American women get more than eight million of them a year. In rare cases the infections enter the bloodstream and are fatal.

Resistant bacteria in meat are believed to cause only a fraction of such infections, but even that would account for infections in several hundred thousand people annually. The E. coli germ that Professor Price has chosen can be deadly, and is made even more dangerous by its tendency to resist antibiotics.

The infection happens when meat containing the germ is eaten, grows in the gut, and then is introduced into the urethra. Dr. Price said the germ could cause infection in other ways, such as through a cut while slicing raw meat. The bugs are promiscuous, so once they get into people, they can mutate and travel more easily among people. A new strain of the antibiotic-resistant bug MRSA, for example, was first detected in people in Holland in 2003, and now represents 40 percent of the MRSA infections in humans in that country, according to Jan Kluytmans, a Dutch researcher. That same strain was common in pigs on farms before it was found in people, scientists say. Dr. Price, 44, began his career testing anthrax for resistance to the Cipro antibiotic for biodefense research in the 1990s. His interest in public health led him to antibiotic resistance in the early 2000s. It seemed like a less theoretical threat.

First line antibiotics were no longer curing basic infections, and doctors were concerned. "I thought, 'Wow this is so obviously crazy, I have to do something about this,' " he said. He has done his research on antibiotics at a nonprofit founded in 2002, the Translational Genomics Research Institute, in Phoenix. His lab in Flagstaff, an affiliate, is financed mostly by federal sources, including the National Institutes of Health and the Defense Department.

Dr. Price, trained in epidemiology and microbiology, has been sounding the alarm about antibiotic resistance for a number of years. He recently told a Congressional committee that evidence of the ill effects of antibiotics in farming was overwhelming.

He thinks the Food and Drug Administration's efforts to limit antibiotic use on farms have been weak. In 1977, the F.D.A. said it would begin to ban some agricultural uses of antibiotics. But the House and Senate appropriations committees — dominated by agricultural interests — passed resolutions against the ban, and the agency retreated. More recently, the agency has limited the use of two important classes of antibiotics in animals. But advocates say it needs to go further and ban use of all antibiotics for growth promotion. Sweden and Denmark have already done so.

Ms. Slaughter said aggressive lobbying by agribusiness interests has played a major role in blocking passage of legislation. According to her staff, of the 225 lobbying disclosure reports filed during the last Congress on a bill she wrote on antibiotic use, nearly nine out of ten were filed by organizations opposed to the legislation.

But the economics of food presents perhaps the biggest obstacle. On large industrial farms, animals are raised in close contact with one another and with big concentrations of bacteria-laden feces and

urine. Antibiotics keep infections at bay but also create drug resistance. Those same farms raise large volumes of cheap meat that Americans have become accustomed to.

Governments have begun to acknowledge the danger. The United States recently promised $40 million to a major drug company, GlaxoSmithKline, to help it develop medications to combat antibiotic resistance. But Dr. Price says that new drugs are only a partial solution.

"A lot of people say, 'let's innovate our way out of this,' " he said. "But if we don't get a handle on the way we abuse antibiotics, we are just delaying the inevitable."

November 3, 2009

Chicago Tribune

An unusual prescription for health care

By STUART B. LEVY

In looking at health-care reform, Congress and the Obama administration are missing a key remedy that could help keep Americans healthy, prevent disease and hold down costs. We urgently need to reduce the development of antibiotic-resistant bacteria that cause new and hard-to-treat diseases, and we can start with food animal production.

For years, the federal government has warned doctors and other health-care providers to administer antibiotics to only those patients with bacteria-related illnesses. Yet regulations still allow large-scale livestock feeding operations - industrial farms - to use antibiotics in ways never recommended for humans. In fact, the Union of Concerned Scientists estimates that up to 70 percent of all antibiotics sold in this country are given to food animals, most of it not to treat or prevent disease but to make the animals gain weight faster and to compensate for the crowded conditions often found in such enormous facilities.

This so-called "non-therapeutic use" involves employing antibiotics that are important for treating diseases and, administering them at sub-therapeutic levels for growth promotion in animals with no sign of illness. Unfortunately, this practice can create perfect conditions for bacteria to become resistant not only to one antibiotic, but to entire classes of the medicines.

When bacteria easily killed by the drugs die, they leave behind only surviving germs that can fight off the antibiotic. Spreading from the animals, these bacteria can move to people not only through direct contact with the livestock or from being around someone who works on an industrial farm, but also just by handling or consuming meat contaminated with the drug resistant germs. Antibiotic-resistant bacteria in meat ultimately may end up in kitchens, where they contaminate countertops and hands. As a result, drug-resistant strains of E. coli and salmonella can migrate from the farm to the human community, spreading from person to person.

This past summer saw several instances of resistant bacteria entering the food supply through tainted meat. For example, in August, a California meat plant recalled more than 800,000 pounds of its ground beef because of the outbreak of an antibiotic-resistant salmonella strain linked to the meat. But the summer also saw the U.S. Food and Drug Administration publicly acknowledge the human health risks posed by industrial farms, saying that the livestock industry should stop the non-therapeutic use of antibiotics because the practice is causing drug-resistant germs to develop. The American Medical Association, World Health Organization, American Association of Pediatricians and many other health organizations also have warned about the link between the rise of antibiotic-resistant bacteria and industrial farms' inappropriate use of antibiotics.

The direct financial costs of antibiotic-resistant bacteria are as bad as the suffering caused by this problem. A recent study put the costs of resistance in U.S. hospitals at greater than $20 billion. Multiple doses of new, powerful and pricey medicines often are needed to kill such germs - and some patients require lengthy hospital stays, or at least miss days at work or school.

These drug resistant strains can cause serious symptoms, including diarrhea, blood-borne infection, abdominal cramps and, in severe cases, organ damage and even death.

Furthermore, with few new antibiotics in the development pipeline from the drug companies, ending the practice of non-therapeutic use on industrial farms could prove critical to buying time for the medicines we already have. Indeed, anything that undermines the effectiveness of current antibiotics only contributes to the health care costs of resistant infections.

Prevention really is the best medicine, especially in this case. It makes much more sense to reduce the chances that new antibiotic-resistant germs will emerge than to let industrial farms continue a practice that endangers public health. The European Union has banned this practice. We should too.

Legislation pending in Congress would address the issue, by amending the Federal Food, Drug, and Cosmetic Act to end the most worrisome industrial farm practices that give rise to antibiotic-resistant bacteria. Called the Preservation of Antibiotics for Medical Treatment Act, it would withdraw the use of seven classes of antibiotics vitally important to human health from use on industrial farms unless animals are actually sick.

Passing this measure would write at least one good prescription for improving our system of health care.

September 3, 2012

The New York Times

Farm Use of Antibiotics Defies Scrutiny

By SABRINA TAVERNISE

The numbers released quietly by the federal government this year were alarming. A ferocious germ resistant to many types of antibiotics had increased tenfold on chicken breasts, the most commonly eaten meat on the nation's dinner tables.

But instead of a learning from a broad national inquiry into a troubling trend, scientists said they were stymied by a lack of the most basic element of research: solid data.

Eighty percent of the antibiotics sold in the United States goes to chicken, pigs, cows and other animals that people eat, yet producers of meat and poultry are not required to report how they use the drugs — which ones, on what types of animal, and in what quantities. This dearth of information makes it difficult to document the precise relationship between routine antibiotic use in animals and antibiotic-resistant infections in people, scientists say.

Advocates contend that there is already overwhelming epidemiological evidence linking the two, something that even the Food and Drug Administration has acknowledged, and that further study, while useful for science, is not essential for decision making. "At some point the available science can be used in making policy decisions," said Gail Hansen, an epidemiologist who works for Pew Charitable Trusts, which advocates against overuse of antibiotics.

But scientists say the blank spots in data collection are a serious handicap in taking on powerful producers of poultry and meat who claim the link does not exist.

"It's like facing off against a major public health crisis with one hand tied behind our backs," said Keeve Nachman, an environmental health scientist at the Johns Hopkins Center for a Livable Future, which does research on food systems.

Antibiotics are considered the crown jewels of modern medicine. They have transformed health by stopping infections since they went into broad use after World War II. But many scientists say that their effectiveness is being eroded by indiscriminate use, both to treat infections in people and to encourage growth in chickens, turkeys, cows and pigs.

Whatever the cause, resistant bacteria pose significant public health risks. Routine infections once treated with penicillin pills now require hospitalizations and intravenous drip antibiotics, said Cecilia Di Pentima, director of clinical services at the Infectious Diseases Division at Vanderbilt University's Department of Pediatrics. Infections from such strains of bacteria are believed to cause thousands of deaths a year.

"The single biggest problem we face in infectious disease today is the rapid growth of resistance to antibiotics," said Glenn Morris, director of the Emerging Pathogens Institute at the University of Florida. "Human use contributes to that, but use in animals clearly has a part too."

The Food and Drug Administration has tried in fits and starts to regulate the use of antibiotics in animals sold for food. Most recently it restricted the use of cephalosporins in animals — the most common antibiotics prescribed to treat pneumonia, strep throat and urinary tract infections in people.

But advocates say the agency is afraid to use its authority. In 1977, the F.D.A. announced that it would

begin banning some agricultural uses of antibiotics. The House and Senate appropriations committees — dominated by agricultural interests — passed resolutions against any such bans, and the agency retreated.

Antibiotic use in people can be closely monitored through the vast infrastructure of the nation's health care system, but there is no equivalent for animals, making it harder to track use on farms and ranches, said William Flynn, the deputy director for science policy at the F.D.A. Center for Veterinary Medicine.

Many drugs are sold freely over the counter through feed suppliers, something the agency is trying to curb. In April, it proposed eliminating the use of certain antibiotics to stimulate growth in animals, and requiring meat and poultry producers to obtain a prescription before giving certain antibiotics to their animals. The agency just finished taking public comments to update the requirement. The scale of the problem became clear in 2010 when the F.D.A. began publishing total pharmaceutical company sales of antibiotics for use in animals raised for human consumption. It turned out that an overwhelming majority of antibiotics produced went to animals, not people. But there is still a glaring lack of information about how the drugs are used, scientists say.

The one set of data that is regularly released — a measure of antibiotic-resistant bacteria carried by meat and poultry — contains such small samples that most scientists say they are reluctant to rely on it.

The dramatic rise in the presence of salmonella on chicken breasts that was resistant to five or more classes of antibiotics, for example, was based on samples from just 171 breasts, an infinitesimal fraction of the more than eight billion birds raised and sold as food in the United States every year.

Another problem is that regulatory responsibility is fractured. The F.D.A. regulates drugs, but agriculture is the purview of the federal Department of Agriculture. The Centers for Disease Control and Prevention also has a role.

'There's nobody in charge," said Dr. Morris, who worked in the agriculture department during the Clinton dministration. "And when no one's in charge, it doesn't et done."

John Glisson, the director of research programs at the U.S. Poultry and Egg Association, an industry group, said in an e-mail reply to questions that poultry feed mills "keep detailed records of antibiotic usage in the feed they manufacture." The F.D.A. "has the authority to inspect and audit these records," he said, adding that the agency "can have access to these records anytime."

But regulators say that in reality, access is not easy. While they may have authority to look at the records from any food manufacturer, they cannot collect or publish the data.

Indeed, in July the National Pork Producers Council argued that its members should not be required to report on antibiotic prescriptions for their animals because it would add complexity.

Regulators say it is difficult even to check for compliance with existing rules. They have to look for the residue of misused or banned drugs in samples of meat from slaughterhouses and grocery stores, rather than directly monitoring use of antibiotics on farms. "We have all these producers saying, 'Yes, of course we are following the law,' but we have no way to verify that," said Dr. Hansen, of Pew Charitable Trusts.

Dr. Flynn, the F.D.A. official, said the agency was moving as fast as it could to make sure antibiotics are used judiciously in farm animals. He called the plan to require animal producers to get prescriptions for certain antibiotics "an important shift."

February 28, 2013

The New York Times

Breeding Bad Bugs

Study after study has found that the practice of feeding subtherapeutic doses of antibiotics to livestock to enhance growth is a threat to public health because it can lead to the breeding of antibiotic-resistant organisms, rendering essential drugs useless against disease-carrying organisms. Now there is alarming new evidence that unchecked antibiotic use in Chinese livestock farming has led to antibiotic-resistant genes in bacteria. China produces and uses more antibiotics than any other country, and nearly half the antibiotics it uses are fed to livestock.

According to a study published in the Proceedings of the National Academy of Sciences, researchers examining manure samples from large-scale, antibiotic-intensive Chinese pig farms found 149 different genes showing antibiotic resistance in hog manure and in the soil. These genes are "diverse, abundant, and potentially mobile," the report said. At antibiotic-free farms, only one-third as many resistant genes were found.

The rise of antibiotic-resistant genes poses a potential worldwide human health risk. While it is possible to block imports of meat and livestock from antibiotic-intensive countries, it is impossible to block the spread of antibiotic-resistant genes, which could turn up in many different kinds of pathogens.

It is absolutely essential that farmers, consumers, politicians and regulators understand that the routine use of antibiotics on farms is, as the authors of the study write, directly correlated with "the rise and spread of associated resistance genes in human pathogens, as well as the direct transfer of antibiotic-resistant bacteria from animals to humans." There is only one valid use for antibiotics in livestock production, and that is treating sick animals. There is no acceptable excuse for using good drugs in ways that will breed bad bugs.

March 3, 2013

The Des Moines Register

Our antibiotics are less effective; routine use in farming is cited

Congress should require more reporting of the drugs' use in livestock

Written by
THE REGISTER'S EDITORIAL BOARD

A soldier shot in World War I may not have been killed by the initial wound. Yet there was a good chance a subsequent infection would take his life. By World War II, that soldier had a better chance of survival due to the wide availability of antibiotics. These miracles of modern medicine fight infections and save lives.

But the vast majority of antibiotics developed to treat people are given to the animals people eat. Farmers add low doses to feed and water to prevent disease in crowded livestock facilities. The drugs also promote growth. A bigger cow, pig, turkey or chicken translates into more money for producers.

How does this widespread use in animals affect humans? It is killing us, a growing number of scientists say.

Bacteria are adaptable little guys. Over time, they develop a resistance to commonly used antibiotics. Those more resilient bacteria then move from animals to humans. The bacteria causing everything from urinary tract infections to pneumonia in humans are more difficult to treat with common antibiotics.

Tens of thousands of Americans are killed each year by drug-resistant infections. It costs the country's health care system billions of dollars.

So what should be done? Obviously, there is a desperate need to develop new antibiotics. People have heard by now they should avoid overusing and misusing these drugs, which can contribute to resistance. But the extensive use of antibiotics in agriculture — and its culpability in a human health crisis — cannot be ignored. Science isn't ignoring it. Neither can Washington lawmakers.

A few years ago, Congress considered following the recommendations of scores of scientists to phase out the use of antibiotics in animal farming, except specifically to treat disease. Though researchers, including those at Iowa State University, estimated the cost to the livestock industry and consumers would be small, the agriculture opposed the legislation — and won. The Food and Drug Administration is trying to rein in the routine use of drugs in animals, but it is unclear whether producers are responding.

At the very least, Congress should require more reporting on what drugs are being used on what animals so scientists can better track the impact on human health."We need to know what's going on," said Dr. Lance Price during a recent meeting with the Register's editorial board. He and his colleagues have traced new strains of antibiotic-resistant pathogens to industrial livestock operations.

Sen. Tom Harkin, chairman of the Health, Education, Labor and Pensions Committee, can ensure such data is gathered by requiring it in the Animal Drug User Fee Act, which the committee is discussing now. Longer term, American producers, who lead the world in aggressive use of antibiotics, should move toward reducing and eliminating the use of the drugs, except to directly treat disease.

It has been more than a decade since producers in Denmark stopped using antibiotics for growth promotion in animals. The small increase in feed costs was ameliorated by the decrease in spending on antibiotics. Pork production rose. It's certainly no coincidence that Denmark has fewer problems with antibiotic-resistant infections in hospitals than the United States does.

It's time for this country to care as much about protecting human health as growing big cows or chickens.

October 23, 2013

President Barack Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Obama:

As representatives of the medical, public health, and sustainable agriculture communities, the undersigned organizations are writing to urge you to direct your Administration to take swift action to end antibiotic overuse and misuse in food animal production. Specifically, we ask that you direct the Office of Management and Budget to finalize Food and Drug Administration Guidance #213 and issue a proposed rule on the Veterinary Feed Directive this fall, in order to initiate the three-year phase-out of growth promotion and production-related uses of antibiotics, and to move to the necessary next steps as required to protect public health.

FDA recognized as early as 1977 that nontherapeutic uses of medically-important antibiotics in livestock feed threaten human health. Soon after antibiotics were discovered, producers of livestock and poultry began using drugs like penicillin and tetracycline as a matter of routine to spur animal growth rates and to enable crowding of animals and poultry to facilitate more efficient production. But, as Alexander Fleming warned, misuse and overuse of antibiotics only enables bacteria to become stronger and survive to reproduce. World health leaders issued strong warnings through the Swann Report in 1969 calling for an end to growth promoting uses. Since that time hundreds of peer-reviewed studies have been published that confirm the connection between drug use on the farm and superbugs in people.

Since FDA acknowledged the human health risk from antibiotic overuse in the 1970s, the call for action from the public health community and consumers has grown more urgent. This is why we appreciate the steps the Administration has taken to initiate new policies to address antibiotic overuse in agriculture. While we believe enforceable requirements are needed to guarantee an end to non-medically necessary uses of antibiotics in food animals, we recognize the potential for the guidance approach to benefit public health as long as certain fundamental principles are upheld: 1) it must clearly limit the use of antibiotics for disease prevention in animals to prevent misuse; and 2) it should include a plan to monitor and report to the public on progress in reducing antibiotic use and antibiotic resistance. We appreciate FDA's careful consideration of these priorities and look forward to working with the agency to maximize the guidance's benefits.

Please direct your administration to finalize a strong FDA Guidance #213 and propose a veterinary feed rule as soon as possible. Thank you again for your commitment to address the critical public health threat of antibiotic resistance. Your leadership can help save the effectiveness of antibiotics in treating dangerous human illnesses.

Sincerely,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American College of Preventive Medicine
American Nurses Association
American Osteopathic Association
American Public Health Association
Center for Food Safety
Center for Science in the Public Interest
Consumers Union
Environmental Working Group
First Focus Campaign for Children
Food & Water Watch
Food Animal Concerns Trust (FACT)
Health Care Without Harm
Healthy Food Action
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Keep Antibiotics Working
League of United Latin American Citizens
March of Dimes
National Consumers League
National Research Center for Women & Families / Cancer Prevention and Treatment Fund
Natural Resources Defense Council
Pediatric Infectious Diseases Society
The Pew Charitable Trusts
Physicians for Social Responsibility
San Francisco Chapter of Physicians for Social Responsibility
Society of Infectious Diseases Pharmacists
Trust for America's Health
Union of Concerned Scientists

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Keep Antibiotics Working
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March of Dimes
National Consumers League
National Research Center for Women & Families / Cancer Prevention and Treatment Fund
Natural Resources Defense Council
Pediatric Infectious Diseases Society
The Pew Charitable Trusts
Physicians for Social Responsibility
San Francisco Chapter of Physicians for Social Responsibility
Society of Infectious Diseases Pharmacists
Trust for America's Health
Union of Concerned Scientists

MAJOR ARTICLE

Hospital and Societal Costs of Antimicrobial-Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship

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(See the editorial commentary by Zaoutis, on pages 1185–6.)

Background. Organisms resistant to antimicrobials continue to emerge and spread. This study was performed to measure the medical and societal cost attributable to antimicrobial-resistant infection (ARI).

Methods. A sample of high-risk hospitalized adult patients was selected. Measurements included ARI, total cost, duration of stay, comorbidities, acute pathophysiology, Acute Physiology and Chronic Health Evaluation III score, intensive care unit stay, surgery, health care–acquired infection, and mortality. Hospital services used and outcomes were abstracted from electronic and written medical records. Medical costs were measured from the hospital perspective. A sensitivity analysis including 3 study designs was conducted. Regression was used to adjust for potential confounding in the random sample and in the sample expanded with additional patients with ARI. Propensity scores were used to select matched control subjects for each patient with ARI for a comparison of mean cost for patients with and without ARI.

Results. In a sample of 1391 patients, 188 (13.5%) had ARI. The medical costs attributable to ARI ranged from $18,588 to $29,069 per patient in the sensitivity analysis. Excess duration of hospital stay was 6.4–12.7 days, and attributable mortality was 6.5%. The societal costs were $10.7–$15.0 million. Using the lowest estimates from the sensitivity analysis resulted in a total cost of $13.35 million in 2008 dollars in this patient cohort.

Conclusions. The attributable medical and societal costs of ARI are considerable. Data from this analysis could form the basis for a more comprehensive evaluation of the cost of resistance and the potential economic benefits of prevention programs.

The emergence of antimicrobial-resistant organisms is accelerating, and novel drug development is not keeping pace [1–9]. When infection control adherence falls short, transmission of antimicrobial-resistant organisms between patients can occur [1, 10–13]. Those who develop antimicrobial-resistant infection (ARI) experience the consequences of ineffective treatment, delayed recovery, recurrent infection, or even death [2, 10, 14–17]. Solutions currently debated include eliminating antibiotics from livestock feed and decreasing the use of antibiotics for human infections that are self-limited or likely to have been caused by viruses [1, 6, 10, 18–22]. Improved adherence to infection control guidelines has become a national priority for preventing health care–acquired infection (HAI) and ARI [23, 24].

Clinicians are obligated to treat each patient as effectively as possible; thus, as more reports of antimicrobial resistance emerge [1, 25], there may be a paradoxical effect, causing providers to leapfrog to the newest broad-spectrum agent to which resistance may

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be less common. There are time and cost constraints for obtaining microbiological cultures to guide treatment decisions, and empirical therapy is perceived to be more cost-effective, especially in ambulatory settings [10]. Moreover, most antimicrobial prescriptions are written by clinicians who are not infectious diseases specialists [10]. More than 132.7 million outpatient antimicrobial courses were prescribed in 2006, and 80% were written by primary care and emergency department clinicians. That same year, of 95.7 million upper respiratory and skin infections, 83% were treated in primary care or emergency departments [26].

We applied an economic approach to the analysis of antimicrobial resistance. Decisions on the best way to spend or invest current limited resources depend on whose point of view is considered [27–29]. In addition, decision alternatives for medical management are usually considered in the present. Hospitals consider expenses such as labor and pharmaceuticals to be a cost of providing health care. For third-party payors, reimbursement of hospital bills is the cost of doing business. For patients and society, loss of life, quality of life, and productivity are additional costs. We argue that the medical and societal costs of future ARI should be considered in the current cost of inappropriate antimicrobial use and infection control lapses.

This report describes an economic analysis of the Chicago Antimicrobial Resistant Project dataset. Our goal was to measure the cost attributable to ARI in hospitalized patients. The sample included health care–acquired and community-acquired ARI, hospital service, treatment setting, and resistant organism subgroups. The results could be used to balance the benefits of antimicrobial use for current patients against the costs to future patients from increased resistance.

METHODS

Overview. A random sample of patients hospitalized at our urban public teaching hospital in the year 2000 was selected. Selection criteria were age >17 years and >5 *International Classification of Diseases, 9th Edition, Clinical Modification* codes at discharge. Exclusion criteria were hospitalization for trauma, burn, or obstetrical care. This random sample was used to measure an overall cost of ARI. To increase the number of patients for the subgroup analysis, we returned to the same eligibility pool and selected all additional patients with microbiological susceptibilities demonstrating resistance. Potential bias was introduced by the additional patients, so the analytic plan included 3 methods and a sensitivity analysis. Patients were the unit of analysis, and each either had an ARI or did not. The major problem was the effect of confounders that are associated with ARI and with increased hospital cost and mortality risk. To measure the cost attributable to ARI, linear regression was used to control for confounding factors in the initial random sample. Next, the expanded sample was analyzed to estimate the attributable cost and mortality for ARI in general and for specific organism subgroups and treatment settings, also with use of regression models. Finally, to address the sampling bias, propensity scores were used to select matched control subjects for each patient with ARI in a case-control study [30–32]. Propensity scores were also used as cost adjusters in the regression models.

This study was deemed exempt from review by the institutional review boards of the study hospital and the Centers for Disease Control and Prevention (CDC).

Measurements. Medical costs were measured from the hospital perspective [27–29]. All patient resource use was abstracted from the electronic and paper medical records, including length of stay in all wards, number and type of laboratory and radiological tests received, specialty consultations, bedside procedures (eg, endoscopy), minutes of operating room time for surgical procedures, and treatments (eg, pharmaceuticals or blood products) [33–36]. Unit costs for each resource were calculated using the hospital expenditure report for the year 2000. To fully capture the cost of hospital care, all costs for hospital operation and management were allocated to patient services; this included all support costs related to administration, employees, buildings, utilities, equipment, vendor contracts, and variable costs for consumables, such as food and supplies. The multiple distribution method was used to allocate support costs to departments that provide directly measurable services to individual patients [27, 34–36]. For physician care, we included the salaries for faculty, residents, part-time providers, and overtime, along with physician support departments (eg, credentialing and the library). Total operating room minutes, clinic hours, and consultation and procedure times were estimated using clinic schedules, operating room and hospital administrative data, and effort reporting. This information was used to determine the proportion of total physician time and cost for providing care on inpatient wards and intensive care units (ICUs). The cost for time spent in institutional educational activities was distributed proportionally across the patient service activities [37].

The resultant total cost for patient service departments included labor, benefits, supplies, equipment used, and allocated administrative and support costs for employees and space occupied. This total was divided by the annual work-output to determine each service unit cost. The variable cost was measured directly for each medication and blood product an individual received. The total cost per patient was calculated by multiplying the quantity of each service used by its unit cost, then summing all costs.

Our previous work demonstrated that initial severity of illness, care in ICUs, surgical procedures, and development of HAI were factors that predict the total cost of care [34]. Severity

Table 1. Patient Characteristics Stratified by Presence of Antimicrobial-Resistant Infection (ARI)

Characteristic	Random sample			Expanded sample		
	All patients	Patients with ARI[a]	Patients without ARI	All patients	Patients with ARI	Patients without ARI
All patients	1253	50 (4.0)	1203 (96)	1391	188 (13.5)	1203 (86.5)
Age, years	54.4 ± 14	52.3 ± 15	54.5 ± 14	54.3 ± 14	53.0 ± 16	54.5 ± 14
Male sex	721 (57.5)	34 (68.0)	687 (57.1)	809 (58.2)	122 (64.9)	687 (57.1)
APACHE III score[a]	40.4 ± 18	48.1 ± 17	40.1 ± 18	42.1 ± 20	54.8 ± 27	40.1 ± 18
Duration of stay, days[a]	8.8 ± 10	26.4 ± 26	8.0 ± 7	10.2 ± 12	24.2 ± 21	8.0 ± 7
HAI[a]	159 (12.7)	34 (68.0)	125 (10.4)	260 (18.7)	135 (71.8)	125 (10.4)
Cost per day, US[a]	1597 ± 556	1975 ± 761	1581 ± 540	1651 ± 634	2098 ± 937	1581 ± 540
Total cost, US$[a]	14,947 ± 21,637	56,745 ± 68,154	13,210 ± 14,919	19,267 ± 32,251	58,029 ± 67,485	13,210 ± 14,919
Death[a]	44 (3.5)	8 (16.0)	36 (3.0)	70 (5.0)	34 (18.1)	36 (3.0)
Hospital service						
Medical	1087	30 (2.8)	1057 (97.2)	1179	122 (10.4)	1057 (89.6)
Surgical[a]	166	20 (12.1)	146 (87.9)	212	66 (31.1)	146 (68.9)
Treatment setting						
Non-ICU	1041	21 (2.0)	1020 (98.0)	1110	90 (8.1)	1020 (91.9)
ICU[a]	212	29 (13.7)	183 (86.3)	281	98 (34.9)	183 (65.1)

NOTE. Data are no. (%) of patients or mean ± standard deviation. APACHE, Acute Physiology and Chronic Health Evaluation; HAI, health care–acquired infection; ICU, intensive care unit.

[a] $P < .001$.

of illness was measured using the highest Acute Physiology and Chronic Health Evaluation (APACHE) III score in the first 24 h of hospitalization [38]. Patients were categorized as treated on a medical or surgical service and in an ICU or non-ICU setting. Only persons initially hospitalized on surgical services were categorized as surgery patients; patients treated at any time in an ICU were categorized as ICU patients.

The HAI definitions used were developed by the CDC for the National Nosocomial Infection Surveillance program and were modified slightly for retrospective use [34, 39, 40]. The same clinical definitions were used to define community-acquired ARI. Drug-resistant organisms were condensed into 4 subgroups: (1) methicillin-resistant *Staphylococcus aureus*, (2) vancomycin-resistant enterococci, (3) *Escherichia coli* resistant to fluoroquinolones or third-generation cephalosporins or *Klebsiella* species resistant to third-generation cephalosporins (AREK), and (4) amikacin- or imipenem-resistant *Enterobacter, Pseudomonas,* or *Acinetobacter* species (AIR). Because individual patients were the unit of analysis, and because some patients had >1 drug-resistant infection, a multiple-ARI variable was created. Infections were further classified as health care acquired or community acquired and by infection site (pulmonary, bloodstream, urinary, surgical site, other, and multisite).

The APACHE III score includes points for age, acute pathophysiology abnormalities, and 7 comorbidities [38]. However, it scores only the single comorbidity with the highest points. To address the potential cost impact of multiple comorbidities, we captured all APACHE III comorbidities in an Expanded APACHE III Score (Ex-APACHE). We also recorded 13 additional comorbidities from the Charlson score that were expected to predict increased hospital cost [41]. To determine whether acute pathophysiology (AP) abnormalities on hospital admission might be an additional confounder, we introduced an AP-APACHE III score that included only that portion of the total APACHE III.

Data analysis and reporting. Descriptive data included demographic characteristics, mean APACHE III score, length of stay, cost per day, total cost, HAI rate, and deaths for those with and without ARI. The statistical significance of between group differences for noncontinuous variables was determined using the χ^2 test or the Fisher exact test. The Student t test was used for continuous variables. Three propensity scores for ARI

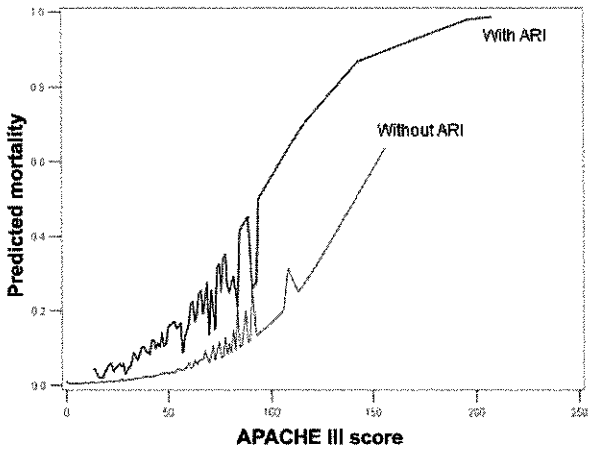

Figure 1. Predicted mortality for patients with and without antimicrobial-resistant infection (ARI). APACHE, Acute Physiology and Chronic Health Evaluation.

Table 2 Comorbidities and Hospital Circumstances Used to Develop Propensity Score

Variable	No. (%) of patients			P
	All	With ARI	Without ARI	
Comorbidities				
Any renal disease	268 (19.3)	65 (34.6)	203 (16.9)	<.001
Renal failure (hemodialysis)	46 (3.3)	22 (11.7)	24 (2.0)	<.001
Acute myocardial infarction	78 (5.6)	12 (6.4)	66 (5.5)	NS
Congestive heart failure	321 (23.1)	37 (19.7)	284 (23.6)	NS
Peripheral vascular disease	88 (6.3)	24 (12.8)	64 (5.3)	<.001
Stroke	115 (8.3)	21 (11.2)	94 (7.8)	NS
Diabetes mellitus	466 (33.5)	57 (30.3)	409 (34.0)	NS
Diabetes mellitus with complications	106 (7.6)	28 (14.9)	78 (6.5)	<.001
Any liver disease	238 (17.1)	49 (26.1)	189 (15.7)	<.001
Cirrhosis	63 (4.5)	8 (4.3)	55 (4.6)	NS
Hepatic failure	86 (6.2)	13 (6.9)	73 (6.1)	NS
Dementia	52 (3.7)	17 (9.0)	35 (2.9)	<.001
Collagen vascular disease	35 (2.5)	6 (3.2)	29 (2.4)	NS
COPD	125 (9.0)	14 (7.5)	111 (9.2)	NS
Cancer	223 (16.0)	46 (24.5)	177 (14.7)	<.001
AIDS	206 (14.8)	39 (20.7)	167 (13.9)	<.05
Hospital circumstances				
ICU care	281 (20.2)	98 (52.1)	183 (15.2)	<.001
Surgery	212 (15.2)	66 (35.1)	146 (12.1)	<.001
HAI	260 (18.7)	135 (71.8)	125 (10.4)	<.001

NOTE. ARI, antimicrobial-resistant infection; COPD, chronic obstructive pulmonary disease; HAI, health care–acquired infection; ICU, intensive care unit; NS, not significant.

were calculated. The first (PS-1) used all measured comorbidities that were statistically significantly associated with ARI ($P < .05$). The second propensity score (PS-2) included surgery and ICU care as predictors. The third score (PS-3) added HAI.

In the initial random sample, attributable medical cost and length of stay were estimated only for ARI overall. Ordinary least-squares linear regression models were used to control for potential confounding. The sensitivity analysis for this sample included the base case, which adjusted for APACHE III score, ICU care, and surgery. Additional models sequentially introduced HAI, Ex-APACHE, Partial Charlson, and PS-1. The expanded sample was used to estimate cost and length of stay attributable to resistance subgroups and for specific treatment settings. The analysis of the expanded sample included 2 designs. Linear regression with progressive addition of confounders to the model was performed, with all patients included. In the last method, PS-2 and PS-3 were used to select 2 matched control groups for ARI patients. The statistical significance of between-group differences for these matched samples was compared using *t* tests. To estimate the total medical cost for the entire cohort, the number of drug-resistant cases was multiplied by our attributable costs for ARI.

Excess deaths attributable to ARI were estimated using the expanded sample. Logistic regression was used to measure the mortality risk associated with APACHE III score, ICU care, and concurrent HAI. The parameter estimates predicting death were used to calculate an adjusted mortality odds ratio for ARI alone. To estimate the societal costs for excess mortality, the number of deaths attributable to ARI was multiplied by the lost productivity cost (in 2000 US dollars) for death in the age group that included the sample mean age. The total mortality costs were calculated using both 0% ($768,015) and 3% discounted rates ($585,903) [42]. After subtracting the actual number of patients with ARI who died, the attributable length of stay for the remainder was multiplied by the daily cost for lost productivity in the year 2000 ($165) [42].

The totals were adjusted for general inflation to 2008 US dollars [43]. We did not use the higher medical inflation rates, because the medical costs used were from the hospital perspective. Hospital charges and third-party payor costs were not used, and no new medical technology implementation was assumed. Cost calculations and analyses included all patients and were completed using SAS software, version 9.2 (SAS Institute), and Excel, version 2002 (Microsoft).

RESULTS

In the year 2000, 23,904 patients were hospitalized, and 4944 (20.7%) met the eligibility criteria. The random sample of 1253 patients was expanded by 138 patients with ARI available from

Table 3. Attributable Medical Costs and Length of Stay for Any Antimicrobial-Resistant Infection (ARI)

Analysis	Regression analysis			
	ARI cost		ARI length of stay	
	US$ ± SE	R^2	No. of days ± SE	R^2
Random sample regression analysis (n = 1253)				
Confounders used in regression				
Surgery, ICU, and APACHE III score	27,715 ± 2399	0.45	12.7 ± 1.2	0.34
Surgery, ICU, and Ex-APACHE III score[a]	27,574 ± 2402	0.45	12.6 ± 1.2	0.34
Surgery, ICU, Ex-APACHE III score,[a] and partial Charlson[b]	27,480 ± 2402	0.45	12.5 ± 1.2	0.34
Adjusted for HAI				
Surgery, ICU, APACHE III score, and HAI	21,018 ± 2380	0.49	9.3 ± 1.1	0.40
Surgery, ICU, Ex-APACHE III score,[a] and HAI	20,906 ± 2382	0.49	9.2 ± 1.1	0.40
Surgery, ICU, Ex-APACHE III score,[a] partial Charlson,[b] and HAI	20,840 ± 2383	0.49	9.2 ± 1.1	0.40
Expanded sample regression analysis (n = 1391)				
Confounders used in regression				
Surgery, ICU, and APACHE III score	27,216 ± 2009	0.46	10.5 ± 0.8	0.41
Surgery, ICU, and Ex-APACHE III score[a]	27,175 ± 2013	0.46	10.4 ± 0.8	0.41
Surgery, ICU, Ex-APACHE III score,[a] and partial Charlson[b]	27,076 ± 2019	0.46	10.3 ± 0.8	0.41
Surgery, ICU, and PS-1	25,871 ± 2054	0.47	10.0 ± 0.8	0.41
Surgery, ICU, PS-1, and AP-APACHE III score[c]	25,641 ± 2062	0.47	9.9 ± 0.8	0.42
Adjusted HAI				
Surgery, ICU, APACHE III score, and HAI	19,626 ± 2189	0.48	6.8 ± 0.8	0.45
Surgery, ICU, Ex-APACHE III score,[a] and HAI	19,623 ± 2191	0.48	6.7 ± 0.8	0.45
Surgery, ICU, PS-1, and HAI	18,767 ± 2213	0.49	6.5 ± 0.8	0.45
Surgery, ICU, PS-1, AP-APACHE III score,[c] and HAI	18,588 ± 2218	0.49	6.4 ± 0.8	0.46
Expanded sample subgroup regression analysis (n = 1391)				
Subgroups and confounders used in regression				
Medical patients (n = 1179)				
ICU and PS-1	18,974 ± 1708	0.39	8.1 ± 0.7	0.33
ICU, PS-1, and HAI	12,505 ± 1821	0.42	4.6 ± 0.8	0.39
Surgical patients (n = 212)				
ICU and PS-1	39,924 ± 7354	0.39	14.7 ± 2.5	0.29
ICU, PS-1, and HAI	31,289 ± 8044	0.40	11.3 ± 2.7	0.31
Non-ICU patients (n = 1110)				
Surgery and PS-1	7200 ± 870	0.35	5.7 ± 0.7	0.25
Surgery, PS-1, and HAI	3731 ± 902	0.40	3.3 ± 0.7	0.30
ICU patients (n = 281)				
Surgery and PS-1	47,727 ± 6391	0.33	15.7 ± 2.2	0.26
Surgery, PS-1, and HAI	35,726 ± 7016	0.36	10.5 ± 2.4	0.31

NOTE. All parameter estimates for cost and length of stay and all overall economic model significance tests and F statistics were significant at $P < .001$. APACHE, Acute Physiology and Chronic Health Evaluation; Ex-APACHE, expanded APACHE III; HAI, health care–acquired infection; ICU, intensive care unit; PS-1, propensity score 1; SE, standard error

[a] Includes all comorbidities in the APACHE III system.
[b] Charlson score for comorbidities not included in Ex-APACHE III.
[c] Includes scores for all abnormal acute pathophysiologic measures in APACHE III system.

the same eligibility group, resulting in a total of 1391 patients. Patients with ARI had significantly different APACHE III scores, HAI rates, and death rates, compared with those without ARI (Table 1). Among those with ARI, 34 (18.1%) died, compared with 36 (3.0%) of patients without ARI; ($P < .01$). The mortality odds ratio, adjusted for APACHE III, ICU care, and HAI, was 2.16, resulting in an attributable mortality rate of 6.5% or 12 excess deaths in the sample caused by ARI alone. Figure 1 illustrates that predicted mortality increased with APACHE III score, with higher increases among patients with ARI. There were 205 unique ARIs among 188 patients, and 260 patients had HAI. Among patients with ARI, 135 (71.8%) had concurrent HAI. Eleven patients (5.9%) were infected with >1 drug-resistant organism. Patients with ARI had significantly

Table 4. Antimicrobial-Resistant Organism Subgroup Distribution, Mean Medical Costs, and Attributable Costs

Variable	R^2	Organism or infection					
		ARI	MRSA	VRE	AREK	AIR	Multiple ARIs[a]
Drug-resistant subgroup distribution (n = 1391)							
Individual patients							
No. (%) of patients	...	188	81 (43.1)	58 (30.9)	30 (16.0)	8 (4.3)	11 (5.9)
Total cost, mean US$ ± SD	...	...	46,236 ± 58,482	66,416 ± 70,747	26,549 ± 27,121	97,444 ± 47,237	157,835 ± 94,181
Community-acquired ARI							
No. (%) of patients	...	...	31 (47.7)	13 (20.0)	19 (29.2)	2 (3.1)	...
Total cost, Mean US$ ± SD	...	...	22,449 ± 18,429	41,963 ± 30,471	19,107 ± 14,817	56,588 ± 29,027	...
Health care–acquired ARI							
No. (%) of patients	...	...	50 (44.6)	45 (40.2)	11 (9.8)	6 (5.4)	...
Total cost, mean US$ ± SD	...	...	60,984 ± 69,254	73,481 ± 77,479	39,403 ± 38,091	111,062 ± 45,444	...
Individual infections							
No. (%) of infections	...	205	94 (45.9)	69 (33.7)	32 (15.6)	10 (4.9)	...
No. (%) of community-acquired ARIs	...	70 (34)	35 (50.0)	14 (20.0)	19 (27.1)	2 (2.9)	...
No. (%) of health care–acquired ARIs	...	135 (66)	59 (43.7)	55 (40.7)	13 (9.6)	8 (5.9)	...
Attributable medical costs, US$ ± SE							
Confounders used in regression							
Surgery, ICU, and APACHE III score	0.54	...	18,380 ± 2605	33,944 ± 3062	8241 ± 4075[b]	48,723 ± 8122	117,312 ± 6766
Surgery, ICU, Ex-APACHE III score[c]	0.54	...	18,303 ± 2612	33,920 ± 3064	8290 ± 4074[b]	49,138 ± 8074	117,210 ± 6769
Surgery, ICU, and PS-1	0.54	...	16,870 ± 2645	31,975 ± 3093	7190 ± 4063[d]	47,845 ± 7932	116,289 ± 6737
Surgery, ICU, PS-1, and AP-APACHE[e]	0.54	...	16,711 ± 2649	31,919 ± 3093	7066 ± 4065[d]	45,966 ± 8143	116,191 ± 6738
Adjusted for HAI							
Surgery, ICU, APACHE III score, HAI	0.55	...	11,842 ± 2693	25,543 ± 3196	3541 ± 4041[d]	42,190 ± 8005	109,110 ± 6716
Surgery, ICU, Ex-APACHE III score,[c] and HAI	0.55	...	11,803 ± 2698	25,545 ± 3197	3599 ± 4039[d]	42,625 ± 7958	109,054 ± 6719
Surgery, ICU, PS-1, and HAI	0.56	...	10,846 ± 2718	24,104 ± 3214	2768 ± 4030[d]	41,563 ± 7827	108,471 ± 6692
Surgery, ICU, PS-1, AP-APACHE III score,[e] HAI	0.56	...	10,732 ± 2722	24,080 ± 3214	2679 ± 4032[d]	40,033 ± 8029	108,413 ± 6693

NOTE. All parameter estimates for cost and all overall economic model significance tests and F statistics were significant at $P<.001$, unless otherwise indicated. AIR, amikacin or imipenem resistant *Enterobacter, Pseudomonas,* or *Acinetobacter* species; APACHE, Acute Physiology and Chronic Health Evaluation; AREK, *Escherichia coli* resistant to fluoroquinolones or third-generation cephalosporins or *Klebsiella* species resistant to third-generation cephalosporins; Ex-APACHE, expanded APACHE; HAI, health care–acquired infection; ICU, intensive care unit; MRSA, methicillin-resistant *Staphylococcus aureus;* PS-1, propensity score 1; SD, standard deviation; SE, standard error; VRE, vancomycin-resistant enterococci.

[a] Patients infected with >1 antimicrobial-resistant organism.
[b] $P<.05$.
[c] Includes all comorbidities in the APACHE III system.
[d] P = not significant.
[e] Includes scores for all abnormal acute pathophysiologic measures in APACHE III system.

Table 5. Mean Cost and Length of Stay for Patients with Antimicrobial-Resistant Infection (ARI), Compared with Matched Control Subjects

Propensity score	Patients with ARI	Patients without ARI	Mean difference	*P*
Propensity score 2[a]				
No. of patients	169	169	...	
Total cost, US$	53,863 ± 60,720	24,794 ± 23,231	29,069	<.001
Total length of stay, days	23.8 ± 20.3	12.8 ± 10.2	11.0	<.001
Propensity score 3[b]				
No. of patients	138	138	...	
Total cost, US$	52,211 ± 59,456	31,003 ± 26,325	21,208	<.001
Total length of stay, days	22.5 ± 20.1	15.9 ± 11.3	6.7	<.001

NOTE. Data are mean ± standard deviation, unless otherwise indicated.

[a] Comorbidities, surgery, and intensive care unit stay.

[b] Comorbidities, surgery, intensive care unit stay, and health care–acquired infection.

higher rates of comorbidities, surgery, ICU care, and HAI, demonstrating the need to control for confounding. Comorbidities associated with ARI were candidates for inclusion in the propensity scores (Table 2).

In the random sample of 1253 patients, the attributable cost of ARI (± standard error) in all patients was $27,715 ± $2399, and the attributable length of stay (± standard error) was 12.7 ± 1.2 days (Table 3). When adjusted to control for the effects of HAI, the attributable cost for ARI was $21,018 ± $2380, and the length of stay was 9.3 ± 1.1 days. In the sensitivity analysis, attributable costs ranged from $20,840 to $27,715. In the expanded sample of 1391 patients, costs ranged from $27,216 (base case) to $18,588 when adjusted for PS-1, AP-APACHE III, surgery, ICU care, and HAI. In the hospital service and treatment setting subgroup analysis, patients in the ICU subgroup incurred the highest costs, followed by those in the surgical group. When adjusted for surgery, ICU care, PS-1, and HAI, the attributable costs (± standard error) in the patient subgroups were as follows: ICU, $35,726 ± $7016; surgical ward, $31,289 ± $8044; medical ward, $12,505 ± $1821; and non-ICU, $3731 ± $902. Among all patients infected with only 1 organism, AIR infections were the most costly, followed by vancomycin-resistant enterococci and methicillin-resistant *S. aureus* infections (Table 4). When used to adjust for confounding, the PS-1 resulted in more robust parameter estimates than did the APACHE III score. Adding the Ex-APACHE III, the AP-APACHE, and Charlson additional comorbidities reduced the attributable cost but did not improve the significance of the regression coefficients. In the matched control analysis, the mean cost difference between ARI cases and matched controls was $29,069 ($P < .001$). (Table 5) This cost difference decreased to $21,208 when HAI was included in the propensity score.

The total attributable hospital and societal cost ranges for ARI in the expanded sample were as follows: hospital, $3.4–

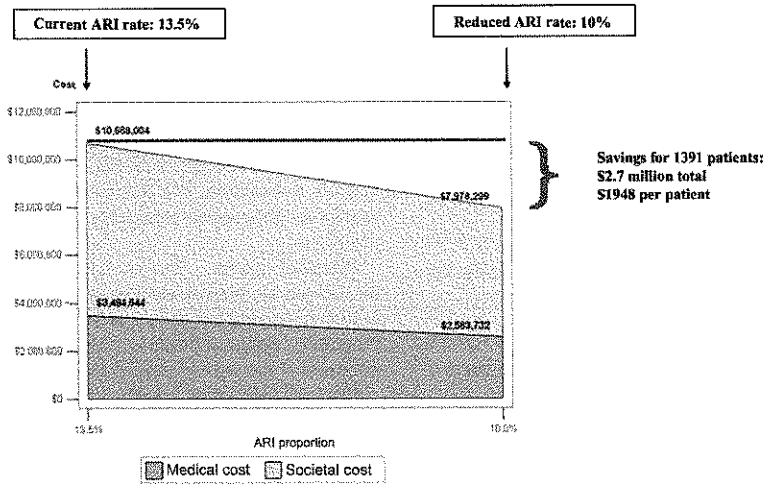

Figure 2. Projected cost savings if antimicrobial-resistant infection (ARI) rates were reduced from 13.5% to 10%.

$5.4 million; mortality, $7.0–$9.2 million; lost productivity, $162,624–$322,707; and total, $10.7–$15.0 million. The total medical cost, if distributed to all sample patients, added $2512–$3929 (16.8%–26.3%) to the mean unadjusted hospital cost for all sample patients. Figure 2 illustrates the potential cost savings for the hospital and society if the ARI rate had been reduced by 3.5% in the cohort of 1391 patients. We used the lowest cost and length of stay figures from the sensitivity analysis to predict savings for this cohort if the ARI rate could have been held at 10%. The study hospital would have saved $910,812, and the societal savings for reduced mortality and lost productivity would have been $1.8 million. In 2008 US dollars, the total attributable medical and societal cost for ARI alone in 188 patients in a single hospital cost a minimum of $13.35 million. Use of our highest estimates resulted in total costs of $18.75 million.

DISCUSSION

Our study is unique in combining hospital treatment subgroups, a variety of resistant organisms, infection sites, and both healthcare and community-acquired infections. In this cohort, the occurrence of ARI was associated with an attributable cost of $21,018 per infected patient, after adjusting for cost confounding associated with initial severity of illness, ICU care, surgical procedures, and concurrent HAI. In the sensitivity analysis, cost estimates were $25,641–$29,069 without adjustment for HAI and $18,588–$21,208 with adjustment for HAI. The death rate was 2-fold higher among those with ARI, even after controlling for APACHE III scores, ICU care, and concurrent HAI. There was wide variation in the cost based on type of infecting organism, hospital service, and treatment setting.

Our findings indicate that significant health and economic benefits could be realized through effective interventions to reduce both ARI and HAI. A variety of programs have been developed to address antimicrobial resistance. They focus on prudent antimicrobial use, education, and infection control [1, 10, 19, 21, 44–48]. Ideally, future investigations will measure the independent effects of antimicrobial use and infection transmission on ARI rates and how they vary by organism, setting, and patient comorbidities. This approach will allow a more complete illustration of the contribution of ARI to total hospital and societal burden that can be used to estimate the potential value of future successful interventions.

There are several limitations to this work. All data are from a single hospital in a single year and did not include several important patient subgroups. Children and patients receiving obstetrical, trauma, and burn care were excluded because of their low numbers and unique infections. There may have been additional risks for high cost or death that we did not measure. Our costs and mortality rates were measured in a subset of hospital patients at high risk and severity of illness; therefore, these numbers cannot be applied to all patients with ARI in the community. In addition, the costs used to estimate lost productivity from hospitalization and death were national averages and may not apply to a sicker population. Reduction in the quality of life would be a more accurate measure of societal cost, but the retrospective design prevented access to that information. This would be an important future study direction. We adapted existing severity of illness scores to address the potential confounding in this study. Although these scores were originally developed for predicting mortality, both have more recently been used to predict cost and length of stay [41, 49] Infections categorized as community acquired may have actually been acquired during prior health care encounters that we were unable to measure, and "community-onset" ARIs are increasingly recognized as being health care associated. The projected savings from a 3.5% reduction in ARI rates assumed an equivalent reduction for all treatment subgroups and organisms.

A strength of our study was that we were able to measure costs with precision and to attribute them to specific subgroups, whereas other studies have had to rely on reported resistance through the use of *International Classification of Diseases, 9th Edition, Clinical Modification* VO9 codes, which indicate the presence of resistance but do not link it to a causative organism [50].

Although we might be critiqued for underestimating, our most conservative costs for ARI were still considerable. This detailed analysis of the cost of antibiotic resistance in a single large teaching hospital gives an indication of the magnitude of the burden imposed by resistance in the United States, and it should lead to increased efforts to control antibiotic resistance.

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Potential conflicts of interest. All authors: no conflicts.

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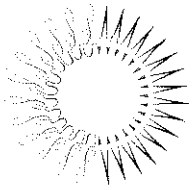

THE PEW CHARITABLE TRUSTS

MEMORANDUM

TO: The Honorable Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget

FROM: Laura Rogers, Director, Campaign on Human Health and Industrial Farming, The Pew Charitable Trusts, lrogers@pewtrusts.org, (202) 552-2018
Shannon Heyck-Williams, Government Relations Officer, The Pew Charitable Trusts, sheyck-williams@pewtrusts.org, (202) 887-8801

DATE: November 13, 2013

RE: **Economic Rationale Supporting Final FDA Guidance #213 and a Proposed Rule on the Veterinary Feed Directive**

The Pew Charitable Trusts agrees with the U.S. Food and Drug Administration's conclusion that growth promoting use of medically important antibiotics in food animals is injudicious and must be ended, and that over-the-counter use of these drugs in animal feed must be replaced by veterinarian prescriptions. These are the principles encapsulated in the agency's Guidance to Industry #213, as well as a proposed rule regarding the Veterinary Feed Directive (VFD), which are at the Office of Management and Budget for review.

Pew would prefer a binding approach to ending growth promotion and all injudicious disease prevention uses (where there is no documentable disease present). In fact, the literature and real-world experience in other nations show little to no economic harm plus public health benefit from broader measures banning all nontherapeutic uses in food animals. Still, we support Guidance 213 and the proposed VFD rule and urge OMB to publish them before the end of 2013 in order to initiate the three-year implementation period, and to move to the necessary next steps as required to protect public health. Pew also urges the administration to quickly improve upon data collection and reporting methods regarding antibiotic use in food animal production, to allow for analysis of public health impact as well as evaluation of alternatives and solutions to current antibiotic practices.

Background

The U.S. Centers for Disease Control and Prevention released a report in September 2013 that sounded an alarm about the looming "catastrophe" of antibiotic resistance. The agency estimated (conservatively) that 2 million people acquire drug-resistant infections inside and outside of the U.S. health care system each year, and 23,000 die because of those infections.[1] Peer-reviewed literature shows that antibiotic resistance – due to all causes – is a costly problem. Health care costs equal as much as $26 billion per year by one estimate, or $35 billion per year when including societal costs such as lost work days and premature death.[2] Meanwhile, we know from government reports and decades of scientific study that antibiotic use in food animals can make people sick with antibiotic-resistant infections. U.S. Food and Drug Administration antibiotic sales reports reveal that 80 percent of all antibiotics sold in the United States are destined for use in food animal production.[3] For this reason, the CDC, FDA, World Health Organization, and Government Accountability Office, among others, indicate that the global threat of antibiotic resistance cannot be adequately addressed without reducing inappropriate uses of antibiotics in animal agriculture.

While there has been no comprehensive federal assessment of the economic impact of reducing agricultural antibiotic use in the United States, individual peer-reviewed studies suggest that curbing overuse in farming does not have to harm U.S. livestock production or the American consumer. In fact, research shows that ending the non-therapeutic use of antibiotics in food animals in the U.S. may have no economic impact on poultry production, small or short-term negative impact on pork production, and apply only minimal cost increase to consumers.[4] A 2012 Consumer Reports survey of meat and poultry products found that grocery items labeled "no antibiotics" were often comparably priced to conventionally raised meats.[5] Research and experience in the U.S. and Denmark also suggest that cost-effective alternative production practices – such as improving barn ventilation, cleaning waste better and more frequently, using straw bedding, and weaning animals a few days later – can safeguard production in the absence of routine antibiotic use.[6]

Denmark, which vies with the United States for status as top pork exporter globally, instituted a ban on non-therapeutic antibiotic use by 2000 that supports these research findings. Studies found there was a greater than 50 percent decrease in the use of antimicrobials per kilogram of pig produced during the time period from 1992-2008, which was associated with Denmark's policy to discontinue the use of growth promoting antibiotics. During this time the mortality rate was steady and production increased, suggesting that this policy did not have a negative impact on swine production in Denmark.[7] Plus, importantly, antibiotic resistance in the animal and human populations declined.[8] A similar story can be told for Finland, Norway, and

Sweden.[9] The Netherlands, also a highly industrialized top pork exporter, is now embarking on real reductions in antibiotic use. Dutch officials report that after implementing better tracking and voluntary measures to reduce use, pork producers have cut antibiotic use in half with no changes in production or increased cost.[10]

Additional Key Facts and Resources

Below is additional information on: the incidence of antimicrobial resistance in the U.S.; estimates of the cost of antibiotic resistance in the U.S.; and the likely contribution to antibiotic resistance caused by routine nontherapeutic uses of antibiotics in food animal production.

A) **The incidence of antibiotic resistance in the U.S.** There are no accurate comprehensive tallies of antibiotic resistant infections in the United States. However, the 2013 CDC report on antibiotic resistance estimated: "in the United States, more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result. The estimates are based on conservative assumptions and are likely minimum estimates. They are the best approximations that can be derived from currently available data."[11] Additionally, independent studies have generated some estimates for particular diseases or in particular facility settings. Examples include:
   1) Methicillin-resistant *Staphylococcus aureus* (MRSA) infections:
      a) In 2005, there were more than 94,000 MRSA infections, and nearly 19,000 deaths. Incidence was highest in patients older than 65 years of age and among African-Americans. According to authors, "Invasive MRSA infection affects certain populations disproportionately. It is a major public health problem primarily related to health care but no longer confined to intensive care units, acute care hospitals, or any health care institution."[12]
      b) From 1999-2005, the estimated number of MRSA-related hospitalizations more than doubled, from 127,036 to 278,203.[13]
      c) The CDC reported that in 2007, 14 percent of people with MRSA infections had acquired them from the general community.[14]
      d) MRSA from an animal reservoir is now responsible for more than 20 percent of all human MRSA infections in the Netherlands.[15]
      e) Livestock-associated MRSA has been found in 49 percent of swine and 45 percent in workers tested in the Midwestern U.S. Results show that MRSA is common in swine production in the U.S. and that these animals could be harboring the bacterium.[16]
      f) A 2013 study of farmworkers and their family members in North Carolina revealed that while MRSA was found in both industrial (using antibiotics nontherapeutically) and antibiotic-free pig farming operations, livestock-associated MRSA and multidrug

resistant MRSA were only found in industrial farming-exposed individuals. The authors concluded: "These findings support growing concern about antibiotics use and confinement in livestock production, raising questions about the potential for occupational exposure to an opportunistic and drug-resistant pathogen, which in other settings including hospitals and the community is of broad public health importance."[17]

2) Other bacterial illness:
   a) The CDC estimates that 48 million people get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases in the United States annually.[18] Many antibiotic-resistant strains of bacteria include those that cause common foodborne illness. These bacteria include, but are not limited to, *Escherichia coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, and *Campylobacter jejuni*. The CDC declared certain antibiotic-resistant strains of foodborne bacteria "serious" public health threats in its 2013 report, such as drug-resistant *Campylobacter* and *Salmonella*, infecting an estimated 310,000 and 100,000 people and killing 28 and 40 people annually, respectively.[19]

B) **Estimates of the cost of antibiotic resistance in the U.S.** Whether regarding specific infections (e.g., MRSA), populations (e.g., the elderly), or facilities (e.g., hospitals or nursing homes), treating antibiotic-resistant infections places a significant cost burden on society. Individuals infected with drug-resistant organisms are more likely to require hospitalization, to remain in the hospital for a longer time, and to have a poor prognosis. For example:
   1) A 2009 study by the Alliance for the Prudent Use of Antibiotics and Cook County Hospital in Chicago estimated that the medical costs attributed to hospitalized patients with antibiotic-resistant infections ranged from $18,588 to $29,069 per patient, while the duration of hospital stay was extended 6.4-12.7 days for affected patients. Additionally, these patients experienced a death rate two-fold higher than in patients without antibiotic-resistant infections. The researchers extrapolated that the added health care costs of antibiotic resistance nationwide could total $26 billion annually, while societal costs could equal as much as $35 billion, including the cost of lost work days and premature deaths.[20]
   2) In 1998, the National Academies of Science (NAS) Institute of Medicine (IOM) noted that antibiotic-resistant bacteria increases U.S. health care costs by a minimum of $4 billion to $5 billion annually.[21]
   3) Additional examples of disease-specific studies of costs conclude:
      a) Methicillin-resistant *Staphylococcus aureus* (MRSA) infections tend to increase hospital costs anywhere from 137 percent to 244 percent over non-infected control

patients, according to a 2008 publication. There are similar cost disparities for vancomycin-resistant *Enterococci* (VRE) and *Acinetobacter baumannii*.[22]

b) A 2007 study estimated that the excess cost of a MRSA infection compared with a methicillin-susceptible *Staphylococcus aureus* infection ranged from about $3,000 to $35,000. This suggests that MRSA alone cost the health care system (patients and hospitals) an extra $830 million–$9.7 billion in 2005.[23]

c) The median hospital charge for patients with MRSA surgical site infections is $92,363, significantly higher than the median hospital charge for those with methicillin-susceptible surgical site infections, $52,791. Also, patients with either type of infection have a significantly higher median charge than do patients without infection ($29,455).[24]

d) Vancomycin-resistant *Enterococci* (VRE) infections generated significantly greater hospital charges than non-infected cases ($13,884 in additional charges and an attributable cost of $9,719 per case); and higher charges than vancomycin-susceptible infections ($12,766 in additional charges and an attributable cost of $8,936 per infection).[25]

4) Separate studies have assessed some of the especially costly impacts of antibiotic-resistant infections among the elderly and others in extended care facilities. For example, gerontologists at a 2005 national conference concluded that drug-resistant and -susceptible infections in long-term care facilities can have a devastating effect on the elderly, causing over 100,000 deaths per year and costing over $1 billion annually to our health care system.[26]

C) The likely contribution to the problem caused by routine nontherapeutic uses of antibiotics in food animal production.

1) The FDA's most recent antibiotic sales report under the auspices of the Animal Drug User Fee Act showed that 80 percent of all antibiotics sold in the United States are destined for use in food animal production. Of the medically important antibiotics (those drugs that the World Health Organization considers highly important or critical for human health), over 70 percent are sold for food animal use.[27] Though the FDA has proposed improving data collection and reporting on antibiotic sales and use, the public does not currently have access to information detailing how much of this total is used nontherapeutically.[28]

2) However, estimates of sales or use probably cannot be directly correlated with the percentage contribution of food animal use to human antibiotic resistance. An article from *Environmental Health Perspectives* provides some background on this: even though nontherapeutic antibiotic use in food animals has been shown to select for antibiotic resistance in both commensal (residing in a body but not causing infection)

and pathogenic (disease-causing) bacteria in: 1) the animals themselves; 2) subsequent animal-based foods; and 3) water, air, and soil samples collected around large-scale animal feeding operations, and that antibiotic-resistant bacteria can be transmitted from swine and poultry to humans, there is "insufficient data available to determine the *percentage* of antibiotic-resistant human bacterial infections that are attributed to animal feeding practices versus practices and behaviors occurring in human clinical settings."[29] (emphasis added)

It is worth noting that there are pitfalls to quantifying the cost of antibiotic resistant infections. Some researchers conclude antimicrobial resistance is likely to have a much greater impact on the national economy than would be estimated by looking at the health care sector alone. Most studies to-date are only microeconomic in scope, focusing on one hospital setting or one bacterium, for example. Few studies have assessed the costs associated with community-acquired antibiotic resistant infections, even though a significant proportion of antibiotic treatments are given outside a hospital.[30] Although the adverse economic and health effects of drug-resistant bacterial infections can only be roughly quantified, it is concluded that antimicrobial resistance is an important health problem and an economic burden to society.[31]

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[1] U.S. Centers for Disease Control and Prevention (CDC) (2013). *Antibiotic Resistance Threats in the United States: 2013.* Atlanta. Available at: http://www.cdc.gov/drugresistance/threat-report-2013/.

[2] Roberts, R. R. et al (2009). Hospital and Societal Costs of Antimicrobial-Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship. *Clinical Infectious Diseases, 49*, 1175-1184. See also: Biomerieux and Alliance for the Prudent Use of Antibiotics (October 19, 2009). Antibiotic-Resistant Infections Cost the U.S. Healthcare System in Excess of $20 Billion Annually. Available at: http://www.biomerieux-usa.com/servlet/srt/bio/usa/dynPage?open=USA_NWS_NWS&doc=USA_NWS_NWS_G_PRS_RLS_73&crptprm=ZmlsdGVyPQ.

[3] FDA. *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals.* Washington, D.C. Available at: http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042896.htm.

[4] See, for example: Graham, J. (2007). Growth promoting antibiotics in food animal production: An economic analysis. *Public Health Reports, 122*, 79-87. Also, a 1999 report by the National Research Council found that a ban on all nontherapeutic uses of antibiotics in food animals would result in only a $4.94-9.72 per capita increase in consumer costs annually (in 1997 dollars). See: National Research Council (1999). *The Use of Drugs in Food Animals: Benefits and Risks.* Committee on Drug Use in Food Animals, Panel on Animal Health, Food Safety, and Public Health, Institute of Medicine. Washington, D.C.: National Academies Press, 185.

[5] Consumer Reports. (2012). *Meat on Drugs: The overuse of antibiotics in food animals & what supermarkets and consumers can do to stop it.* Yonkers, NY: Consumer Reports.

[6] See, for example: MacDonald, J. M. and William D. McBride (January 2009). *The Transformation of U.S. Livestock Agriculture: Scale, Efficiency, and Risks.* Economic Research Service. Washington, D.C.: U.S. Department of Agriculture; MacDonald, J.M. and S.L. Wang (2011). Foregoing sub-therapeutic antibiotics: the impact on broiler grow-out operations. *Applied Economic Perspectives and Policy,* 1-20; McEwan, S.A. and P.J. Fedorka-Cray (2002). Antimicrobial use and resistance in animals. *Clinical Infectious Diseases 34 (Suppl 3)*: S93-106; and Miller, G.Y. et al (2003). Productivity and economic effects of antibiotics used for growth promotion in U.S. pork production. *Journal of Agricultural and Applied Economics, 35(3)*: 469-482.

[7] Aarestrup, F. M. et al (2010). Changes in the use of antimicrobials and the effects on productivity of swine farms in Denmark. *American Journal of Veterinary Research, 71(7)*, 726-733. See also: Ministry of Food, Agriculture and

Fisheries, Danish Veterinary and Food Administration (December 8, 2009). Information note regarding the Danish and EU restrictions of non-therapeutical use of antibiotics for growth promotion. Available at: http://www.foedevarestyrelsen.dk/english/SiteCollectionDocuments/25_PDF_word_filer%20til%20download/05kontor/Info_om_vaekstfremmerforbud_samt_oevrige_riskmanagement_str_UK.pdf.

[8] DANMAP (2008). *Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, foods and humans in Denmark.* Danish Integrated Antimicrobial Resistance Monitoring and Research Programme. Available at: http://www.danmap.org/Downloads/Reports.aspx.

[9] See, for example: Grave, K. et al (2006). Usage of veterinary therapeutic antimicrobials in Denmark, Norway and Sweden following termination of antimicrobial growth promoter use. *Preventive Veterinary Medicine 75 (1-2)*: 123-132; and Bengtsson, B. and M. Wierup (2006). Antimicrobial resistance in Scandinavia after ban of antimicrobial growth promoters. *Animal Biotechnology 17(2)*: 147-156.

[10] NETHMAP/MARAN (2013). *Nethmap: Consumption of antimicrobial agents and antimicrobial resistance among medically important bacteria in the Netherlands. MARAN: Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands in 2012.* Available at: http://www.wageningenur.nl/nl/Expertises-Dienstverlening/Onderzoeksinstituten/central-veterinary-institute/Publicaties-CVI/MARAN-Rapporten.htm.

[11] CDC (2013) *op. cit.*

[12] Klevens, M.R. et al (2007). Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States. *Journal of the American Medical Association 298(15)*: 1763-1771. See also: *New York Times*, October 16, 2007, "Infection Killed 19,000 in 2005, Study Says," http://www.nytimes.com/2007/10/16/health/16cnd-infect.html.

[13] Klein, E. et al (2007). Hospitalizations and deaths caused by methicillin-resistant *Staphylococcus aureus*, United States, 1999-2005. *Emerging Infectious Diseases 13(12)*: 1840-1846.

[14] WebMD. (n.d.). Understanding MRSA Infection -- the Basics. Retrieved November 11, 2013, from http://www.webmd.com/skin-problems-and-treatments/understanding-mrsa-methicillin-resistant-staphylococcus-aureus.

[15] van Loo, I. et al. (2007). Emergence of methicillin-resistant Staphylococcus aureus of animal origin in humans. *Emerging Infectious Diseases 13(12):* 1834-1839.

[16] Smith, T.C. et al (2009). Methicillin-resistant *Staphylococcus aureus* (MRSA) strain ST398 is present in Midwestern U.S. swine and swine workers. *PLoS ONE 4(1)*: e4258.

[17] Rinsky, J.L. et al (2013). Livestock-associated methicillin and multidrug resistant *Staphylococcus aureus* is present among industrial, not antibiotic-free livestock operation workers in North Carolina. *PLoS ONE 8(7)*: e67641.

[18] CDC (February 6, 2013). Estimates of Foodborne Illness in the United States. Retrieved November 11, 2013, from http://www.cdc.gov/foodborneburden/.

[19] CDC (2013) *op. cit.*

[20] Roberts (2009) *op. cit.*

[21] Harrison, P. and J. Lederberg, eds (1998). *Antimicrobial Resistance: Issues and Options*. Workshop Report, Forum on Emerging Infections, Division of Health and Sciences Policy, Institute of Medicine. National Academy Press: Washington, D.C.

[22] Scott, R.D. and R. R. Roberts (2008). The Attributable Costs of Resistant Infections in Hospital Settings: Economic Theory and Application. In: *Antimicrobial resistance: problem pathogens and clinical countermeasures*, New York: Informa Healthcare.

[23] Klein, E. (2007) *op. cit.*

[24] Cosgrove S.E. and Y. Carmeli (2003). The impact of antimicrobial resistance on health and economic outcomes. *Clinical Infectious Diseases* 36: 1433-7.

[25] Kaye, Keith S. et al (June 2004). Reference group choice and antibiotic resistance outcomes. *Emerging Infectious Diseases* 10(6).

[26] Chilton, Lynn L.. (2005). Infections and Antimicrobial Resistance in the Elderly Living in Long-Term Care Settings, *Highlights of the NCGNP 23rd Annual Convention*. Available at: http://www.medscape.org/viewarticle/493678.

[27] FDA (2011) *op. cit.*

[28] Note: The Union of Concerned Scientists has made estimates that as much as 70 percent of all antibiotics and related drugs (antimicrobials) sold in the U.S. are administered to food animals for nontherapeutic purposes, i.e., not to treat disease but for growth promotion, feed efficiency, and disease prevention. See: Mellon, M. et al

(2001). *Hogging It!: Estimates of Antimicrobial Abuse in Livestock.* Cambridge, MA: Union of Concerned Scientists, p. 63.

[29] Sapkota, A.R. et al (May 2007). What do we feed to food-production animals? A review of animal feed ingredients and their potential impacts on human health. *Environmental Health Perspectives 115(5)*: 663-670.

[30] For a more thorough discussion on the methodology of assessing the economic impact of antibiotic resistance, see: McGowan, J.E. (2001). Economic Impact of Antimicrobial Resistance. *Emerging Infectious Diseases 7(2);* and, Smith, R.D. et al (2006). A macroeconomic approach to evaluating policies to contain antimicrobial resistance: a case study of methicillin-resistant *Staphylococcus aureus* (MRSA). *Applied Health Economics and Health Policy* 5(1): 55-65.

[31] Holmberg, S.D. et al (1987). Health and economic impacts of antimicrobial resistance. *Reviews of Infectious Diseases* 9(6):1065-78.

November 12, 2013

The Honorable Sylvia Matthews Burwell
Director, Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Dear Director Burwell:

We are writing to urge you take swift action to curb unnecessary uses of medically-important antibiotics in food animal production. Specifically, we support prompt finalization of a strong Food and Drug Administration Guidance #213 ending antibiotic use for growth promotion and unnecessary disease prevention, as well as publication of rule proposals to expand veterinary oversight of in-feed antibiotic use and to collect data on antibiotic use in animal agriculture. We have more than enough scientific evidence to justify curbing the rampant use of antibiotics for livestock, and, as former FDA Commissioners, we appreciate that the Obama administration is poised to take significant action on this elusive public health challenge, even up against tremendous industry pressures.

We are convinced that feeding low doses of antibiotics to livestock and poultry is a recipe for disaster. The FDA first raised concerns about this practice in the 1970s when it proposed a rule that was thwarted by Congress. Since then, the antibiotic resistance crisis has only grown. We recognize that we are facing what the Centers for Disease Control and Prevention and World Health Organization name a looming "catastrophe" of failing antibiotic treatments caused by overuse and misuse of antibiotics in both human medicine and agriculture. FDA reports now show that 80 percent of all antibiotics in the United States are being sold for use in farming—an increase over previous years. All segments of society should be part of the solution, especially that which uses the vast majority of the antibiotics.

The FDA issued a draft version of its policy in April 2012 and received public comments, as required, but the comment period closed over a year ago. Drugmakers have been left awaiting further instruction. The new guidelines cannot come soon enough. The FDA annually examines bacteria on retail meat and poultry, and each year the bugs show more resistance to antibiotics. Moreover, several new studies using genetic analysis demonstrate with great precision the evolution and transmission of resistant pathogens not traditionally linked to food. Methicillin-resistant *Staphylococcus aureus* is a troublesome new source of livestock-associated infections, and the *E. coli* that cause drug-resistant urinary tract infections can also be transmitted to people via food.

Action by the Obama administration would be an initial—and long-awaited—step to encourage livestock producers to stop relying on massive overuse of antibiotics to compensate for overcrowding, poor hygiene, and lax animal health management. This administration should finalize Guidance 213 and end antibiotic use for growth promotion and unnecessary disease prevention, tell the public how data will be collected to ensure that its voluntary strategy is working and then, if antibiotic misuse continues unabated, apply the full force of regulation. It should also require veterinarian oversight of antibiotic use in feed.

It has been 36 years since the FDA moved to restrict injudicious antibiotic practices that threatened the public's health. It should not wait any longer to finish the job. You have our support to take the next step.

Sincerely,

Donald Kennedy, Ph.D.
Former Commissioner
U.S. Food and Drug Administration

David Kessler, M.D.
Former Commissioner
U.S. Food and Drug Administration

Cc: Secretary Kathleen Sebelius, U.S. Department of Health and Human Services
Commissioner Margaret A. Hamburg, M.D., Food and Drug Administration

September 26, 2013

Chef Sam Kass
Executive Director and Policy Advisor for Nutrition Policy
Let's Move Initiative, Office of the First Lady
Executive Office of the President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Chef Kass:

As fellow chefs, we are writing to ask you to support much-needed policies to rein in the overuse of antibiotics in food animals and ensure that these drugs remain effective for future generations. We share your deep commitment to creating a more sustainable and healthy food system, and believe that antibiotics should only be used to treat sick animals, not to compensate for unsanitary conditions or make animals grow faster. The cost of these farming practices to public health is simply too high. At a minimum, President Obama and his administration should swiftly finalize policies drafted by the Food and Drug Administration to end the most egregious misuses of antibiotics and expand veterinary involvement in their use on the farm.

The fact that antibiotic overuse on industrial farms contributes to the development of drug-resistant superbugs is not news. Back in 1977, FDA first tried to implement policies to restrict antibiotic use for food animal production. However, Congress prevented the agency from acting. Since that time hundreds of peer-reviewed studies have confirmed the connection between drug use on the farm and resistant infections in people. The calls for action from the public health community and consumers have grown only more urgent.

At our restaurants every day, we strive to serve meat and poultry raised on farms where antibiotics are not misused. We are committed to making sure that our food is raised in a way that does not put the health of our patrons and the greater public at risk. We are doing our part and call on government and industry to do theirs.

Under President Obama's leadership, FDA resumed its long-delayed effort to curb the overuse and misuse of antibiotics in food animal production. While the agency did not continue its original strategy of mandating restrictions, it is pushing a mix of voluntary and mandatory measures that instruct drug companies to stop marketing antibiotics for growth promotion and routine disease prevention and expand veterinary oversight of antibiotic use on the farm (i.e., Guidance #213 and changes to the Veterinary Feed Directive). More than 14 months have passed, though, and Guidance #213 remains in draft form and there still is no draft rule amending the Veterinary Feed Directive.

As America's First Chef, you have the unique opportunity to help make our food system safer and more sustainable. Please encourage President Obama and his administration to quickly finalize policies to stop antibiotic overuse and misuse on industrial farms.

Sincerely,

Hugh Acheson
5&10, the National, Empire State South
Athens, GA

Joseph Aguayo
La Piazza Locale
Phoenix, AZ

Daniel Ahern
Glutenfreegirl.com
Vashon, WA

Moomat Ahiko
Poppy Restaurant
Watertown, WI

Vince Alberici
Chef Consultant
Havertown, PA

Nicole Aloni
Self Employed Food Professional
Seattle, WA

Chris Amendola
Fleet Street Kitchen
Baltimore, MD

Bobbe Anderson
Goddess Personal Chef Service
North Easton, MA

Lynne Anderson
Jamaica Plain, MA

Jefferson Anderson
Virginia Mason Medical Center
Seattle, WA

Eve Aronoff
Frita Batidos
Ann Arbor, MI

John Ash
Culinary Institute of America
Santa Rosa, CA

Lisa Aspenson
Mona Lisa's
Eau Claire, WI

John Atwood
Jonathan's Harbor Special Events Food Service
Stone Harbor, NJ

Mike Bacha
Emory University Hospital
Atlanta, GA

Tom Bacon
The Weary Traveler
Madison, WI

Kyle Bailey
Birch & Barley/GBD
Washington, DC

Sarah Baker
Freelance
Cambridge, MA

Carrie Balkcom
American Grassfed Association
Denver, CO

Jeremy Barlow
Sloco
Nashville, TN

Jill Barron
Mana Food bar
Chicago, IL

Kim Bartmann
Barbette, Bread & Pickle, Bryant Lake Bowl, Gigi's Café, Pat's Tap, Red Stag Supperclub
Minneapolis, MN

Barbara Barton
MORE Healthy Foods
Montello, WI

Fedele Bauccio
CEO Bon Appetit Management Company
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Constance Bearden
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Jeremy Bearman
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Tomorrow's Table
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Crossroads Café
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Reuben Bhate
The Modern, Union Square Hospitality group
Jersey City, NY

Claire Biesty
Chefs Collaborative
Highland Falls, NY

Bonnie Lee Biren-Thibodeau
Medway, MA

Hillary Birtley
Local Harvest Cafe and Catering
St. Louis, MO

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FOODCalendar Publications
New York, NY

ChuK Blessum
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Christopher Blobaum
Legacy Restaurant Partners
Atlanta, GA

Pete Bonahoom
Galatic Pizza
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David Bonom
Tenafly, NJ

Diane Borker
Chef Magazine
Chicago, IL

David Boucher
Amaranth Bakery
Milwaukee, WI

Mary Jo Bouman
Via Iago
Dover, MA

Mary Jo Bouman
Via Lago Catering
Dover, MA

Jeannie Boutelle
The Local Beet/Edible Chicago Magazine
Chicago, IL

Thomas Boyle
Union League Club of Chicago
Chicago, IL

William Bradley
New England Aquarium
Boston, MA

Doug Bradley
ARAMARK at the Cleveland Clinic
Strongsville, OH

Chef Alain Braux
Peoples Pharmacy
Austin, TX

Roy Breiman
Cedarbrook Lodge
Seattle, WA

Carlin Breinig
Personal Chef
Alpharetta, GA

James Briscione
The Institute of Culinary Education
New York, NY

Cathy Brock
PPS Nutrition Services
Portland, OR

Sean Brock
Husk Restaurant
Nashville, TN

Walter Bronowitz
Seattle Children's Hospital
Lake Forest Park, WA

Nancy Brown
Carried Away Cuisine
Kilmarnock, VA

Steven Brown & David Dahmes
Tilia
Minneapolis, MN

John Bryant
Mountain Restaurant Group
Knoxville, TN

marina Bsuor-Fiore
Le Petit Cafe
Bloomingon, IN

John Bubala
Open Kitchen Chicago
Chicago, IL

Natasha Buck
Eurest but represent myself
Lowell, MI

Cammie Buehler
Epicure Catering & Cherry Basket Farm
Omena, MI

Mark Buley
Barley Swine
Austin, TX

Lilly Burdsall
Midwest Culinary Institute at Cincinnati State College
Cincinnati, OH

Anthony Burgess
La Prima Food Group
College Park, MD

Paul Burkhouse
Foxtail Farms
East Farmington, WI

Michael Buttles
The Art Institute of Jacksonville
Jacksonville, FL

Carla Caesar
Intel
Hillsboro, OR

Helen Cameron
Uncommon Ground
Chicago, IL

Michael Cameron
Uncommon Ground
Chicago, IL

Maria Campbell
Art Institute of Philadelphia
Media, PA

Floyd Cardoz
North End Grill
New York, NY

Teresa Carew
On Safari Foods, Inc.
Seattle, WA

Jacqueline Carey
Celilo Restaurant
Hood River, OR

Seth Caswell
Sudo Cafe and Local Host Café, Bon Appetit at Google
Kirkland, WA

Charles Catlin
Google
Mountain view, CA

Jessica Chakraborty
Thyme Natural Market and Cafe
Forest Hills, NY

Robert Chambers
Private Chef
Woodside, NY

Angela Chan
Women Chefs & Restaurateurs
Oakland, CA

Wendy Chan
Definity Marketing
New York, NY

Gabriel Charpentier
St Julien Hotel
Boulder, CO

Jacqueline Church
Boston, MA

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Finely JP's Bar & Restaurant
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Craig Deihl
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Michael Vigo
The Game Changers
Staten Island, NY

Sergio Vitale
Aldo's Ristorante Italiano; Chazz, a Bronx Original
Baltimore, MD

Brian von Eggers CEC
Wildhorse Resort & Casino
Pendleton, OR

Ype Von Hengst
Silver Diner
Rockville, MD

Kurt von Kahle
Kurt's Kitchen
Cambridge, MA

Brooke Vosika
Four SeasonsHotel - Boston
Boston, MA

Brook Waalen
Cafe Wren
Luck, WI

Marilyn Wade
Relish Restaurant Group
Cincinnati, OH

Derek Wagner
Nicks on Broadway
Providence, RI

Valerie Wall
Whitehorse Meadows Farm
Arlington, WA

Todd Walline
Blue Hills Country Club
Kansas City, MO

Jim Watkins
Bastyr University
Kenmore, WA

Matt Weingarten
Chefs collaborative
Brooklyn, NY

Jon West
Barley Swine
Austin, TX

Maureen Whitehouse
Cambridge, MA

Rod Williams
Slow Money Maine
Biddeford, ME

Kristi Willis
Kristi's Farm to Table
Austin, TX

Daniel Wolinsky
Frankies 570
New York, NY

Dan Wood
Private chef
Auburn, WA

Ryan Woods
Owlery
Bloomington, in

Monika Woolsey
Hip Veggies
Phoenix, AZ

Jin Soo Yang
Bamboo Sushi
Portland, OR

Matthew Weingarten
Sodexo
New York, NY

Susan West
Saltwater Connections
Buxton, NC

Cathy Whims
Nostrana, Oven and Shaker
Portland, OR

John Wight
Jordan Pond House
Franklin, ME

Virginia Willis
Virginia Willias Culinary Enterprises, Inc.
Atlanta, GA

nancy parker Wilson
Greenvale Vineyards
Portsmouth, RI

Mary Wood
D'Artagnan, Inc
Medford, MA

Stewart Woodman
Heidi's
Minneapolis, MN

Louis Woods
HCAT Institute at Anne Arundel Community College
Glen Burnie, MD

Clifford Wright
www.CliffordAWright.com
Santa Monica, CA

Patricia Yeo
Big Bowl/Lettuce Entertain You
Chicago, IL

Alex Young
Zingerman's Roadhouse
Ann Arbor, MI

Jeffrey Zurofsky
Witchcraft
New York, NY

Supermoms Against Superbugs

#saveabx

September 26, 2013

Mrs. Michelle Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mrs. Obama:

Can you imagine a world where ear infections, gonorrhea, meningitis, salmonella, sinus infections, strep throat, syphilis, tuberculosis, and urinary tract infections cannot be treated by antibiotics anymore? And, one in which surgeries cannot be performed because antibiotics do not work anymore? I am not being apocalyptic when I say that we are heading in that direction—and fast. As a mother and a public health professional who helped found the University of Chicago MRSA Research Center located just a few blocks from your and my Hyde Park homes, I am writing to alert you to a public health and medical crisis: the misuse and overuse of antibiotics in industrial food animal farming.

I care profoundly about the loss of effective antibiotics because my otherwise healthy and beautiful 1½ year-old son, Simon Sol Sparrow, died from an antibiotic-resistant superbug, MRSA (methicillin-resistant *Staphylococcus aureus*). On an ordinary Friday morning, nine years ago, Simon woke not feeling well and by nightfall he went into septic shock. He never woke again. It was months before we learned that Simon had died of MRSA. Simon's infection could not be treated with antibiotics because the MRSA strain he contracted had evolved to be resistant to the effects of antibiotics.

The Centers for Disease Control and Prevention just released a report about the looming "catastrophe" and "nightmare" of failing antibiotic treatments, caused by overuse and misuse of the drugs in human medicine and agriculture. While many parents understand that pediatricians are trying to reduce unnecessary antibiotic use in children, it surprises them to learn that antibiotics are a regular over-the-counter livestock feed and water supplement intended to increase growth and lessen the chance of infection in crowded, industrial farms. Dispensing antibiotics in this manner—regularly, at sub-therapeutic levels to healthy animals—is the perfect formula for bacteria to mutate into "superbugs." The concern is that if this issue is not addressed quickly in a systemic way, our once-upon-a-time wonder drug (antibiotics) will be rendered completely useless.

Decades of scientific literature show that antibiotic use in food animals can generate antibiotic-resistant superbugs, threatening human health. Science has also now demonstrated an association between living near livestock farms and manure-treated fields and antibiotic-resistant infections.

During his reelection campaign, President Obama said his administration was "taking steps to limit antibiotic use for livestock. This will help ensure that antibiotics are used only [to] address diseases and health problems, and not for enhancing growth and other production purposes." I am grateful for, and support, the President's commitment.

To restrict agricultural misuse of antibiotics, the Food and Drug Administration took two important steps in April 2012:

(1) It announced that it would issue a draft rule to require veterinary orders (akin to a doctor's prescription) for adding antibiotics to feed.

(2) It released a draft policy, Guidance for Industry #213, which would end most production uses of antibiotics over a three-year period.

Because of the long timeframe for implementation, if President Obama's administration does not finalize this policy before the end of 2013, the president will be relying on his successor to complete this effort to protect the public's health.

In a March 2013 letter to President Obama, the American Academy of Pediatrics, the March of Dimes, and several dozen leading public health, medical, environmental, and consumer leaders recommended that "by the start of the summer [2013] the FDA issue a finalized and strengthened guidance." The public is still waiting for his proposal.

This sense of urgency prompted more than 10,500 parents and caregivers to sign a petition, in August 2013, addressed to President Obama asking him to take prompt action. More than 200,000 commented favorably on Guidance for Industry #213 when it was first released in April 2012.

I am leading a group of moms, dads, grandparents, and other caregivers in a campaign called Supermoms Against Superbugs. Together we are alerting policymakers and the public about the need to curtail the misuse and overuse of antibiotics, especially in industrial farming. Attached are 68 short biographies of some of my fellow Supermoms Against Superbugs, each with riveting stories of their own.

There are so many problems that we cannot fix. Antibiotic resistance is one problem that we can fix. As you continue to lead the national conversation about children's health, we hope that you will also address antibiotic resistance and the proper use of these drugs in food production. I thank you and President Obama in advance for honoring Simon and taking steps to ensure his death was not in vain. Indeed, all children will benefit from your actions.

Most respectfully,

Everly Macario, Sc.D., M.S., Ed.M.
5629 S. Dorchester Avenue
Chicago, IL 60637

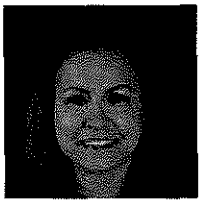
CC: Sam Kass, Executive Director and Policy Advisor for Nutrition Policy, Let's Move Initiative, Office of the First Lady

Supermoms Against Superbugs

#saveabx

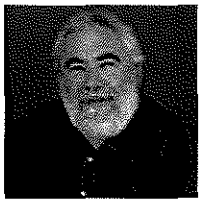
Supermoms Against Superbugs, an initiative of the Pew Campaign on Human Health and Industrial Farming, is a movement of moms, dads, grandparents, and other caregivers who want to end the overuse of antibiotics in food animal production in order to help preserve the effectiveness of antibiotics.

Yolanda Adams
Racine, WI



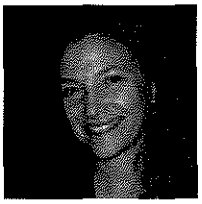
Committed to protecting children's health in her community and excited to advocate for responsible antibiotic use, Yolanda Adams is the president and CEO of the Urban League of Racine and Kenosha Inc. serving residents in southeastern Wisconsin. She earned a bachelor's degree in accounting from Carthage College in Kenosha, WI. Adams is a member of the League of United Latin American Citizens, or LULAC, council 325, a former state director of LULAC Wisconsin and a former board member of the national council. In addition, Adams serves as an executive officer of the Kenosha branch of the NAACP and the NAACP Wisconsin State Conference of Branches. She was the first Latina elected official in Kenosha and served as the board president of the Kenosha Unified School Board for two terms until 2006.

Bruce Aidells
Kensington, CA



A strong proponent of raising livestock responsibly, Bruce Aidells is America's go-to guy for all issues involving meat and meat cookery. He is called upon for information and insights by national media outlets including *The New York Times*, *The Washington Post*, *Los Angeles Times*, *Chicago Tribune*, and many more. Aidells, who founded Aidells Sausage Co. in 1983, also has a reputation as an innovator in the gourmet sausage industry. He left the sausage company in 2002 to pursue his food writing and television career. Since 1982, Aidells has written 12 cookbooks including his latest, *The Great Meat Cookbook*. Aidells has had a regular cooking segment on "View From the Bay" on the San Francisco affiliate of ABC for the past four years. He also has his own cooking show, "Good Cookin' With Bruce Aidells," on the national Disney cable channel Live Well Network. He has appeared on many other television shows. Aidells was a contributing editor at *Bon Appetit* magazine and is a contributing editor at *Eating Well* magazine.

Jennifer Amdur Spitz
Chicago



Jennifer Amdur Spitz has a personal interest in banning the overuse of antibiotics in healthy food animals. In 2006, her 16-year-old son Sam became seriously ill from antibiotic-resistant campylobacter. Sam made a full recovery, but the experience inspired the family to get involved in efforts to create a safer food system. To that end, Amdur Spitz and her husband, filmmaker Jeff Spitz, co-founded Groundswell Educational Films NFP and produced Food Patriots, a documentary film and public engagement campaign. Amdur Spitz is principal of Amdur Spitz & Associates, a Chicago public relations firm she founded to work with nonprofit organizations, foundations, and entrepreneurial businesses.

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Gina Asoudegan
Lambertville, New Jersey

Gina Asoudegan is Director of Communications at Applegate, the leading brand of natural and organic meat in the U.S. At Applegate, Gina is responsible for advocating for effective policies around issues such as school foods and the overuse of antibiotics in livestock. Gina's strategy has been to use art, music, and film to build awareness about food related issues. She is currently working with Uji Films on *Resistance*, a documentary about the growing crisis of antibiotic resistance. Outside of Applegate, Gina is the founder of the Bucks County Foodshed Alliance, a non-profit organization dedicated to building the infrastructure for the production, distribution, and sale of locally grown and produced food. The organization has instituted farm-to-table programs in schools, established farmers markets, and fostered the transition of conventional to organic farming.

Carrie Balkcom
Denver, CO

Carrie Balkcom is the executive director of the American Grassfed Association, or AGA. AGA is the national multispecies entity organized to protect and promote grass-fed and pasture-based farming and ranching. Balkcom grew up on a Florida cattle ranch and has stayed connected to the agriculture and livestock industry. She has spoken, presented, and coordinated numerous regional and national conferences, and is well known in agricultural, culinary, and sustainable-agricultural circles.

Jeremy Barlow
Nashville, TN

Jeremy Barlow is author of *Chefs Can Save the World*, a call to action to those who cook, urging them to use their collective power to overhaul the nation's food system. Barlow is executive chef and owner of Sloco, a Nashville neighborhood sandwich shop that operates sustainably, using approximately 99 percent locally grown food. Barlow was founder of Tayst Restaurant and Wine Bar and its executive chef from 2004-2013, Nashville's first certified green restaurant. A 2011 featured chef at the James Beard House, he attended the Chefs Boot Camp for Policy and Change, hosted by the James Beard Foundation and The Pew Charitable Trusts. He is co-chair of the Food Policy Council for metropolitan Nashville and Davidson County, which advises the city on food policy decisions.

Mary Kathryn Barnet
Myersville, MD

Mary Kathryn Barnet and her husband, Andrew, own and operate a small livestock and vegetable farm that provides "affordable, clean, and delicious food" to their community. Barnet is committed to raising her pigs, turkeys, and chickens as naturally as possible, never using antibiotics or growth hormones. As a new mother, Barnet wants to end the overuse of antibiotics on industrial farms to ensure our antibiotics continue to work when we need them most.

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Astra Bester
Plano, TX

Astra Bester is a working mom concerned about the overuse of antibiotics in food animal production. In 2001, Astra suffered from an antibiotic resistant infection that took 17 weeks to fight. She believes that, by reducing the amount of antibiotics used in the food industry, we will not only save our health, but reduce health care costs and stop the increasing rise of superbugs.

Diane Birmingham
Denver, CO

Diane Birmingham has been raising antibiotic awareness for years. She is particularly concerned about people's reliance on antibiotics in the treatment of disease, and the development of superbugs due to antibiotic use in livestock. She has an M.S. in environmental and public health from the University of Wisconsin-Madison and over 35 years of experience working as a registered nurse in public health and healthcare. She grew up on a farm in Iowa and fondly remembers a time when raising your own food was the norm. She currently works educating patients with chronic disease about staying well.

Lori Brinkman
Norwood Young America, MN

Lori Brinkman and her husband Dan own and operate a small farm in Carver County, MN, where they raise heritage hog breeds on pasture, poultry, and goats, selling directly to consumers as well as to restaurants and small grocers. In addition to operating the farm, Brinkman is the county feedlot administrator and inspector for Carver County in the Public Health and Environment Division. A mother of five, Brinkman holds a bachelor's degree in environment and resource protection from the University of Minnesota.

Amanda Buchanan
Weiser, ID

A former Peace Corps volunteer, Amanda Buchanan is a perennial volunteer and advocate. She helped to organize and currently co-chairs the Weiser River Resource Council, a chapter of the Western Organization of Resource Councils, to promote small farms, safe food, and positive stewardship of the environment and natural resources through community action. Buchanan has worked with Consumers Union since 2008 on a variety of issues, including food safety, health care reform, and patient safety. She also serves as a member of the board of trustees for her community hospital.

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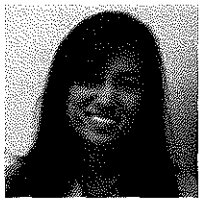
Brittany Chin
Greenville, SC



Brittany Chin is a registered and licensed dietitian concerned with the increasing prevalence of antibiotic-resistant bacteria. At Health Diagnostic Laboratory Inc., she counsels patients one-on-one to improve the status of their cholesterol and diabetes labs and promotes a healthy lifestyle among them. Active in the health and wellness of her community, she is president-elect of the Piedmont Dietetic Association. Chin graduated cum laude from Syracuse University in 2010 with a bachelor's degree in nutrition science and dietetics and completed her dietetic internship training at the Medical University of South Carolina. She is pursuing a master's degree through Boston University's health communications program.

Anne Dennis Copsey
Kaneohe, HI

Anne Dennis Copsey established the *Staphylococcus* Educational Leadership Foundation (SELF) to organize a network of experts in diagnostics, infectious disease management, public health, clinical microbiology, drug discovery, and infection prevention. SELF creates and implements research, education, and mentoring initiatives to improve clinical and patient outcomes in healthcare and community settings. Through Clinical Exchange programs, SELF creates awareness about antibiotic resistance within existing healthcare systems and communities. Anne has worked in medical education for over 16 years with a focus on new and unique therapies in multiple specialties including infectious disease, dermatology, gastroenterology, ophthalmology, and neurology. She received a BA from the University of Southern California and an MA from Teachers College, Columbia University. Anne is a competitive open water swimmer and ocean advocate, sailing most weekends.

Cecilia Di Pentima
Nashville, TN

Dr. Cecilia Di Pentima is a leader in the effort to conserve antibiotics in human medicine and says that these efforts should extend to food animal production. She is an associate professor of pediatrics, director of the pediatric infectious diseases clinical services, and director of the antimicrobial stewardship program at Monroe Carrell Jr. Children's Hospital at Vanderbilt. She completed medical school at National University of Rosario, School of Medical Sciences, Rosario, Argentina. She earned her master's in public health from the University of Texas Health Science Center at Houston and completed her pediatric residency and pediatric infectious disease fellowship at Baylor College of Medicine in Houston. She became a faculty member at Thomas Jefferson University and Nemours/Alfred I. duPont Hospital for Children in Wilmington, DE, and initiated one of the first pediatric antimicrobial stewardship programs in the United States in 2004 before joining Vanderbilt University.

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Penny Dunn
Fairport, NY

Penny Dunn has made taking care of her family her top priority. They teach their children by example, making the best choices for themselves and their daughters. Health, education, and happiness are frequently examined, reevaluated, and improved, if possible. Penny holds a BS and MS in Materials Science and Engineering from Alfred University. Before taking on her most challenging and rewarding career as stay-at-home mom to two daughters, she worked in the engineering field in manufacturing, research and development, and as a consultant.

K. Bartlett Durand Jr.
Black Earth, WI

K. Bartlett Durand Jr. is known as "the Zen Butcher," a moniker given to him by director Mike Gebert in his documentary *The Butcher's Karma*. Named one of the original Badger Bioneers in 2011 for his pioneering work revitalizing small-scale meat processing, he has also won the SLoFIG Business Plan Competition at the Good Food Financing Festival and Conference. Durand started his career as an attorney, then developed the marketing and branding of Otter Creek Organic Farm products through a separate company, Local Choice Marketing. He is the managing member for Black Earth Meats, the first meat processor in his region to obtain a U.S. Department of Agriculture license, certified organic status, and third-party "certified humane" standing. Black Earth Meats was featured on "Wisconsin Foodie" in 2012, and in 2013 it became the focus of an episode of "Bizarre Foods With Andrew Zimmern," which emphasized the importance of small-scale butchery in the world of sustainable meat production.

Suzanne Goin
Los Angeles, CA

One of Los Angeles' most popular chefs, Suzanne Goin cooks with a palette of colors and flavors that showcase the best farmers and producers from the Southern California markets. In all four of her restaurants, Lucques, A.O.C., Tavern, and The Larder at Maple Drive, her passion for seasonal cooking is reflected in her ever-changing menus and artfully presented dishes bursting with colors and textures that embrace the beauty and decadence of California gardens. She has earned numerous accolades including *Food & Wine Magazine*'s "Best New Chefs of 1999," the James Beard Foundation's "Best Chef: California" in 2006, and four nominations for the national Outstanding Chef Award in 2008,2009, 2010, and 2011. She has been the exclusive caterer for the annual Screen Actors Guild (SAG) Awards for three years, and, in 2011, prepared a dinner for President Obama and 60 guests at her restaurant, Tavern. She has been featured prominently in *Bon Appetit, Gourmet, Saveur* and *Food & Wine* magazines and was named Chef of the Year by *Planned Parenthood Los Angeles* in 2012. Her latest achievement is the launch of L.A. Loves Alex's Lemonade, which she co-founded in 2010 to raise research funds for childhood cancer and the Alex's Lemonade Stand.

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Esperanza Gonzalez
Round Lake Beach, IL

A proud mother and grandmother, Esperanza Gonzalez is committed to protecting future generations from antibiotic-resistant bacteria and, in particular, individuals within vulnerable and disenfranchised populations. She has more than 35 years of experience serving farmworker and Latino communities throughout Illinois, providing preventive health care and collaborating with health service providers in the public and private sectors. An experienced clinical counselor and therapist, Gonzalez received a master's degree in clinical psychology and minored in bilingual education. She is also the president of the Illinois Association of Agencies and Community Organizations for Migrant Advocacy and a member of the League of United Latin American Citizens.

Diana Goodpasture
Akron, OH

Diana Goodpasture has spent the last 30 years as a bus driver for special-needs children. Involved with her church as well as local charities, she was healthy and active until she contracted an antibiotic-resistant infection, *Salmonella* Heidelberg, which was responsible for the recall of 36 million pounds of ground turkey in 2011. The severity of her illness and associated pain kept Goodpasture in the hospital for five days. It was not until after she had gotten sick that she gave much thought to how food is produced or the steps it takes to get it to the table. Despite a weakened immune system and her struggles, Goodpasture says, "I'd much rather not have to tell those in government that we need safe food, but until they realize what's really for dinner, I'm going to tell my story."

Michelle Gottlieb
Marblehead, MA

Michelle Gottlieb is the co-coordinator of Health Care Without Harm's national healthy food and healthcare program and Food Matters' clinical education and advocacy program. She has also worked with Health Care Without Harm's safer chemicals program. Formerly, Gottlieb was the co-executive director of Greater Boston Physicians for Social Responsibility where she specialized in children's health, women's health, and reproductive health. She worked with pediatric care providers from around the country to develop the pediatric environmental health toolkit, which provides materials to assist pediatric caregivers in incorporating environmental health into their practice. Prior to moving to the Boston area, Gottlieb helped develop a new program on health, environment, and development at the World Resources Institute in Washington. She holds a B.A. from Barnard College, Columbia University, and a master's degree from the Yale School of Forestry and Environmental Studies where she focused on environmental public health and policy. She serves on the Board of Health in Marblehead where she lives with her husband and three children.

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Robert M. Gould
San Francisco, CA

A physician who relies on effective antibiotics to keep his patients healthy, Robert M. Gould graduated from Albert Einstein College of Medicine, and from 1981 until 2012, he worked as a pathologist at Kaiser Hospital in San Jose, CA. In 2012 Gould was appointed an associate adjunct professor in the department of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco School of Medicine, where he serves as director of health professional outreach and education for the UCSF program on reproductive health and the environment. Since 1989, he has been president of the San Francisco-Bay Area chapter of Physicians for Social Responsibility. In 2003, he was national president for the organization and will serve again in that capacity in 2014. Since 1986, Gould has been active in the peace caucus of the American Public Health Association, for which he has been chairman for numerous years. In 2009 the organization awarded Gould the Sidel-Levy Award for Peace. He has been recognized as an expert on the environmental and public health impacts of nuclear weapons.

Mary Graba
Champlin, MN

"Antibiotics saved my life," says Mary Graba. "They are a precious resource that must be preserved." In 1980, Mary Graba faced a difficult and painful illness that doctors were unable to diagnose. Losing weight and incapable of keeping food down, she and her sister, a manager of a hospital lab, took matters into their own hands. Graba's sister collected a sample for bacterial testing and found that Graba was infected with *campylobacter*, which she was told often originates in chickens. Graba suspects that her illness originated at a restaurant where she was served undercooked chicken. Graba and her husband Rogers are committed to preserving antibiotics for their children and others.

Melissa Graham
Chicago, IL

Melissa Graham, a former attorney, is the founding Executive Director of Purple Asparagus, an award-winning non-profit organization dedicated to educating families about eating foods that are good for the body and the planet alike. Through its Delicious Nutritious Adventures program, Purple Asparagus has taught thousands of parents and children about healthful, sustainable eating in schools, community centers, and farmers' markets throughout Chicago and its surrounding areas. Melissa speaks and writes regularly on childhood nutrition and sustainability, both in Chicago communities and online—blogging at Little Locavores, as The Sustainable Cook on The Local Beet, and as a regular contributor to Kiwi Magazine's KiwiLog and Williams-Sonoma's Blender blog. *The Chicago Tribune awarded her a 2011 Good Eating Award* and the International Association of Culinary Professionals recently honored Melissa as the Culinary Youth Advocate of 2012.

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Rock Harper
Alexandria, VA

Rock Harper is committed to serving his community through good food raised responsibly. He is director of kitchen operations at DC Central Kitchen, a nonprofit organization that offers job training, meal distribution, and local farm partnerships to help alleviate poverty, hunger, and homelessness. Harper won the third-season competition of the television show "Hell's Kitchen."

Jenni Harris
Bluffton, GA

Jenni Harris is the fifth generation of the Harris family to tend cattle at White Oak Pastures in Bluffton, where she raises poultry and cattle without antibiotics. After living on the farm her entire life, Harris went to Valdosta State University and earned a degree in business marketing in 2009. After graduation, she set out to learn the cattle industry. She moved to Atlanta and interned at Buckhead Beef, a Sysco company. She put in time in every department, from shipping and receiving to the cut shop, and was later hired to work as a sales associate. In June of 2010, Harris returned home to work full time. As the marketing manager for White Oak Pastures, she promotes her family's grass-fed beef and lamb and free-range chicken to distributors, retailers, and restaurateurs. Harris also serves on the boards of Georgia Organics, Slow Food Atlanta, and Flint Riverkeeper.

Will Harris
Bluffton, GA

The Harris family has raised cattle on the same Georgia farm since 1866 for five generations. In 1995 Harris began converting his operations into the vertically integrated pastured livestock farm that it is today. After receiving his animal science degree from the University of Georgia, Will Harris returned home to raise calves, in a monoculture, for long-distance shipment to industrial feedlots where commodity beef is produced. Confinement feeding of corn, pesticides, chemical fertilizers, subtherapeutic usage of antibiotics, and hormone implants were key to this program, until he changed his practices. His farm is the only one in the United States that has its own U.S. Department of Agriculture-inspected processing plants for red meat and poultry.

Amanda Hedin
Minneapolis, MN

Amanda Hedin has two very important reasons to be passionate about antibiotics: She relied on these drugs to treat her own twin girls who were born at 28 weeks gestation. Reagan and Eden Hedin struggled more than any babies should, but they showed tremendous courage and bravery. The girls taught Hedin more about love and patience than any other life experience or person. Because of their girls' journey, Amanda and her husband Scott established Eden's Garden, a nonprofit to honor the

memory of Eden, who passed away after 241 days in the hospital. Premature babies are particularly prone to infections and often rely on antibiotics, which is why Hedin is advocating for judicious drug use on the farm. Hedin also works for Children's Hospitals and Clinics of Minnesota as part of the mother baby clinical service line where her work includes deepening relationships with obstetrics providers in the Twin Cities area.

Lauren Herbert
Eugene, OR

Lauren Herbert is a pediatrician and pediatric infectious diseases specialist who relies on antibiotics to treat her patients. She lives and works in the Eugene-Springfield area in Oregon. She also is an assistant professor for Oregon Health and Sciences University. Herbert completed her pediatric training at Oakland Children's Hospital and infectious diseases training at University of California, San Francisco. She works with other physicians to promote appropriate antibiotic use.

Grant Hittinger
Bethlehem, PA

A husband and father of three, Grant Hittinger strongly believes in fighting for the health and safety of infants and children who rely on antibiotics. He and his wife lost their first child at birth to a mysterious illness and endured an extraordinarily difficult pregnancy with their second. These issues led Hittinger to volunteer with the March of Dimes and become one of the top fundraisers in his area for seven consecutive years. In 2013, his family was selected to be one of the March of Dimes' ambassador families for the Lehigh Valley in Pennsylvania. Hittinger also has a niece who contracted methicillin-resistant Staphylococcus aureus, or MRSA, twice in a two year span, but is fortunately healthy today.

Kim Howland
Enid, Oklahoma

After working 10 years in a hog farming operation, Kim Howland knew a lot about the management and growth of the animals for which she cared. But it was not until her husband contracted a methicillin-resistant *Staphylococcus aureus* (MRSA) infection that she became concerned about the overuse of antibiotics in food animal production. Kim is committed to helping reduce overuse and misuse of antibiotics in meat and poultry operations.

Margie Kelly
Chicago, IL

Margie Kelly first became aware of the consequences of antibiotic overuse when her daughter Grace was diagnosed with methicillin-resistant *Staphylococcus aureus*, or MRSA. Grace's pediatrician, Lauren Herbert, was aware of the warning signs of the disease and developed a treatment plan. When speaking to friends and writing about the public health crisis caused by overuse of antibiotics in livestock, Kelly realized how

lucky it was that her daughter was diagnosed early and successfully treated without any lasting health effects.

Alyssa Kent
Fairfield, CT

When Alyssa Kent had a baby girl 15 weeks early, she learned how vital antibiotics are. Virginia Kathryn was born weighing just 1 pound and 7 ounces and spent 124 days in the neonatal intensive care unit battling many complications related to her prematurity and her parents worlds were forever changed. Premature babies are particularly prone to infections and often rely on antibiotics, which is why Kent is advocating for judicious drug use on the farm. Kent now is not only a full time architect, but she also a full-time mom and full-time advocate for prematurity and perinatal health. She is trained as an architect and serves as the director of sustainable design for Becker + Becker, a boutique real estate development and architecture firm based out of Fairfield.

Janice Kim
Oakland, CA

Dr. Janice Kim is a pediatric infectious disease specialist with extensive experience in the public health sector in the fields of environmental health and communicable diseases. As a public health physician, she is concerned that the increasing prevalence of antibiotic resistance will leave few effective drugs to treat serious infections. As a member of the American Academy of Pediatrics, Kim has served on its Committee on Environmental Health, where she contributed to the AAP policy statement *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*.

Courtney Kliever
Sherwood, OR

Courtney Kliever's son Liam was born ten weeks early and spent seven weeks in the St. Vincent NICU. This experience inspired Kliever to advocate for changes to our environment and food system that help keep children healthy, including making sure antibiotics are used judiciously for animals so they continue to work when kids need them most. Kliever has worked in the healthcare field for 15 years. She is a mother of three children, including Liam who is now seven years old, and, along with her husband, is very active with the March of Dimes.

Ken Koehler
Old Orchard Beach, ME

Shortly after cooking hamburger, Ken Koehler came down with an antibiotic-resistant salmonella infection. While the Old Orchard Beach resident is still easily fatigued and unable to fully enjoy a meal, he still appreciates that things could have been worse. Koehler knows full well how important it is to preserve antibiotics for appropriate uses and wants officials in Washington to know, too.

Supermoms Against Superbugs

#saveabx

Supermoms Against Superbugs, an initiative of the Pew Campaign on Human Health and Industrial Farming, is a movement of moms, dads, grandparents, and other caregivers who want to end the overuse of antibiotics in food animal production in order to help preserve the effectiveness of antibiotics.

Melissa Lee
Troutdale, OR

Melissa Lee's daughter, Ruby, was only 10 months old when she contracted a foodborne infection, *Salmonella* Heidelberg, found in the ground turkey meatballs she ate with spaghetti just days before. The infection was resistant to several antibiotics. Fortunately, her doctor was able to effectively treat her with an antibiotic known as cephalosporin. Being relegated to standing by, able to do little besides hope and pray that Ruby would recover is not an experience Melissa would wish on anyone. That is why Melissa is working to help ensure that other families are protected from such circumstances in the future.

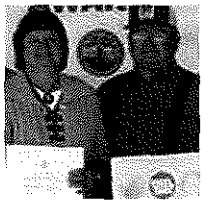
Marja Lutsep
New York, NY

Marja Lutsep is a working mother with two little boys. When her oldest son was 2, he contracted his first of several methicillin-resistant Staphylococcus aureus, or MRSA, infections, providing the family with a crash course in superbugs. Lutsep's experience has motivated her to take action to eliminate practices that breed superbugs and to preserve the effectiveness of antibiotics that cured her son's infections.

Everly Macario
Chicago, IL

In 2004, Everly Macario's son Simon Sparrow—a previously healthy 1-and-a-half year old—died suddenly. It was not until months later that the cause of Simon's death was confirmed to be community-associated methicillin-resistant *Staphylococcus aureus*, or MRSA. In 2008, Macario joined colleagues at the University of Chicago Medicine in founding the MRSA Research Center. She also advocates on behalf of the Stop MRSA Now campaign. Macario's goals include raising awareness of antibiotic resistance, making the term "MRSA" as familiar a household term as "AIDS," and serving as a catalyst for simple steps that can be taken to reduce the overuse and misuse of antibiotics in both humans and animals. Macario has a doctorate in public health from Harvard University.

Cindy and Vic Madsen
Audubon, IA



Cindy Madsen and her husband Vic live on a small farm—Madsen Stock Farm—in Audubon County, IA, where they raise hogs, chickens, and cattle without antibiotics, hormones, or other drugs. The farm also grows organic corn, beans, alfalfa, oats, and other small grains. Madsen Stock Farm has direct-marketed their chicken for the past 24 years, pork for the last 14 years, and home-raised beef since 2011. Madsen has been an active member of Practical Farmers of Iowa for the past 26 years. She and

her husband have been presented with numerous awards, including the Spencer Award for Sustainable Agriculture (2010), the Practical Farmers of Iowa Sustainable Agriculture Achievement Award (2009), and the Iowa Governor's 2012 Iowa Farm Environmental Award.

Arica Michelle McKinnon
Owings Mills, MD

A dedicated volunteer for the March of Dimes, Arica Michelle McKinnon appreciates how important antibiotics are for keeping premature babies healthy. She is passionate about raising awareness on the challenges of preterm births and advocates for more prevention, education, and research programs to improve premature birth outcomes and to promote maternal and child health. These causes are very near to her because she is a mother of a preemie born at just under 24 weeks. McKinnon is a graduate of the University of Tennessee, Knoxville, and is an account manager at a leading radio research and marketing firm. Originally from Atlanta, she resides in Owings Mills with her husband Steven and 15-month-old son Kingston.

Rachel McNally
Cranston, RI

Rachel McNally has three children, all of whom were born prematurely, spending extensive time in a neonatal intensive care unit. These experiences increased her awareness of the vulnerability of children and families to illness and the importance of effective antibiotic treatments. Primarily a stay-at-home mom, McNally is also an adjunct instructor at the Community College of Rhode Island and a freelance writer. She and her husband are committed supporters of March of Dimes.

Mary Sue Milliken
Santa Monica, CA

A mother and chef, Mary Sue Milliken takes care to serve her children and patrons meat and poultry raised without antibiotics. She is co-chef and owner of the critically acclaimed Border Grill restaurants in Santa Monica, downtown Los Angeles, and Las Vegas as well as a gourmet taco truck. A pioneer of world cuisine since she created the City Café and CITY Restaurant in Los Angeles in the 1980s, Milliken is a leading ambassador of authentic Mexican cuisine, setting the standard for gourmet Mexican fare for over two decades. She was the first female chef to work at Chicago's prestigious Le Perroquet in the late 1970s, going on to train at a Michelin two-star restaurant in Paris and later to help found Women Chefs & Restaurateurs. A business partner with Chef Susan Feniger for over 25 years, Milliken is co-author of five cookbooks. She competed on Bravo's "Top Chef Masters," winning $40,000 for her charity, Share Our Strength. She also co-starred in Food Network's "Too Hot Tamales" and "Tamales World Tour." She has also appeared as a guest on "Iron Chef America," "Oprah," "Good Day LA," and "The Today Show."

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Dana Mirman
Naples, FL

Dana Mirman survived a life-threatening infection in December 2011 and credits her recovery to her doctors' prompt diagnosis and the efficacy of the antibiotics they used to treat her. She is a writer, television producer, and public relations executive. A summa cum laude graduate of Binghamton University in New York, Mirman was an associate producer for ABC's "20/20" and has also developed content for TLC, Animal Planet, National Geographic Wild, Discovery, and "The Montel Williams Show." A native New Yorker, Mirman resides in southwest Florida with her family. She serves as a member of the board of directors of Sepsis Alliance, the national nonprofit organization devoted to raising awareness of sepsis.

Sarah Mobry
Savage, MN

Sarah is the mother of a four-year old and is the foodservice manager at a school serving students in preschool through eighth grade. In college, she merged her personal interest in animal welfare with an academic education in microbiology and nutrition. Now, Sarah uses her position in the field of school nutrition to converse with food distributors, government staff, and non-profit organizations about improving the food industry. She demonstrates a commitment to sustainable living and wellness through volunteer work with non-profit groups and by educating others about the future of food and its implications for our health.

Janelle Moses
Wapato, WA

Janelle Moses owns Holy Cow Grassfed Beef an Animal Welfare Approved, USDA Organic, American Grassfed, and Food Alliance certified cattle farm. Moses is committed to raising her cows humanely and without antibiotics on 128 acres of lush pasture. She is a member for the South Yakima Conservation District board.

Jason Newland
Kansas City, MO

In August 2006, Jason Newland joined the faculty at Children's Mercy Hospitals and Clinics in Kansas City, MO, where he is the director of the antimicrobial stewardship program and the medical director of patient safety and systems reliability. His current research focuses on the use of antimicrobials and the impact of an antimicrobial stewardship program at a children's hospital. Jason Newland grew up in southwest Oklahoma and obtained a B.S. in preprofessional studies at the University of Notre Dame and a medical degree from the University of Oklahoma College of Medicine in 2000. He completed his pediatric residency at the University of Nebraska and Creighton University Medical

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Centers in 2003 and a fellowship in pediatric infectious diseases at the Children's Hospital of Philadelphia in 2006. Newland distinguishing himself with teaching awards at both.

Marilyn Noble
Denver, CO

As the communications director for the American Grassfed Association, Marilyn Noble is committed to supporting farmers who raise their animals on pasture without confinement, added hormones, and antibiotics. She also educates consumers about the benefits of grass-fed meats for animals, the environment, rural communities, and families. She writes and speaks about sustainable agriculture and is a best-selling cookbook author. She also serves as the board chair for Slow Food Denver. Noble is a passionate advocate for a more healthy, clean, and just food system.

Nancy Oakes
San Francisco, CA

Nancy Oakes is an award-winning chef who serves meat and poultry raised without antibiotics. Virtually every poll of readers in the San Francisco Bay Area has named Nancy Oakes as the most popular chef and her restaurant, Boulevard, as the city's favorite. Boulevard is also one of a select group of restaurants to receive coveted Michelin stars. In 2001 Oakes won the James Beard Foundation Award for Best Chef in California, and in 2012 she received the foundation's distinguished Outstanding Restaurant Award.

Avani Patel
Chicago, IL

Avani Patel spent seven years as a sports writer at the *Chicago Tribune*. Three years ago, she left sports to join the editorial board where she wrote about food and product safety, education, juvenile justice, AIDS in Africa, pirates, and sports. As an editorial writer, Avani said her job "is to think about a broad range of issues, burrow deeply into the ones that most affect our lives, and explain the best way forward. In the course of my job, I get to interview scholars, politicians, activists and ordinary citizens. It's a big responsibility. But it's also a lot of fun." Avani has since left the editorial board at the *Chicago Tribune*. As a new mom, she says she has come full circle: "After years of watching games with a reporter's eye, I've gone back to what I started as: an equal opportunity sports fan."

Anna Persmark
North Field, MN

Anna Persmark is a sophomore at Carleton College in Northfield. Her interest in antibiotic resistance began in high school after a unit about resistant tuberculosis and was heightened after reading Michael Pollan's *The Omnivore's Dilemma*. Becoming more aware of the increasing use of antibiotics and the growing resistence of bacteria to them, Persmark grew concerned about the dramatic overuse of antibiotics in both

medicine and agriculture. In high school, her final thesis concerned resistant strains of pneumococcus and antibiotic overuse. She plans to pursue a career in either medicine or public health, and would like to raise awareness about antibiotic overuse on her college campus.

Andrea Reusing
Chapel Hill, NC

Committed to the environment and health through her cooking, Andrea Reusing owns Chapel Hill restaurant, Lantern, where she blends ingredients from small farms in North Carolina with Asian flavors. Since opening in 2002, it has been named one of "America's Top 50 Restaurants" and "best farm-to-table restaurants" by *Gourmet*; one of "America's 50 Most Amazing Wine Experiences" by *Food & Wine*; and as "Restaurant of the Year" in 2009 by Raleigh's *News & Observer.* Reusing is the 2011 winner of the James Beard award for Best Chef: Southeast. She serves on the boards of the Center of Environmental Farming Systems and Chefs Collaborative and was recently appointed by Governor Beverly Perdue to the Sustainable Local Food Advisory Council. Reusing's first book, *Cooking in the Moment: A Year of Seasonal Recipes*, was named one of 2011's most notable cookbooks by *The New York Times*.

Maggie Rivera
Crystal Lake, IL

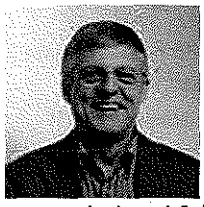
The daughter of a former migrant farmworker, Maggie Rivera has been an advocate for human rights since the age of 16, volunteering and serving on the boards of numerous nonprofit organizations. As a mom, Rivera is concerned with antibiotic overuse on industrial farms and how this practice contributes to the development of superbugs that can infect people. She holds a bachelor's degree in behavioral science and a master's degree in business management/organization leadership, and she currently manages her family's grocery store businesses. She is the Midwest vice president for the League of United Latin American Citizens.

Marilyn Roberts
Seattle, WA

Marilyn Roberts is a professor of environmental and occupational health sciences and an adjunct professor of global health at the School of Public Health, University of Washington. She has specialized in examining different environmental sources, such as marine and fresh water beaches, for the presence of potential human pathogens including methicillin-resistant *Staphylococcus aureus*, or MRSA, and vancomycin-resistant *enterococci*, or VRE. Roberts is also interested in the presence and spread of antibiotic-resistant genes in the environment. She received her doctorate in microbiology and immunology from the University of Washington, where she specialized in the molecular characterization of the pathogen *Neisseria gonorrhoeae*, which causes gonorrhea. She is the recipient of numerous grants from the National Institutes of Health and, more recently, from the Washington State

Department of Labor and Industries. Roberts has published over 195 peer-reviewed articles on her research.

Daniel J. Rosenthal
Chicago, IL



A widely recognized expert on sustainability in the food service industry, Daniel J. Rosenthal, president of the Rosenthal Group Inc. and founder of the Green Chicago Restaurant Coalition, has over 40 years of experience in all aspects of the restaurant industry. Since 1988, Rosenthal has launched and operated over 40 restaurants around the country. His Chicago restaurant ventures include Trattoria No.10, 5 Sopraffina Marketcaffès, and Poag Mahone's Carvery and Ale House. In October 2007, Rosenthal and fellow restaurateur Ina Pinkney founded the Green Chicago Restaurant Coalition, which has grown to include over 300 restaurant and 150 affiliated businesses. Over the years, the coalition's original mission of bringing sustainable products and services to restaurants at affordable prices has also expanded and now includes educational initiatives, targeted advocacy on behalf of its membership, and the creation of the Guaranteed Green certification program for restaurants. Rosenthal has been recognized for his environmental efforts with awards from the *Chicago Tribune*, *Chicago* magazine, and the Illinois Environmental Council. He has spoken at numerous schools and before national audiences at the National Restaurant Association Show, the Chef's Collaborative Annual Conference, the DC State of the Plate, and the International Foodservice Sustainability Symposium.

Lin Rosenthal
Chicago, IL

Lin Rosenthal, wife of Daniel J. Rosenthal, is also committed to sustainable food. She has served as vice president and treasurer of the Rosenthal Group Inc. since 1992. She graduated from Cornell University's School of Hotel Administration in 1970, and shortly afterward, she was hired as assistant to the vice president of food and beverage for Hilton International Co. in New York. Since marrying Daniel Rosenthal, she has held positions in catering at the Drake Hotel and was the assistant manager of the Hampshire House Hotel (currently the Raphael) in Chicago. Taking time off for a family, Lin Rosenthal continued her education at Harper College, completing a two-year accounting degree program. She returned to the business world in 1992 as vice president of market development for the Rosenthal Group and today serves as treasurer of the company.

Maria and Ron Rosmann
Harlan, IA

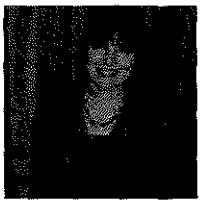
Rosmann Family Farms, located near Harlan in west central Iowa, is owned and operated by Ron and Maria Vakulskas Rosmann where, along with their son Daniel, they raise cattle and hogs without antibiotics. Free of pesticide use since 1983, the 700-acre farm is organically certified for grain and livestock production. Dissatisfied with conventional farming practices, Ron Rosmann began to explore sustainable agriculture methods in the 1980s. He teamed up with like-minded individuals who

formed Practical Farmers of Iowa, which is devoted to profitable, environmentally-sound farming practices. Maria Rosmann was raised in Sioux City, IA, and received a journalism degree from Creighton University. She owns and operates their on-farm store, Farm Sweet Farm. The store carries their meats and popcorn, along with hundreds of items for personal care use, cooking, and more.

Paula Rothman
Baltimore, MD

After earning a BA in industrial arts in 1973, Paula Rothman was a ministerial intern for several years, while nearly earning another BA in biblical literature. She started a family and an art business and has shown her drawings and etchings in juried art shows, winning several awards with exhibits in collections in the United States, Germany, and South America. Her two daughters have taught her to care about the Earth, understanding that if we do not safeguard our environment, we are all at risk.

Diane Schmidt
Chicago, IL



Diane Schmidt, a Chicago parent who became frustrated with the poor quality of food offered on children's menus in restaurants, applied her background in health education, marketing, and culinary arts to get kids eating healthier foods by creating Healthy Fare for Kids. It began in 2011 as a grass-roots initiative asking restaurants to offer healthier food for children on their menus. Today, Healthy Fare for Kids has grown into a multifaceted approach to improve children's health, reaching over 11 million people. Schmidt holds undergraduate and graduate degrees in health education and an M.B.A. from Northwestern University's Kellogg School of Management.

Jeanne and Allan Sexton
Sheffield, IL

Jeanne and Allan Sexton started Meadow Haven Farm, in Sheffield, Illinois. Allan, a retired veterinarian, was raised on a farm in Ohio that raised mixed crops (wheat, corn, oats, soybeans) and a variety of livestock (hogs, beef and dairy cattle, sheep, and chickens). His mother supplied a local college with free-range eggs in the early 1950s. In his veterinary practice, he saw the need to move toward more holistic practices and, when he retired, decided to return to farming in a holistic, organic, sustainable way. Searching for good rich soils, he settled upon Bureau County, Illinois, and, after securing his farm, set upon a path to not only certify it as organic, but to go further and produce the most healthful food he could. Jeanne was born and raised in Albuquerque New Mexico, camped a lot with her family growing up, traveed from coast to coast, andfell in love with the outdoors. She was teaching when she met Allan. They have five children and fourteen grandchildren. Early on, she became used to reconstructing her life to follow Allan's many entrepreneurial interests, so when he brought up going back to farming, she jumped at the chance. They have a certified organic farm, raising livestock: pastured pork, free-range chicken, eggs & turkey, and grass-fed beef. Jeanne: "I put on my overalls every day, and love it."

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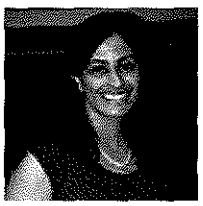
Sam Spitz
Chicago, IL

In 2006, 16-year-old Sam Spitz ate chicken contaminated with antibiotic-resistant campylobacter, battling the foodborne pathogen for months and ultimately losing 30 pounds. He made a full recovery, but the experience inspired him and his family to become passionate advocates for a more sustainable food system. Spitz will graduate from Colgate University in this spring and start graduate school at Oxford University in the fall.

Robert H. Sprinkle
College Park, MD

A pediatrician who advocates for responsible antibiotic use on industrial farms, Robert H. Sprinkle works at the intersection of politics and the life sciences. He holds a bachelor's degree from Dartmouth College, a medical degree from the University of Cincinnati, and trained clinically at the University of Virginia and the University of Texas Southwestern Medical Center, Dallas. He is a diplomat of both the American Board of Family Medicine and the American Board of Pediatrics and a fellow of the respective clinical academies. Sprinkle maintains current certification in both specialties and medical licensure in four states. He also holds a Ph.D. from Princeton's Woodrow Wilson School of Public and International Affairs. At Princeton he was supported by a MacArthur Foundation Social Science Research Council Fellowship in International Peace and Security. In 1995 he joined the University of Maryland School of Public Policy, where he is now a tenured associate professor. Sprinkle is the author of *Profession of Conscience: The Making and Meaning of Life-Sciences Liberalism* and co-author of papers and chapters in clinical medicine, bioethics, health policy, bioengineering, environmental policy, political theory, and biosecurity.

Pranita Tamma
Baltimore, MD



Pranita Tamma, a pediatric infectious diseases physician at Johns Hopkins Hospital, runs its pediatric antimicrobial stewardship program. She actively educates prescribers and develops guidelines to promote the appropriate and judicious use of antibiotics, then monitors patient outcomes after the implementation of these practices. Tamma's research focuses on optimizing antimicrobial therapy in children by both evaluating clinical outcomes of the antibiotics they receive and using novel diagnostic techniques to improve the prescription of antibiotics to them. Her ultimate goal is to improve the outcomes of children with infections while reducing the unnecessary harm caused by avoidable antibiotics, including antimicrobial resistance.

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Lynn Thompson
Osseo, WI

Lynn Thompson is committed to promoting health and the responsible use of antibiotics. She has spent over 35 years in the health care field in both conventional and alternative medicine. Thompson is pursuing a doctorate in quantum medicine.

Danielle Wadsworth
Lewiston, ME

Danielle Wadsworth acquired an antibiotic-resistant strain of *Salmonella typhimurium* from ground beef she had eaten. Wadsworth became so ill that, connected to IV drips, her doctors debated a blood transfusion and visitors had to don full hospital garb when they visited her. A woman of action as well as faith, Wadsworth's experience taught her how devastating antibiotic resistance can be and how crucial antibiotics are.

Patricia Whisnant
Doniphan, MO

Patricia Whisnant, a veterinarian, and her husband Mark own and operate Rain Crow Ranch, which raises grass-fed beef, pasture pork, and pasture poultry. They advocate a sustainable management protocol that utilizes open pasture rotation and maintains respect for the biological and behavioral instincts of the animals that are raised without the use of antibiotics or synthetic hormones. Whisnant is president of the American Grassfed Association, which offers third-party certification of grass-fed standards. Rain Crow Ranch is certified for high animal welfare by Animal Welfare Approved and is U.S. Department of Agriculture-certified organic. Whisnant is also the founder and owner of American Grassfed Beef and Fruitland American Meat, a humane-certified processing facility.

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COMMITTEES:
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SMALL BUSINESS

United States Senate

WASHINGTON, DC 20510-1502

April 24, 2013

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

We write today in order to request increased transparency in the Food and Drug Administration's publication of data regarding food-animal antimicrobial drugs, and to improve the effectiveness of the agency's veterinary medicines program.

We support your efforts in *Guidance for Industry 209* and *Draft Guidance for Industry 213*. We request that the FDA set a clear timeline to develop an antimicrobial data collection strategy based on the Advanced Notice of Proposed Rulemaking published on July 27, 2012. As part of developing this strategy, we ask that the FDA assess current data collection and dissemination, in consultation with the United States Department of Agriculture and the Centers for Disease Control & Prevention, in order to determine data needs and if additional data could be made public subject to Section 512(l) of the Food, Drug and Cosmetic Act. We would request that this needs assessment be published and presented to Congress, and that any available additional data that the agency already collects under the Animal Drug User Fee Act of 2008, such as dosage form, strength, container size, and marketing status, be published beginning with the next annual report. We expect that you will ensure policies are in place when publishing additional public data to ensure no proprietary or personal identifiable information of businesses or producers is released in violation of any applicable laws or standards. We would also request that the FDA finalize *Draft Guidance for Industry 213* as soon as possible in order to begin to eliminate injudicious uses of antimicrobial drugs, as well as a plan for evaluation of the implementation of this policy.

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315 FEDERAL BUILDING
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(563) 582-2130

320 6TH STREET
110 FEDERAL BUILDING
SIOUX CITY, IA 51101
(712) 252-1550

The steps above will provide scientists with more data to further evaluate the effectiveness of current public health programs. We look forward to working collaboratively with you in order to ensure your agency's programs and policies are effective in order to protect public health, maintain a safe food supply system, and preserve effective antimicrobial drugs for humans and animals.

Sincerely,

Tom Harkin
United States Senator

Lamar Alexander
United States Senator

Dianne Feinstein
United States Senator

Kirsten E. Gillibrand
United States Senator

Mark Kirk
United States Senator

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October 30, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

ATTN: Comment Docket No. FDA-2012-N-0447 "Antimicrobial Animal Drug Sales and Distribution Annual Summary Report Data Tables"

Dear Commissioner Hamburg:

The Pew Charitable Trusts (Pew) thanks you for this opportunity to comment on the U.S. Food and Drug Administration's (FDA) revised information collection and reporting activities on antimicrobial animal drug sales under Section 105 of the Animal Drug User Fee Act (ADUFA). Pew commends the FDA for heeding public comments regarding the inadequacy of current reporting and issuing proposed changes to the annual sales data report. The revised content and format of data tables are important steps to enhance the public's understanding of antibiotic resistance and provide some useful information to the public and researchers about how medically important drugs are used in food animals. However, Pew would like to recommend additional improvements to the reporting format and content, including amending the definition of "therapeutic" antibiotic use to more clearly exclude inappropriate uses for so-called "disease prevention" purposes that, in practice, are similar or identical to growth promotion. Further, Pew would like to reiterate strong interest in additional data collection activities that can paint a fuller picture of antibiotic use in animal agriculture than ADUFA sales reporting can do alone.

According to a new report from the Centers for Disease Control and Prevention (CDC), *Antibiotic Resistance Threats in the United States, 2013*, two million Americans suffer antibiotic-resistant infections each year and at least 23,000 die. Resistant strains of two commonly foodborne bacteria—*Salmonella* and *Campylobacter*—are responsible for about 20 percent of the illnesses. The report noted: "antibiotic use in food animals can result in resistant *Campylobacter* that can spread to humans;" and "*Salmonella* spreads from animals to people mostly through food. Antibiotic use in food animals can result in resistant *Salmonella*, and people get sick when they eat foods contaminated with *Salmonella*."

By making agricultural antibiotic use more transparent, the U.S. Food and Drug Administration (FDA) can guide the development of precise policies that protect human and animal health.

Thank you for responding to public comments requesting additional information about the medical importance of data, as well as the route of administration for antibiotics. The newly proposed Tables 3 and 4 should enable the public to better understand how livestock and poultry producers are administering antibiotics, and whether they are medicines used commonly in human medicine to treat serious illness. This should help public health officials identify areas for concern (e.g., a scenario whereby a majority of antibiotics are given to animals through feed, and are from highly important drug classes used to treat dangerous human infections). The data may also show encouraging signs that certain antibiotics are not being fed in large quantities to animals, which could prompt researchers to look for other explanations for specific drug-resistant bacteria in meat or infections in people.

Also, Pew appreciates the FDA's inclusion of Table 6 in answer to requests for information about the marketing status of antibiotics used in agriculture. Pew expects this table to hold greater value after full implementation of finalized Guidance #213 and expansion of the Veterinary Feed Directive system. In fact, this table should help show whether the guidance plan is effective at moving medically-important antibiotics that are used in feed from the over-the-counter data category to the prescription/VFD category, in line with judicious use principles.

Pew understands that the agency's release of detailed data is constrained by 512(l) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(l)) and the Trade Secrets Act (18 U.S.C. 1905), designed to protect confidential business information. However, Pew would like to see greater explanation of confidentiality limitations caused by the "mosaic" effect, as it is not easily apparent what other sources of antibiotic sales or use data are publicly available to be layered onto data reported under ADUFA. This broad interpretation of confidentiality restrictions has so hampered data reporting in Table 5, for instance, that the information presented is of questionable additional value, particularly when based on definitions that only further muddle the intent of the agency's judicious use guidelines. If the FDA wishes to be transparent about implementation of judicious use policies and the data collected under ADUFA, there are further refinements that could be made to the tables to enhance public health.

Definitions Matter

Pew is very concerned that the data tables are based on flawed definitions of "therapeutic and production" uses. These terms are not exhaustive and not mutually exclusive. The FDA uses an overly broad definition of "therapeutic indications" that fails to take account of the range of antibiotic uses under current "disease prevention" label claims, some of which would not meet the judicious therapeutic use criteria posed by Guidance #209 and Draft Guidance for Industry #213. A more defensible approach would be to adopt the WHO-FAO-OIE definition of "therapeutic use": application of antimicrobials in curative doses in an adequate period of time to combat an established infection. This definition would necessarily exclude those uses for disease prevention that are at insufficient dosages and duration to kill bacteria, and do not occur in the presence of actual infection, i.e., uses the agency has deemed injudicious along with growth promotion and feed efficiency.

Likewise, the agency should refine its definition of disease prevention to exclude those same uses that do not meet the judicious use test. Using the agency's own reasoning, injudicious uses in healthy animals with no documentation of specific health risk should be included instead in the "production" category of use. If the division of data is impossible, the FDA should at minimum make clear in revised ADUFA data reports that its use of the term "therapeutic" to include all prevention does not signal that the agency accepts or condones all preventive uses, in line with the thinking presented in Guidance #209 and Draft Guidance #213.

Pew recognizes that drug applications and approvals have evolved over time with differing terminology, and that drawing a line between these terms may be difficult, especially when data presentation is limited by the number of drug sponsors. However, we expect the agency to uphold definitions in its data reports that, at minimum, adhere to the principles put forth by the guidance documents, which animal-drug sponsors have indicated they will soon implement. Failing this, the data would be more legitimately and clearly separated into "treatment" and "non-treatment" uses, perhaps based on dosages effective enough to kill bacteria.

More Could Be Reported

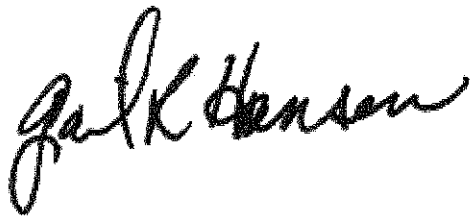
Data is collected from animal pharmaceutical manufacturers about the amounts sold every month. As such, there should be a table that reports sales by month for each drug class. FDA has collected data by monthly sales since at least 2008. The data may help researchers determine whether there is seasonality to sales linked to specific diseases and inspire novel treatment or prevention approaches.

Section 105 of ADUFA also requires that the FDA collect information pertaining to target animals and production classes. Pew urges the agency to add a table to the next ADUFA sales report that would present species-level information in the most detailed way that would still protect confidentiality, such as grouping sales first by medical importance. Should the data not adequately reflect antibiotic sales by species or production class, the agency should ask drug sponsors to produce estimates. If FDA does not believe that ADUFA is the appropriate vehicle, the agency should swiftly issue a proposed rule for alternate data collection methods that can answer the important question of which species and production classes of animals are getting medically-important antibiotics and the indications for administration.

In addition, the public's understanding of antibiotic use in animal agriculture is further challenged by the agency's inclusion of non-food animal data in the tables. Pew urges the agency to find ways to separate out companion and food animal data wherever possible, and to explain cases where the data cannot be separated.

The collection and public distribution of this information is critical to slow the spread of resistant infections. As the CDC's Dr. Steven L. Solomon recently said, "We want to get everyone in our society engaged in understanding the big picture of antimicrobial resistance, and that this is a very complex, holistic problem that we all need to be working together to solve... But let's not approach them one at a time. Let's turn our attention to the big picture and begin to solve that in a societal way."

Sincerely,



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