The Preservation of Antibiotics for Medical Treatment Act of 2005 (S. 742/H.R. 2562)

Summary

Mounting scientific evidence shows that the routine feeding of antibiotics to farm animals that are not sick promotes development of antibiotic-resistant bacteria that can be transferred to people, making it harder to treat bacterial infections in humans. Antibiotic feed additives are used to promote slightly faster growth and to compensate for crowded, stressful, and often unsanitary animal-husbandry conditions. The Union of Concerned Scientists estimates that 70% of the antibiotics used in the United States are used as feed additives for chicken, hogs, and beef cattle; such use occurs without a prescription.

The American Medical Association, the American Academy of Pediatrics, the American Public Health Association, the National Association of County and City Health Officials, and the National Campaign for Sustainable Agriculture are among the more than 350 health, consumer, environmental, sustainable agriculture, and other organizations that have called for an end to the routine use of medically important antibiotics as feed additives. The National Academy of Sciences estimates that a ban on nontherapeutic antibiotics would raise meat prices by less than $5 to $10 per person annually, and has called for "substantial efforts" to reduce agricultural overuse of antibiotics.

Although the Food and Drug Administration is theoretically empowered to withdraw agricultural antibiotics from the market under existing law, in practice its procedures are so cumbersome that such withdrawals could take years for each type of antibiotics. Indeed, withdrawal proceedings for other kinds of agricultural drugs have taken up to 20 years to complete.

To avoid these unacceptable delays, the bill amends the Federal Food Drug and Cosmetic Act to withdraw approvals for feed-additive use of seven specific classes of antibiotics: penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides. Each of these classes contains antibiotics also used in human medicine. The cancellations automatically take effect two years after the date of enactment unless, prior to that date, the antibiotic's producer demonstrates to a reasonable degree of certainty that use of the drug as a feed additive does not contribute to development of resistance affecting humans.

The bill is consistent with FDA's Guidance 152, which establishes safety criteria for using antibiotics in agriculture. Careful analysis of Guidance 152 indicates that use of these seven classes of antibiotics as feed additives does not comply with the Guidance's safety criteria. (In April 2005, leading medical and environmental groups filed a formal Citizen Petition with FDA, urging FDA to restrict feed-additive uses of the seven classes of antibiotics as being inconsistent with the Guidance's safety criteria. However, legislation is still necessary because of FDA's lengthy and cumbersome procedures for taking action on unsafe agricultural drugs.)

The bills would ban *only* the feed-additive uses of the named drugs for "nontherapeutic" purposes, defined as use "in the absence of clinical signs of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose." By specifically targeting the nontherapeutic use of antibiotics, the bill properly allows for sick animals to receive treatment and for legitimate prophylaxis. The bills leaves farmers with many options including other nontherapeutic antibiotics that are not used in human medicine, as well as improved animal husbandry practices such as those utilized in Europe and on some U.S. farms.

In addition, the legislation provides that if a nontherapeutic antibiotic that is now used only in animals (i.e., one that is not one of the seven named antibiotics) also becomes potentially important in human medicine, the drug would be automatically restricted from nontherapeutic use in agricultural animals unless FDA determines that such use does not contribute to development of resistance affecting humans. An antibiotic is defined as becoming potentially important in human medicine if FDA issues an Investigational New Drug determination or receives a New Drug Application for the compound.

To assist public health officials in tracking implementation of the phase out, the bill also requires producers of agricultural antibiotics to submit data on the quantity of drugs they sell, along with in formation on the claimed purpose and the dosage form of those drugs, beginning in 2005.

The Senate bill also authorizes funds to farmers to help defray costs of phasing out nontherapeutic use of medically important antibiotics, and provides for research and demonstration projects to assist farmers in this transition. 5.05