



July 31, 2012

The Honorable Frank Lucas
 Chairman
 Committee on Agriculture
 United States House of Representatives
 1301 Longworth House Office Building
 Washington, DC 20515

The Honorable Collin Peterson
 Ranking Member
 Committee on Agriculture
 United States House of Representatives
 1301 Longworth House Office Building
 Washington, DC 20515

The Honorable Jack Kingston
 Chairman
 Subcommittee on Agriculture
 Committee on Appropriations
 United States House of Representatives
 2362-A Rayburn House Office Building
 Washington, DC 20515

The Honorable Sam Farr
 Ranking Member
 Subcommittee on Agriculture
 Committee on Appropriations
 United States House of Representatives
 2362-A Rayburn House Office Building
 Washington, DC 20515

Dear Chairmen Lucas and Kingston and Ranking Members Peterson and Farr:

We are writing in response to the July 3, 2012 letter to you, from the Animal Health Institute and other organizations involved with meat and poultry production, about the Consumer Reports "Meat On Drugs" report. We would welcome having an opportunity to meet with you to discuss our report and its findings further. Consumers Union, the advocacy arm of Consumer Reports, prepared this response, which was also reviewed by staff at the Johns Hopkins Center for a Livable Future.

Consumers Union has undertaken a Meat Without Drugs campaign because antibiotic resistance has become a major public health crisis. We urge Congress to pass the Preservation of Antibiotics for Medical Treatment Act (PAMTA). We believe that one of the best ways to reduce the level of antibiotic resistance in bacteria is to minimize the use of antibiotics in food-animal production. The Food and Drug Administration (FDA) recognizes this point. FDA notes in their Guidance for Industry (GFI) #209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," that the related GFI #152¹ is "premised on

¹ FDA. 2003. Guidance for Industry #152 Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern. At:

the concept that increasing the exposure of bacterial populations to antimicrobial drugs increases the risk of generating resistance to those antimicrobial drugs.”² We agree completely.

There is also broad scientific consensus on this point. A recent article in the science journal *Nature* stated, “Given how difficult it is to control how resistant bacteria behave and spread worldwide, reducing antibiotic use is something we must do for the future health of all—animals and people.”³

Consumers Union has asked the thirteen largest supermarket chains to only sell meat and poultry from animals raised without antibiotics to address directly this issue—the problem of antibiotic resistance from use/overuse/misuse of antibiotics in food-animal production—a problem the government has not yet been able to solve. In a recent Consumer Reports poll, 86 percent of respondents indicated that they believed they should be able to buy meat and poultry raised without antibiotics in their local supermarket.⁴ We hope that our communications with consumers and supermarkets will lead to a significant reduction in the use of antibiotics in food-animal production.

On a policy level, we believe the FDA should restrict the use of antibiotics in food animals to treatment of veterinarian-diagnosed sick animals only. FDA should not allow any use for other purposes. We recognize that at present “no antibiotics” production systems often work in tandem with systems that allow use of antibiotics, and that some small amount of antibiotic use will likely always be needed to treat disease in food animals. However we believe that based on experiences in other countries, antibiotic use in the United States can be greatly reduced without significant impact on the price or supply of meat⁵ and poultry.⁶

We would like to offer the following specific responses to points raised in the letter of July 3 from organizations involved in livestock production (hereafter referred to as the “producers’ letter”) which focussed on the following paragraph (the paragraph, attributed to our report, actually appeared in a press release): “Some 80 percent of all antibiotics sold in the United States are used not on people, but on factory farm animals, to make them grow faster and to prevent disease in crowded and unsanitary conditions. This is creating “superbugs” on farms to which humans are being exposed and causing life-saving drugs to become less effective.”

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>

² Pg. 18, FDA. 2012. Guidance for Industry #209 The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. At:

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>

³ Pg. 465 in Aarestrup F. 2012. Sustainable farming: get pigs off antibiotics. *Nature*, 486: 465-466.

⁴ Pg. 8 in Bohne M and J Halloran. 2012. *Meat On Drugs*. Consumer Reports: Yonkers, NY. 25 pp. At:

http://www.consumerreports.org/content/dam/cro/news_articles/health/CR_percent20Meat_percent20On_percent20Drugs_percent20Report_percent2007-12b.pdf

⁵ Hayes DJ, Jensen HH, Backstrom L and J Fabiosa. 2001. Economic impact of a ban on the use of over the counter antibiotics in US swine rations. *International Food and Agribusiness Management Review* 4: 81-97. At:

<http://ageconsearch.umn.edu/bitstream/34371/1/04010081.pdf>

⁶ Graham JP, Boland JJ and E Silbergeld. 2007. Growth promoting antibiotics in food-animal production: an economic analysis. *Public Health Reports*, 122: 79-87. At: http://www.jhsph.edu/sebin/s/a/antibiotics_poultry07.pdf

Specific comments:

Assertion: The producers’ letter states that one cannot compare human and animal data on antibiotic use since fully “40 percent of the animal antibiotics counted are compounds not used in human medicine, and therefore, their use in animals cannot be compared with those used in humans.”

CU Replies: We disagree; **comparisons of the animal and human data are valid.** The National Antimicrobial Resistance Monitoring System (NARMS) Frequently Asked Questions (FAQ) about Antibiotic Resistance includes the following: Q: “Which antibiotics used in food-producing animals are related to antibiotics used in humans? A: The majority of antibiotics used in food-animals belong to classes of antibiotics which are also used to treat human illness; these include tetracyclines, sulfonamides, penicillins, macrolides, fluoroquinolones, cephalosporins, aminoglycosides, chloramphenicols, and streptogramins. Because these classes of antibiotics are similar, then bacteria resistant to antibiotics used in animals will also be resistant to antibiotics used in humans.”⁷

In addition, 2010 FDA data show that roughly 29 percent of antibiotics used in animal production are ionophores,⁸ a class of antibiotics that are not used in human medicine.⁹ However, in the absence of adequate data demonstrating safety, we are concerned about the ability of some ionophores to promote resistance to medically important antibiotics in disease-causing (e.g. pathogenic) bacteria. A study by scientists from the United States Department of Agriculture (USDA) Agricultural Research Service and Cornell University involving monensin, one of the most commonly used ionophores in cattle production in the U.S., demonstrated that while use of monensin in cattle feed and the selection of monensin-resistant ruminal bacteria did not lead to resistance to 15 of 16 antibiotics tested, there was a 32-fold increase in resistance to bacitracin, which is used in human medicine.¹⁰ This study demonstrates that one cannot claim that ionophores cannot select for cross resistance to any antibiotic used in human medicine. The study called for more research.¹¹ So, it is appropriate to consider ionophore use as part of the antibiotics used in animal agriculture.

Assertion: Regarding the phrase “...but on factory farms ...” the producers’ letter states, “The antibiotic sales data used in the report comes from manufacturers and refers to all antibiotics sold, regardless of the type of operation on which they are used.”

CU Replies: We agree that the data cover antibiotic use on all types of farms. As noted in our report, we’re in fact concerned with any antibiotic use on a farm of any size—whether factory farm or small family farm—except for treatment of sick animals.

⁷ http://www.cdc.gov/narms/faq_pages/11.htm

⁸ FDA. 2010. Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. At: <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM277657.pdf>

⁹ At: <http://www.bioagrimix.com/haccp/html/ionophores.html>

¹⁰ Houlihan AJ and JB Russell. 2003. The susceptibility of ionophores-resistant *Clostridium aminophilum* F to other antibiotics. *Journal of Antimicrobial Chemotherapy*, 52: 623-628. At: <http://jac.oxfordjournals.org/content/52/4/623.full.pdf>

¹¹ Pg. 627 in Ibid.

Assertion: Regarding the phrase “...to make them grow faster and to prevent disease...” the producers’ letter notes that “Antibiotics are approved by FDA for use in four specific and discrete ways: treatment of disease, control of disease, prevention of disease and growth promotion/feed efficiency. Treatment, control and prevention of disease are defined as therapeutic uses ...”

CU Replies: We agree that the 80 percent of antibiotics sold in the U.S. for use in food-animal production are used to treat and control disease, as well as to prevent disease and make animals grow faster. However we disagree with FDA policy in this matter. We believe that antibiotics should not be used on healthy animals and should only be used to treat veterinarian-diagnosed sick animals. Antibiotics should not be given in low, sub-therapeutic doses (which can foster resistance); governmental regulations note such sub-therapeutic uses include disease prevention and growth promotion.¹² Sub-therapeutic use accounts for the vast bulk of antibiotic use on animals. A 1988 Institute of Medicine (IOM) report asserted that 63 percent of antibiotic use in animal (e.g. cattle, swine and poultry) production is for disease prevention.¹³

Assertion: Regarding the phrase “... in crowded and unsanitary conditions ...” the producers state that “This often repeated assertion simply defies logic from an economic and good animal husbandry standpoint. It can cost producers hundreds of thousands of dollars to erect indoor facilities—facilities designed by experts giving careful consideration to promote productivity by helping minimize economic losses caused by disease and the associated necessary treatment of sick animals.”

CU Replies: **The producers appear to be arguing that economic forces ensure that producers will follow good animal husbandry practices and maximize animal health, food safety, and animal well being. We disagree.** A typical industrial broiler chicken system involves placing 20,000 to 30,000 day-old chicks in a shed; by the last two weeks of life, there is only slightly more than half a square foot of living space per 4.5 to 6 pound bird.¹⁴ We regard these conditions as crowded. Regarding sanitation, a case in point is Wright County Egg and Quality Egg, the companies associated with a recall of more than 500 million eggs in August 2010, the largest egg recall in history, because of *Salmonella enteritidis* contamination.¹⁵ Inspections revealed numerous problems, including piles of manure in some of the chicken houses that were so high as to have pushed the doors open.¹⁶ An FDA report issued earlier this month found that slightly over 40 percent of the egg farms surveyed violated the FDA’s Egg

¹² 21 CFR §558.15(a) At: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol6/pdf/CFR-2011-title21-vol6-sec558-15.pdf>

¹³ Table IV-9, pg. 75 in Institute of Medicine (IOM). 1988. *Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed*. National Academies Press. Washington, D.C.

¹⁴ Humane Society of United States. 2008. Human Health Implications of Intensive Poultry Production and Avian Influenza. At: <http://www.humanesociety.org/assets/pdfs/farm/HSUS-Public-Health-Report-on-Avian-Influenza-and-Poultry-Production.pdf>

¹⁵ FDA. 2010. *Salmonella enteritidis* Outbreak in Shell Eggs. Updated November 30, 2010. At: <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>

¹⁶

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/ORAElectronicReadingRoom/UCM224399.pdf>

Safety Rule.¹⁷ Clearly, economic forces alone cannot be relied on to ensure human and animal health and safety in animal agriculture.

Assertion: The producers' letter states that "indoor confinement in the pork industry has allowed producers to virtually eliminate trichinosis and toxoplasmosis, diseases that research has shown are re-emerging and pose a challenge to production systems where animals are more readily exposed to outdoor pest and disease risks."

CU Replies: We see no evidence that reducing use of antibiotics will lead to an increase in trichinosis and toxoplasmosis in pork. First, reducing the use of antibiotics does not necessarily lead to a reduction in the use of indoor confinement systems. The experience of Sweden¹⁸ and Denmark,¹⁹ where pigs are still raised indoors despite substantial reductions in antibiotic use,²⁰ shows that this is not the case.

Beyond that, however, the data do not support the producers' contention that outdoor, non-confinement systems pose a "challenge" with regard to trichinosis in pork, or that these diseases are "re-emerging." The level of trichinosis due to consumption of pork products is currently very low and continues to drop, and very few cases are associated with non-commercial pork production. Trichinosis is a reportable disease in 48 states. According to the U.S. Centers for Disease Control and Prevention (CDC), between 1975 and 1981, there were about 750 cases of trichinellosis related to pork products; whereas between 1997 and 2001, there were only 22 cases and between 2002 and 2007 only 10 cases directly related to pork products.²¹ In fact, beginning with the 1997-2001 period, there have been more cases of trichinellosis from consumption of wild game meat (31 cases) than from consumption of pork products.²² As the CDC noted, "The number of reported trichinellosis cases attributed to commercial pork consumption remains low. The greatest number of cases continues to be associated with consumption of meat other than pork, especially bear meat."²³

Furthermore, while from 1997-2001, of the 22 cases associated with pork products, nine were from non-commercial pork (home-raised or direct from the farm),²⁴ by the 2002-2007 period, only two cases were associated with non-commercial pork, and those were both from wild boar raised on a farm or sold at a farmers market. Thus for 2002-2007, there were no cases of

¹⁷ <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/ucm311029.htm>

¹⁸ <http://www.q-porkchains.org/e-learning/resources/lr1.aspx>

¹⁹ Danish Agricultural and Food Council. Danish Pig Producers and Animal Welfare. At: [http://www.agricultureandfood.dk/~media/agricultureandfood/About percent20us/Danish percent20Agriculture percent20and percent20Food/AnimalWelfare2010ashx.ashx](http://www.agricultureandfood.dk/~media/agricultureandfood/About%20us/Danish%20Agriculture%20and%20Food/AnimalWelfare2010ashx.ashx)

²⁰ Editorial. 2012. Pig Out. *Op cit.*; Hayes DJ, Jensen HH, Backstrom L and J Fabiosa. 2001. Economic impact of a ban on the use of over the counter antibiotics in US swine rations. *Intl Food and Agribusiness Management Review*, 4: 81-97. At: <http://ageconsearch.umn.edu/bitstream/34371/1/04010081.pdf>

²¹ Kennedy ED, Hall RL, Montgomery SP, Pyburn DG and JL Jones. 2009. Trichinellosis Surveillance—United States, 2002-2007. *MMWR Surveillance Summaries*, 58(SS09): 1-7. At: <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5809a1.htm>

²² IBID.

²³ Pg. 1 in IBID

²⁴ Roy SL, Lopez AS and PM Schantz. 2003. Trichinellosis Surveillance—United States, 1997--2001. *MMWR Surveillance Summaries*, 52(SS06): 1-8. At: <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5206a1.htm>

trichinosis associated with consumption of ordinary pork that was home-raised or sold direct from the farm.

As far as we can tell, the concern over trichinosis and toxoplasmosis appears to stem from a single 2008 study which looked at the rate of exposure to *Salmonella*, *Trichinella*, and *Toxoplasma* in pigs reared in either antimicrobial-free (ABF) or conventional (intensive, indoor) production systems in three states. The study, funded by the National Pork Board, found that there were higher rates of exposure (as evidenced by the presence of antibodies) to *Salmonella* and *Toxoplasma*, but not *Trichinella* in the ABF systems.²⁵ However it is unclear how the pigs in the two categories were chosen for this study. Only two pigs were positive for *Trichinella* exposure, both from an ABF system, but that number is too low to be statistically significant. Without more information about how the farms/pigs were chosen, we can't properly interpret how representative the results are.

Assertion: The producers state, “We have been encouraged by the significant changes taking place in the regulation of antibiotics. FDA has initiated a process to extend veterinary oversight of medically important antibiotics used in animal agriculture, which includes elimination of the growth promotion uses of these compounds. The net result of this process will be to place medically important antibiotics used in agriculture under the supervision of a licensed veterinary medical professional and use them only for therapeutic purposes. Our members are working with FDA to enact these changes and believe these efforts work to address consumers' calls for the elimination of growth promotion uses.”

CU Replies: We agree that the FDA proposal to place antibiotics used in animal agriculture under the supervision of a veterinarian and to ask drug companies and livestock growers to voluntarily eliminate growth promotion uses of antibiotics are steps in the right direction. However, we do not believe the drugs should be used for disease prevention. FDA should limit antibiotic use in food-animals to treatment of veterinarian-identified sick animals. The FDA notes in its GFI #209 that their GFI #152,²⁶ is “premised on the concept that increasing the exposure of bacterial populations to antimicrobial drugs increases the risk of generating resistance to those antimicrobial drugs.”²⁷ We agree. As the producers' letter points out, growth promotion accounts for only 13 percent of all antibiotic use on animals according to a 2007 survey by the Animal Health Institute. Thus eliminating use for growth promotion will have only a minor impact on total antibiotic use on food animals. Furthermore, the industry could still use the antimicrobial drugs, simply by classifying them as used for disease prevention rather than growth promotion.

Assertion: The producers' letter states, “the issue of antibiotic resistance is scientifically complex and cannot be addressed with simple solutions—at best, such solutions are ineffective and in some situations, could make the problem worse. The Danish experience should serve as a lesson about the complexity of this issue. A 2011 General Accounting Office Report stated:

²⁵ Gebreyes WA, Bahnson PB, Funk JA, McKean J and P Patchanee. 2008. Seroprevalence of *Trichinella*, *Toxoplasma*, and *Salmonella* in antimicrobial-free and conventional swine production systems. *Foodborne Pathogens and Disease*, 5(2): 199-203. At: http://www.foodpolitics.com/wp-content/uploads/pork_09.pdf

²⁶ FDA. 2003. *Op cit.*

²⁷ Pg. 18 in FDA, 2012. *Op cit.*

‘Danish officials told us that Denmark's resistance data have not shown a decrease in antibiotic resistance in humans after implementation of the various Danish policies [to ban animal antibiotic uses], except for a few limited examples.’ ”

CU Replies: We agree that the issue of antibiotic resistance is scientifically complex. That is why the federal government has assembled a multiagency program focused solely on the problem of antibiotic resistance called National Antimicrobial Resistance Monitoring System (NARMS). According to a report of the World Health Organization Regional Office for Europe, “Ensuring the prudent use of antibiotics in animals is ... of utmost importance.” It continues, “In the context of food-animal production, prudent use means eliminating non-therapeutic uses, including for growth promotion and as feed additives.”²⁸

Regarding the GAO report, the industry has taken a quote out of context and oversimplifies. It is difficult to reverse resistance rates in a short period of time after curtailing antibiotic use. However, the measures taken in Denmark should not be construed as ineffective. In fact, the **Danish experience shows that antibiotic use can be significantly decreased, and can lead to a reduction in antibiotic resistance in bacteria in food animals and retail meats with no increase in bacteria that cause foodborne illness, and to some reduction in antibiotic resistance in humans.** The GAO report cited notes that producer fears were *not* borne out by the Danish experience: “Producer organizations in the United States have expressed concerns that reductions in antibiotic use may lead to an increase in foodborne pathogens on meat, but industry officials in Denmark said that their data show no increase in the rates of these bacteria on meat products.”²⁹

The GAO report also noted that “Danish data on antibiotic resistance in food-animals and retail meat show reductions in resistance after policy changes in most instances ... the percentage of *Enterococcus* from food-animals that are resistant to antibiotics banned for growth promotion has decreased since the bans were implemented. Officials also mentioned declines in resistance among *Campylobacter* bacteria (which can cause foodborne illness in humans) from food-animals and retail meat. For example, officials said that resistance to the critically important class of drugs called macrolides has decreased in *Campylobacter* bacteria from swine.”³⁰ Those declines mean that illnesses resulting from these foodborne bacteria will be easier to treat and public health will benefit.

GAO states that in Denmark “the prevalence of vancomycin-resistant *Enterococcus faecium* from humans has decreased since avoparcin was banned for use in animals in 1995.”³¹ Vancomycin-resistant *E. faecium* (VRE) is a major concern in health-care settings. Data from a U.S. study found that 4 percent of the healthcare-associated infections reported to the CDC’s National Healthcare Safety Network from January 2006 to October 2007 were from vancomycin-

²⁸ Pp. 26-27 in WHO Regional Office for Europe. 2011. Tackling antibiotic resistance from a food safety perspective in Europe. At: http://www.euro.who.int/_data/assets/pdf_file/0005/136454/e94889.pdf

²⁹ Pg. 41 in Government Accountability Office (GAO). 2011. Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals. At: <http://www.gao.gov/assets/330/323090.pdf>

³⁰ Pg. 40 in GAO. 2011. Op cit.

³¹ Pg. 41 in GAO. 2011. Op cit.

resistant *E. faecium*, second only to methicillin-resistant *Staphylococcus aureus* (MRSA).³² So, a decline in prevalence in VRE does have a significant human health impact.

Assertion: The producers note that “Livestock and poultry are sometimes treated with antibiotics to prevent, control and treat diseases, but strict withdrawal periods must be followed to ensure that no residues are contained in the products we consume ... antibiotics, when used properly and under the oversight of a veterinarian, are critical to making food safe.”

CU Replies: It is incorrect to state that no antibiotic residues occur in the food we eat. Rather, there are legally permitted levels—called tolerances—for every antibiotic approved for a food use. Some tolerances may be zero for certain antibiotics in certain foods, such as for erythromycin in milk, but the majority of tolerances are non-zero.³³ However, Consumers Union’s primary concern is not residues of antibiotics in food, but rather the development of antibiotic-resistant bacteria resulting from the use of antibiotics in food animals.

We disagree that antibiotics “are critical to making food safe.” Similar to the approach in the human medical field (and for the same reasons), antibiotics are critical to treating diseases and should be used judiciously. *Consumer Reports* most recent tests of chicken, in 2009, found *Salmonella* and/or *Campylobacter* in about two-thirds of the samples and 68 percent and 60 percent of the *Salmonella* and *Campylobacter*, respectively, were resistant to one or more antibiotics.³⁴ Antibiotic use is clearly not eliminating pathogens from chicken. Meanwhile, to the extent that antibiotic use selects for resistant pathogens, it worsens the public health problem of foodborne infections that are difficult to treat. Minimizing antibiotic use will help minimize the selection pressure for resistant pathogens. Thus, in our view, antibiotics are not critical to making our food safe; rather their overuse/misuse makes food more unsafe.

In sum, we face an extremely serious problem of loss of effectiveness of antibiotics in human medicine. It is essential to reduce the substantial use of antibiotics in food animals to address this problem. We urge meat and poultry producers and the FDA to phase out the use of antibiotics except for treatment of sick animals. We urge Congress to mandate these important changes through passage of PAMTA.

Sincerely,

Michael Hansen, Ph.D.
Senior Scientist

Jean Halloran
Director, Food Policy Initiatives

³² Hidron AI, Edwards JR, Patel J, Horan TC, Sievert DM, Pollock DA, Fridkin SK; National Healthcare Safety Network Team; Participating National Healthcare Safety Network Facilities. NHSN annual update: antimicrobial-resistant pathogens associated with healthcare-associated infections: annual summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2007- 2007. *Infect Control Hosp Epidemiol*, 29(11): 996-1011. At: <http://www.ncbi.nlm.nih.gov/pubmed/18947320>

³³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=556>

³⁴ Pg. 22 in Consumer Reports. 2010. How safe is that chicken? *Consumer Reports*, January: pp. 19-23.