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# Multiple challenges - legislative, legal, regulatory and marketplace - to antibiotic use

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## Introduction

Antibiotic use in pork production has been an issue of concern with public health and veterinary medicine groups for several decades. Consumer advocacy organizations, many of which disagree with modern agricultural practices and industry structure, have used concern about antibiotic resistance to advance their agenda. Recently, there have been a number of actions taken that will likely have significant impacts on how veterinarians and pork producers access and use antibiotics.

## Legislative challenges

The Preservation of Antibiotics for Medical Treatment Act (PAMTA) was introduced in 2007 by Congresswoman Louis Slaughter, and had been introduced in previous Congresses by Senator Edward Kennedy. It is sponsored in this Congress by Representative Louis Slaughter and Senator Diane Feinstein. PAMTA was not attached as an amendment to the Farm Bill passed by the Senate, nor in the Farm Bill that has passed the House Agriculture Committee. At this writing the Farm Bill has not moved to the House floor where additional amendments may be offered.

PAMTA, however, is not the only legislative activity that has the potential to affect antibiotic use in agriculture. Recently, Representative Slaughter sent a letter to over 60 fast food companies, producers, processors and grocery chains asking them to disclose their policies on antibiotic use in meat and poultry production. In addition to asking for company policy she asked the restaurants to provide a breakdown of the percentages of beef, pork and poultry which were raised "without any antibiotics", raised with antibiotics for "therapeutic reasons" or raised with "routine use of antibiotics". Many of the companies that replied cited FDA regulations and did not, or were unable to, provide specific answers to the breakdowns on percentages of antibiotic use classifications provided by Representative Slaughter.

The results of Representative Slaughter's survey are likely to be referenced when the Animal Drug User Fee Act (ADUFA) is reauthorized in 2013. When ADUFA was last authorized a requirement that animal health sponsors report calendar year antibiotic sales was attached. During the public meeting leading up to the start of negotiations this year the advocacy groups signaled that they would press to require additional antibiotic use data as part of the ADUFA reauthorization.

## Legal challenges

Recently a US Magistrate Judge from New York issued a summary judgment in the case of Natural Resources Defense Council (NRDC) v United States Food and Drug Administration. In 1977 (that is not a typo – it is 1977!) FDA issued notices of opportunity for hearing (NOOH) announcing its intent to withdraw approval of penicillin, chlortetracycline and oxytetracycline for growth promotion. Although the notices were properly promulgated and over twenty drug sponsors requested hearings to defend the growth promotion approvals no hearings were ever held. NRDC argued that in the years since 1977 there was no evidence that FDA had changed its position that growth promotion uses of these drugs was unsafe thus FDA should be compelled to complete the withdrawal proceedings initiated by the 1977 notices. It was this request to proceed with the process – that is to hold the hearings to determine if these uses should be withdrawn – that the judge ordered. The court did not order a specific outcome to these hearings, but required FDA to re-issue a notice of opportunity for a hearing to the relevant drug sponsors who may present evidence to support that use of the drugs is safe. FDA has filed an appeal of this decision, and instead is citing the regulatory actions they are taking to address concerns with growth promotion uses of antibiotics.

## Regulatory challenges

While the legislative and legal challenges outlined above could potentially result in changes in antibiotic availability or uses, recent FDA regulatory actions will lead to real changes over the next 3-5 years. In April, 2012 FDA published three documents; Final Guidance for Industry (GFI) #209, Draft GFI #213 and a draft text of revisions to the Veterinary Feed Directive (VFD). While many in the lay press positioned these Guidances as "guidelines", guidance documents are treated as regulation by FDA and

lay out the framework of how the agency will conduct business.

Guidance for Industry #209 was first published as a draft Guidance in 2010 and signaled a major shift in thinking by FDA by laying out the following two principles:

Principle 1: *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.*

> In light of the risk that antimicrobial resistance poses to public health, FDA believes the use of medically important antimicrobial drugs in food-producing animals for production purposes (e.g., to promote growth or improve feed efficiency) represents an injudicious use of these important drugs. Production uses are not directed at any specifically identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products. In contrast, FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals.

Principle 2: *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.*

> Most of the feed-use antimicrobial drugs are currently approved for over-the-counter use in food-producing animals for purposes that include the treatment, control, and prevention of disease as well as for production purposes (i.e., for growth promotion uses such as increased rate of weight gain). In addition to instituting voluntary measures that would limit use of medically important antimicrobial drugs in food-producing animals to uses that are considered necessary to assure the animals' health, FDA also believes it is important to phase-in the voluntary practice of including veterinary oversight or consultation in the use of these drugs. As noted above, FDA believes that this practice is an important mechanism for helping to assure appropriate use.

While GFI #209 laid out the principles, GFI #213 addresses the implementation. Much of GFI #213 is focused on actions that animal health sponsor companies should take to "voluntarily" comply. This includes:

- surrendering growth promotion/improvement of nutritional efficiency claims
- migrating marketing status so that veterinary oversight of "medically important" antimicrobials can be demonstrated
- sharing their intentions on compliance and intention to seek additional label claims with the agency within 90 days of publication of Final GFI #213
- making all label changes within three years

Also spelled out in GFI #213 is the expectation that veterinary oversight would need to be demonstrated not only for antimicrobials administered in feed, but also those administered in water. Furthermore, FDA provided the companies information on the type of data and submissions that would be required to gain disease prevention or control claims for compounds or dosages previously used for growth promotion. While positioned as "voluntary" it was stated in the GFI that if sponsors did not comply actions would be initiated under the authority granted FDA by the Food, Drug and Cosmetic Act.

The third document published by FDA was draft text of codified language for Veterinary Feed Directive. The agency has determined that marketing status is how they intend to demonstrate veterinary oversight of antimicrobial use (for those antimicrobials used, or in classes used, in human medicine) in feed and water. Those antimicrobials, when administered in water will move to Rx marketing status and when administered in feed will move to VFD marketing status. FDA realized that the current VFD structure, if applied to most antimicrobials used in feed for all food animals and poultry, would be unwieldy and overly complex. In the draft text provided the agency made changes to simplify the process for both producers and veterinarians while adding collection of certain other data not currently required. Comments have been submitted for the draft text is open for comment, and it will be subsequently published as a proposed rule that would be open for further comment. The agency also stated their intention to work with USDA to conduct listening sessions to specifically understand how VFD might impact producers in remote areas and potential ways to address their circumstances.

## Marketplace challenges

Advocacy groups that want to restrict antimicrobial use in food animals are attempting to utilize tactics similar to those used by animal rights activists – that is challenging retailers and restaurants to demand changes in animal production practices utilized by their suppliers. In addition to the efforts outlined above by Representative Slaughter Consumers Union, the public policy and advocacy arm of Consumer Reports, recently launched a new marketplace campaign urging supermarkets to sell only meat raised without antibiotics. They also have asked USDA to clarify and tighten labeling standards for "antibiotic free" meat. It is uncertain if these campaigns will meet with the same reaction as the animal rights campaigns,

especially in light of the ongoing regulatory restrictions being enacted by FDA.

## Conclusion

Swine veterinarians and pork producers will likely see changes in uses and marketing status of certain antimicrobials administered in feed or water over the next few years. In addition to those changes expected due to regulatory actions, other challenges may impact antimicrobial use in pork production.