Pass the Preserving Antibiotics for Medical Treatment Act (PAMTA) to Stop the Non-therapeutic Use of Antibiotics in Animals.

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Abstract:

The role of antibiotic use in livestock production in the development of antibiotic resistance is receiving greater attention by consumers, government regulators, and industry. The majority of antibiotics are not used in humans but in livestock production for growth promotion, disease prevention, and treatment. The FDA released Guidance 213 in 2013, which is a voluntary guideline that seeks to end the use of antibiotics for growth promotion among healthy animals. The FDA still allows for the use of antibiotics in healthy animals to prevent possible disease, as described in an existing guidance from 2009. To curb the development of antibiotic resistance it is necessary to limit all non-therapeutic use of medically important antibiotics. The Preserving Antibiotics for Medical Treatment Act (PAMTA), which has been introduced by Rep. Louise Slaughter (D-NY), will prohibit the use of eight medically important antibiotic classes for non-therapeutic reasons in animals. Evidence from Denmark where all non-therapeutic use of antibiotics is banned indicates that it is possible for producers to maintain productivity and the health of their animals without relying on antibiotics. The development of antibiotic resistance in livestock is ongoing and current FDA regulation and market pressures will not be enough to halt their spread, necessitating stronger government regulation.

Antibiotic resistance is a growing public health problem. Over 2 million people in the United States annually become infected with bacteria that are resistant to our current arsenal of antibiotics and 23,000 die from those infections.[1] This problem is exacerbated by the widespread use of antibiotics by meat producers. In 2011, 61% of antibiotics sold to meat producers are considered "medically important" in that they are also used to treat human infections.[2] This contributes to the staggering 80% of antibiotics in the US being used for animals and not in humans.[2] A 2012 study by the FDA found that 68% of *E. coli* found in ground turkey tested were resistant to more than three antibiotics.[3] *E. coli* is the second most common infection in humans and kills 36,000 people annually in the US.[4] Antibiotic resistant strains that develop in food animals can reach human populations in various ways, through contaminated meat, produce, and through waterway contamination. Antibiotics have been administered routinely in animal feed in the US to speed growth, prevent diseases that result from crowded conditions, and treat infected animals. These first two uses are "non-therapeutic" uses and typically require low-dose, prolonged treatment of healthy animals, which provides an ideal breeding ground for resistant bacteria. Medically important antibiotics must be preserved only for disease treatment purposes, and the Preserving Antibiotics for Medical Treatment Act will ensure that these antibiotics will be kept from non-therapeutic use.

The FDA has recently produced two voluntary guidelines that attempt to curb the non-therapeutic use of antibiotics. In 2012, Guidance 209 addressed preventive use of medically important antibiotics and 2013's Guidance 213 specifically addressed growth promotion.[5,6] The hope is that these guidelines will lead meat producers to use antibiotics only as prescribed by a veterinarian for prevention or treatment. While veterinarian

oversight is a laudable goal, the FDA is placing a large amount of faith in the ability of veterinarians to shape producer's practices and limit the use of antibiotics. Veterinarians are not regulated in the same way that medical doctors are for potential connections to pharmaceutical companies and Guidance 209 does not require disclosure of financial conflicts of interest. This may not be too surprising considering that the majority (4 of 6) of the veterinarians on the FDA expert panel for this guidance themselves had financial ties to the pharmaceutical industry.[7] The veterinary oversight recommended in the guidelines will soon be addressed by a rule on veterinary feeding directives from the FDA, of which a proposed rule was released in December 2013.[8] The proposed rule will make it easier for veterinarians to prescribe antibiotics so that producers can obtain them in accordance with 209's judicious use policy. By doing so, the FDA does not seem to be limiting producer use of antibiotics in practice. Veterinarians also appear resistant to enacting the FDA's definition of judicious use, particularly the requirement to identify a potential infecting organism prior to prescribing preventive antibiotics.[9] This does not inspire confidence that these voluntary regulations will result in meaningful changes in the ways that producers use antibiotics and thus little change in the development of antibiotic resistance.

Preventive use still relies on antibiotics as a first line of defense and can mask poor animal husbandry practices that create an environment conducive to infection. In the long run it will serve producers and the public interest to better to avoid infection-prone practices in the first place and preserve antibiotics to be effective to treat sick animals and people. As in growth promotion, preventive antibiotics are administered primarily though feed to large numbers of healthy animals for protracted periods of time. They also can result in increased growth, which will allow producers to achieve their desired ends but

purportedly as a side effect instead of as the main reason for the antibiotic. This could make Guidance 213 by the FDA result in antibiotic use that is simply a change in name rather than an effective curbing of antibiotic use that can reduce the development of antibiotic resistance.

To protect public health and the future of animal production in this country it is necessary to enact legislation that prohibits the use of antibiotics for non-therapeutic purposes. Consumer pressure seems to be making inroads with major poultry producers Tyson and Perdue phasing out antibiotic use for growth promotion.[10] They continue to stand by their use of antibiotics as a prevention tool as justified and in line with current guidelines. This continued reliance on preventive antibiotics and the motivation of drug companies to continue to sell antibiotics in great volume make both producers and pharmaceutical companies unlikely to be moved easily by the voluntary guidelines or consumer pressure. To ensure that antibiotics are only used to treat sick animals will require pressure on the FDA. Rep. Louise Slaughter, the only microbiologist in Congress, has introduced the PAMTA bill every year since 2007.[11] PAMTA will limit eight medically important antibiotics to therapeutic use only, halting their use in growth promotion and prophylaxis. While the bill has failed to pass the House for the past eight years, the growing awareness of the public on the harms of antibiotics and demand for action on the part of food companies and the government make now an opportune time to pursue passage of PAMTA once more.

The tide of public opinion is turning on the issue of antibiotics as a habitual part of meat production from passive acceptance to concern and actual purchasing changes. Media coverage echoes this with recent coverage mainly focused on several high profile

companies who are demanding antibiotic-free meat from their suppliers in order to meet consumer demand. These companies include Chipotle for pork and Costco, Chik-fil-A, McDonald's for chicken.[12,13] Some producers are now changing their practices to remove growth production use of antibiotics but will continue to use antibiotics prophylactically, as is the case with Tyson. Most media coverage does not go into the distinction between preventive use and therapeutic use. A common counterargument by the industry and those against government regulation to increased regulation of antibiotic use is that market and consumer demand will suffice to move the industry away from overuse of antibiotics. While consumer pressure is laudable and indicative of increased public awareness, consumers are not fully informed as to the continued potential harms of preventive antibiotic use. Without this knowledge and pressure, companies can continue their practices with antibiotics but market their product as being free of "unnecessary" antibiotics. For this reason stronger governmental oversight is necessary.

The meat industry, pharmaceutical companies, and veterinarians are all stakeholders who will be affected financially by the passage of PAMTA and have come out in opposition. Producers in the US cite concerns about poorer animal health, diminished productivity, and increased expense that will result if they are not allowed to use antibiotics prophylactically. Denmark, which prohibited non-therapeutic use of antibiotics in 1999, provides an excellent real world counterpoint to this argument. Since then studies have found that animal mortality remained at the same levels in 2008 compared to 1992, productivity increased, and the cost of raising pork only increased by a little over a dollar per pig and with no cost difference in poultry.[14] At the same time, there were significant reductions in the amounts of antibiotic resistant bacteria in fecal samples from both food

animals and their caretakers.[15] Pharmaceutical companies are also threatened by diminished sales if the voluntary guidelines are followed by producers and they may move to enhanced courting of veterinarians to insure continued sales by prescription. If PAMTA were to pass then they would lose even that method of sales and could face lower profits on antibiotic sales. The political clout of animal producers and pharmaceutical companies is sizable and should not be underestimated. Veterinarians via the American Veterinary Medical Association have come out against PAMTA citing that it will harm their ability to protect animal welfare and have instead voiced support for Guidance 209 which will increase their presence (and potential profit) in livestock raising.[16] On the supporting side over 300 organizations have endorsed PAMTA including medical professionals, the public health community, food justice groups, and environmental groups. These advocacy groups repeatedly have called out the potential of continued allowance of preventive use as a backdoor for producers to continue using antibiotics habitually. They support stronger restrictions on all non-therapeutic use of antibiotics in animals like PAMTA.

Consumer pressure and market forces are a step in the right direction but not sufficient to make the changes necessary to protect public health. Current action by the FDA is limited by its voluntary nature, overreliance on veterinarian oversight, and continued support of preventive use that may mean little change in the day-to-day practices of meat producers. PAMTA is the legislation we need to make lasting changes in the antibiotic use by the meat industry to preserve antibiotics for use in human healthcare.

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Pass the Preservation of Antibiotics for Medical Treatment Act (PAMTA) to Protect Human and Animal Health.

Antibiotic Resistance is a Growing Problem

- Annually over 2 million people in the United States become infected with bacteria that are resistant to our current arsenal of antibiotics and 23,000 die from those infections. (CDC)
- Antibiotic resistance costs the US $20 billion a year in excess health care costs, $35 billion in other societal costs and more than 8 million additional days that people spend in the hospital. (CDC)

Use of Antibiotics by the Meat Industry is a Problem

- Over 80% of the antibiotics used in the US are used in animals and not in human medical treatment, and the majority of those are used in healthy animals for growth promotion or prevention.
- In 2011, the majority (61%) of antibiotics sold for use in food animals are medically important antibiotics that are used in humans like tetracycline and penicillin.

Current guidelines are insufficient to stop the development of antibiotic resistance.

- The FDA has only been able to create voluntary guidelines that seek to end the use of antibiotics in growth promotion but still allow their use in prevention.
- Preventive use is a loophole that producers can use to continue using large amounts of antibiotics instead of improving their husbandry practices.

PAMTA will stop antibiotic resistance by preserving antibiotics for use in treatment of sick animals.

- PAMTA will restrict 8 classes of medically important antibiotics to therapeutic use only, halting their use for production and preventive purposes.
- PAMTA will not let producers continue the status-quo under the guise of prevention but will keep antibiotics useful for treating animal and human disease.

Data supports that limiting preventive use won't result in more sick animals but can drive producers to more sustainable husbandry practices with minimal economic impact.

- From 1999 to 2008, antibiotic use in Danish pigs dropped by more than 50% and productivity increased.
- Production of weaning pigs increased from 18.4 million in 1992 to 27.1 million in 2008 while animal mortality did not increase.

Public Support is High for Action Against Overuse of Antibiotics by Industry

- The public is more and more aware of the importance of antibiotic resistance and the role of animal production. Companies are beginning to phase out antibiotics for growth promotion but stand by their use of preventive antibiotics even when consumers want no antibiotics in their meat.
- Stronger governmental regulation is necessary, pass PAMTA now!

Stakeholders For the Passage of PAMTA

1. **Alliance for Prudent Use of Antibiotics** http://www.tufts.edu/med/apua/ A group affiliated with Tufts University that conducts research and educational projects to control and monitor antibiotic resistance, has a global membership. Also advocates for policy that promote surveillance of antibiotic resistance, development of new antibiotics, and keep antibiotics out of livestock production and designated for human medical use.

2. **Center for Science in the Public Interest**. Argues that preventive use of antibiotics drives development of antibiotic resistance. Member of Keep Antibiotics Working group. http://www.cspinet.org/ar/

3. **Congresswoman Louise Slaughter, D-NY**. Wrote the bill that will protect 8 classes of antibiotics for human use and for sick animals only, stated that the voluntary FDA measures were not enough to curb the development of antibiotic resistance. http://www.louise.house.gov/press-releases/rep-slaughter-voluntary-regulation-on-antibiotics-inadequate-to-protect-public-health-no-enforcement-mechanism-or-criteria-for-success/

4. **Pew Charitable Trusts**. Supports increased regulation of antibiotic use in animal husbandry, including prohibition of production use and preventive antibiotics and mandatory regulations. http://www.pewtrusts.org/en/projects/antibiotic-resistance-project

5. **National Resource Defense Council**. Sued the FDA to compel mandatory regulations prohibiting non-therapeutic use of antibiotics in healthy animals, including prevention. http://www.nrdc.org/food/saving-antibiotics.asp

6. **Keep Antibiotics Working**: A coalition of health, consumer, agricultural, environmental, humane and other advocacy groups with more than eleven million members dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in food animals. http://www.keepantibioticsworking.com/

Stakeholders Against the Passage of PAMTA

1. **Animal Health Institute**: Collection of animal pharmaceutical manufacturers. Argues that the status quo use of antibiotics in animal feeding is necessary for food safety and sufficient to prevent antibiotic resistance. http://www.ahi.org/
2. **National Chicken Council**. Poultry Farmers and Producers, argues that its current uses of antibiotics are in line with FDA guidelines and preventive use is necessary for animal health. http://www.nationalchickencouncil.org/questions-answers-antibiotics-chicken-production/

3. **American Meat Institute.** A trade association for poultry and meat producers that argues that preventive use of antibiotics are necessary and will result in less use of antibiotics overall. https://www.meatinstitute.org/index.php?ht=d/sp/i/102248/pid/102248
4. **National Pork Producers Council** States that even the voluntary guidelines will be harmful to small producers. http://www.nppc.org/2012/04/fda-antibiotics-guidance-problematic-for-producers/
5. **National Cattlemen's Beef Association**: Argues that preventive use of antibiotics is just as important as for treatment of disease. http://www.beefusa.org/ourviewscolumns.aspx?NewsID=4334
6. **American Veterinary Medical Association**. Veterinarians have opposed PAMTA because they feel preventive use is justified, that producers are not using antibiotics inappropriately, and that Guidance 209 is sufficient to protect human health. https://www.avma.org/Advocacy/National/Documents/IB_PAMTA_4-1-2014.pdf