

August 14, 2009

Ms. Melody Barnes
Assistant to the President for Domestic Policy
The White House
Washington, DC

Dear Ms. Barnes:

The undersigned organizations represent American food producers and the industries which serve them. As the first line of defense against food-borne illness and key to this nation's priority on domestic and global food security, we write to convey the significant political and scientific complexity of the use of antibiotics on farms to prevent, treat and control disease in food producing animals. We also wish to make you aware of the actions taken by our groups, both individually and collectively, to ensure these important, safe, effective Food & Drug Administration (FDA)-approved products are used judiciously, minimizing risk to human health.

Most of our organizations participated in a June 18, 2009, FDA outreach session hosted by Commissioner Dr. Margaret Hamburg and Principal Deputy Commissioner Dr. Joshua Sharfstein. This meeting focused on the use of antibiotics on farms. We subsequently formally asked Commissioner Hamburg for a continuing dialogue to discuss the specifics of this issue and explore what science-based, practical options are open to industry and the agency. We have formally requested FDA convene a Washington, DC, meeting of U.S. risk assessment experts to discuss the current body of science on this issue and we're awaiting FDA's response. Further, as part of our interest in educating FDA's leadership, Deputy Commissioner Sharfstein visited a modern hog farm in Illinois on August 5, and we hope Commissioner Hamburg's schedule will allow her to visit a cow/calf operation and feedyard in the near future. We also intend to invite Drs. Hamburg and Sharfstein to visit an FDA-regulated feed mill, as well as modern poultry operations.

The bottom line for on-farm antibiotic use is this: Farmers and ranchers strive daily to provide best possible management of their animals through superior genetics, nutrition, veterinary care, housing and handling. Optimal animal health and welfare leads to production of safe, affordable and abundant food, critical to U.S. food security. Maintaining the health of U.S. herds and flocks requires farmers and ranchers to have all approved safe and effective technologies, including animal health products, available to us.

However, despite the unsubstantiated allegations surrounding these uses, no conclusive scientific studies have been offered demonstrating the use of antibiotics on farms contributes significantly to an increase in human resistance. In fact, a growing body of evidence shows just the opposite, namely the responsible, professional use of these products reduces pathogens in and on foods, enhancing animal welfare while not contributing to resistance.¹

¹ A 2004 study done by scientists at the University of Minnesota College of Veterinary Medicine in which the potential risks associated with increased levels of antibiotic-resistant bacteria in meat were compared with the potential benefits associated with decreased risk of food-borne illness found potential benefits to human health associated with the use of antibiotics in chicken far exceeded the relatively low increased human health risks associated with antibiotic resistance.

A 2008 Iowa State University study by Dr. Scott Hurd, et al, former U.S. Department of Agriculture (USDA) deputy under secretary for food safety, demonstrated that when pigs have been sick at some point during their lives, those animals have a greater presence of pathogens than do animals who were prevented from becoming ill.² An Ohio State University study by Dr. Wondwossen Gebreyes, et al, published in 2008, examined modern housing systems, often the target of anti-technology activism. Gebreyes found levels of three food-borne illness pathogens were higher in animals raised in outdoor systems without the use of antibiotics.³

The White House must be aware removing antibiotics from on-farm use may jeopardize or seriously complicate President Obama's food safety priorities. On July 1, 2009, the President's Food Safety Working Group released its report to the President, detailing its priorities. Primary among these priorities is prevention of food-borne illness, and one of the chief strategies to achieve this goal is the further reduction of pathogens on meat, poultry and eggs from already low levels. To remove the judicious on-farm uses of antibiotics from the array of tools proven to be effective in reducing pathogens in meat and poultry works against this priority, and may make the goal unattainable.

The Institute of Food Technologists (IFT) released a June, 2006 Expert Report – “*Antimicrobial Resistance: Implications for the Food System*” – which concluded: “There is evidence there are significant human health benefits from subtherapeutic antibiotic use to prevent subclinical disease in food animals and reduce levels of *Salmonella* and *Campylobacter* contamination of poultry carcasses.” IFT recommended policymakers focus on interventions to reduce food-borne pathogens rather than focusing on resistant pathogens.⁴ The report also stated: “Eliminating antibiotic drugs from food production may have little positive effect on resistant bacteria that threaten human health; in fact, such actions abroad have resulted in more antibiotic use and more resistant bacteria in some cases.”

Action to ban some uses of certain antimicrobial products and restrict the use of others failed in Europe. As a result of banning the use of antibiotics for growth promotion, several European countries are documenting a significant increase in animal diseases – many not seen in Europe for 20 years – and an increase in the use of antibiotics by veterinarians to treat those diseases.

In fact, recently published literature shows resistance patterns in humans rarely decline as a result of such action. Data from The Netherlands shows penicillin and tetracycline resistance in *Salmonella typhimurium* have increased in humans since the ban, while these same resistances declined in the U.S. over the same period.⁵ Europe, following the same precautionary strategy espoused by U.S. critics of on-farm antibiotic use, has jeopardized animal health and welfare, food safety and security and demonstrated no improvement in human health.

The U.S. must learn from the European experience to avoid the same mistakes.

Current Government, Industry Safeguards

There is no incentive for farmers and ranchers to misuse or overuse antibiotics. These animal health products are expensive, but nonetheless are vital tools in maintaining the health and

² Hurd H.S., Brudvig J., Dickson J, et al. 2008. Swine health impact on carcass contamination and human foodborne risk. *Public Health Reports*: (123) pp 343-351.

³ Gebreyes W., Bahnsen P., Funk J., et al. 2008. Seroprevalence of *Trichinella*, *Toxoplasma* and *Salmonella* in antimicrobial-free and conventional swine production systems. *Foodborne Pathogens & Disease*: (5) pp 199-203.

⁴ The Institute of Food Technologists expert report can be found at http://members.ift.org/IFT/Research/IFTExpertReports/antimicrobial_report.htm

⁵ MARAN-2007; Monitoring of Antimicrobial Resistance and Antibiotic Useage in Animals in The Netherlands in 2006/2007.

welfare of the animals in our care. The basis of any policy discussion must begin with an understanding of and appreciation for the current regulatory status of these products. The following realities must be considered:

- A stringent FDA approval process was made more vigorous with the addition of significant FDA risk assessment requirements in 2003. Some of the compounds affected by proposed legislation supported by critics are undergoing review under these new requirements.
- Strict federal residue monitoring of all meat and poultry routinely demonstrates remarkable cooperation among animal health companies, feed companies, producers and regulatory agencies in ensuring antimicrobial products are used appropriately.
- Post-approval product risk assessments allow policymakers to measure the risks and benefits of a proposed policy, and these have been conducted and published by FDA, sponsors and researchers. Some additional compounds have been examined by these risk assessments, showing extremely low (sometimes zero) levels of risk.
- Food safety monitoring and surveillance programs have been established by government agencies and sponsors to track the development of antibiotic-resistant bacteria.
- FDA-required reporting by drug sponsors provides annual reports to the agency detailing any adverse impact of approved products.
- Pathogen reduction programs have led to documented reductions in pathogens on meat, contributing to decreased food-borne illness.

Responsible use programs have been developed specific to feed, livestock and poultry organizations to give feed companies and producers specific guidelines and assistance on the safe and proper use of antibiotics in health management systems. These programs are similar to voluntary advisory programs in place by the American Medical Association (AMA) and the American Academy of Pediatrics (AAP).

Such programs, their “start date” and where they may be viewed on the web, are listed below:

Poultry Industry -- American Association of Avian Pathologists (AAAP) “Statement on Use of Antibiotic Feed Additives by the Poultry Industry” with references (2008) www.aaap.info
 “Guidelines to Judicious Therapeutic Use of Antimicrobials in Poultry” (2000) www.avma.org/issues/policy/jtua_poultry.asp

Pork Industry -- National Pork Board (NPB) and National Pork Producers Council (NPPC) “Take Care – Use Antibiotics Responsibility” (2005) www.pork.org Pork Quality Assurance Plus (PQA Plus) (1989, revised 2007) www.pork.org/Producers/PQA/PQAPlusEdBook.pdf

National Cattlemen’s Beef Assn. (NCBA) Beef Quality Assurance Program (BQA, 1987); Producers Guide for Judicious Use of Antibiotics www.beef.org

American Feed Industry Association (AFIA) Safe Feed/Safe Food Certification Program (2004) www.afia.org

National Grain & Feed Association (NGFA) Model Feed Quality Assurance Program (1994) www.ngfa.org

Our organizations were actively involved in the development of the American Veterinary Medical Association's (AVMA) Judicious Therapeutic Use of Antimicrobials Guidelines for antibiotic use in animals. On July 28, 2009, AVMA – which coordinated the development of the original judicious use guidelines in cooperation with various species' veterinary organizations, the Centers for Disease Control & Prevention (CDC) and FDA -- notified stakeholders it has established an Antimicrobial Use Task Force.

This task force will include not only AVMA veterinary experts, but experts from the American Association of Avian Pathologists, the American Association of Bovine Practitioners, the American Association of Equine Practitioners, the American Animal Hospital Association, the American Association of Swine Veterinarians, the Aquatic Veterinary Medicine Committee, the Council on Public Health & Regulatory Veterinary Medicine, the Council on Biologic & Therapeutic Agents (epidemiology), the Food Safety Advisory Committee and the American Association of Small Ruminant Practitioners.

AVMA also invited representatives of all major livestock and poultry producer groups, as well as the animal health and feed industries, to provide non-voting representatives to the task force's two planned meetings. Further, FDA's Center for Veterinary Medicine (CVM), the CDC and the National Association of State Public Health Veterinarians have been invited to participate.

Critics Offer No New Data or Evidence

We are aware of the July 24, 2009 letter sent to you by Keep Antibiotics Working (KAW), Union of Concerned Scientists, the Pew Commission on Industrial Food Production, the Humane Society of the U.S. (HSUS), et al, praising what they perceive to be the Administration's formal position on the use of low-level antibiotics in agriculture. However, our reading of Dr. Sharfstein's testimony before the July 13, 2009 Rules Committee hearing reveals a very carefully worded statement referencing interest in the "idea" of limiting certain uses of the antibiotics on farm, but stopping far short of endorsing any legislation or espousing a formal administration position.

However, just as in their Rules Committee testimony, these groups – which have long waged political campaigns against on-farm antibiotic use and other technologies used by farmers and ranchers, as well as veterinarians, to protect the food supply – offer no new information or data to make their case, but rather echo inaccurate messages. At the same time, we find it curious these organizations make no mention of the continuing challenge of overprescription of antibiotics in human medicine or of increasing data which suggests prior direct human exposure to antibiotics is the greatest factor for acquiring infections with antibiotic-resistant bacteria.⁶

Further, these arguments belie a significant lack of understanding of modern food production. To suggest "minor" adjustments in U.S. animal husbandry practices or a shift to European-style animal production will obviate the need for animal health intervention is naïve. The natural behavior of flock birds and herd animals means these animals will be exposed to disease no matter what production system is used and no matter what underlying philosophy guides production. As to following so-called "European production practices," this recommendation ignores significant differences in cultures, economies of scale, breeds and varieties of animals raised, marketing differences, differences in the ability of veterinarians to prescribe products and government intervention in on-farm production practices.

⁶ Dr. Michael P. Doyle, microbiologist/food safety expert and chair, IFT expert panel, in the June 26, 2006 press release accompanying the release of the IFT *Expert Report* – "Eliminating Antibiotics from Food Animals is Unwise."

Conclusion

When all is said and done, U.S. farmers and ranchers – and most consumers – are more confident knowing animal health care, assistance and advice are provided by veterinarians and animal scientists, not by PhD issue advocates or animal rights activists.

FDA has always been an agency which makes regulatory decisions based on science and over time has done an exemplary job of standing apart from political battles. Since his inauguration, President Obama's repeated pledge to base his Administration's regulatory decisions on "the best available science" and "the rule of law" gives us confidence the Administration will not embrace an ill-advised, politically motivated call to curb on-farm uses of antibiotics.

A 2007 study by Dr. Alan G. Mathew, et al, University of Tennessee, makes this point as well when Mathew writes: "As livestock producers, animal health experts, the medical community and government agencies consider effective strategies for control, it is critical that science-based information provide the basis for such considerations, and that the risks, benefits and feasibility of such strategies are fully considered so that human and animal health can be maintained while at the same limiting the risks from antibiotic-resistant bacteria."⁷

It is also encouraging to note the Bipartisan Policy Council's Science for Policy Project⁸ has recommended to the Administration strategies to assist it in preventing the politicization of science. Says the report: "(The conflict between science and politics has) left the U.S. with a system plagued by charges that science is being 'politicized' and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations adopted, issues can drag on without conclusion and policy debate is degraded."⁹

As American food producers, we are hopeful we will be permitted to continue our discussions on this complex issue with the leadership of FDA. Contrary to our critics' characterization of our position on this issue, we have not "dug in." Rather, we welcome honest discussion of science-based, pragmatic options allowing producers to farm in the best interests of their animals and customers while providing consumers assurance our use of these vital, safe and effective production tools is professional, judicious and does not jeopardize these products' effectiveness in human medicine.

Thank you for consideration of our views. Please feel free to contact any of the organizations listed below if you require additional information.

Sincerely,

⁷ Mathew, Alan G.; Cissell, Robin, Liamthong, S; 2007. "Antibiotic Resistance in Bacteria Associated with Food Animals: A United State Perspective of Livestock Production," *Foodborne Pathogens & Disease*, November 2, 2007: (4) pp 115-133

⁸ The Bipartisan Policy Center was formed in 2007 by former Senate Majority Leaders Howard Baker (R, TN), Tom Daschle (D, SD), Bob Dole (R, KS) and George Mitchell (D, ME). The Science for Policy Project is chaired by former House Science Committee Chair Rep. Sherwood Boehlert (R, NY) and former FDA Commissioner Dr. Donald Kennedy, retired editor of *Science* magazine.

⁹ Ibid; "Expert Panel Offers Advice on Separating Science, Politics"; Robin Bravender, *New York Times*, August 5, 2009.

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Rep. Collin Peterson, chair, House Agriculture Committee
Sen. Saxby Chambliss, ranking member, Senate Committee on Agriculture, Nutrition & Forestry
Rep. Frank Lucas, ranking member, House Agriculture Committee
FDA Commissioner Dr. Margaret Hamburg
FDA Principal Deputy Commissioner Dr. Joshua Sharfstein