

For the Record

Straight talk about antibiotic use in food-animal production presented by ALPHARMA Inc., Animal Health

September 2005

FOOD CONSUMERS NEED A DOSE OF BALANCE WHEN CONSIDERING THE ISSUE OF RELATIVE RISK

Any rational grocer would think it crazy to remove grapes from inventory to prevent risk of slip and fall accidents, just as no restaurant owner would close down the bar to avoid risk of choking incidents. Why urge such frantic precaution regarding animal antibiotics?

Three activist groups and two medical associations did just that when they [petitioned the Food and Drug Administration](#) in early April to immediately halt most uses of antibiotics to improve productivity of livestock. The coalition claimed most of the antibiotics commonly used in animal feed were too risky to be allowed on the market any longer. Yet, it was no change in the drugs at issue that spurred their panic — many have been used safely for decades. Instead, the activists argued that the antibiotics should now be banned because FDA last year changed its policy to guide drug makers in how they should confirm that their products — current and future — pose no significant risks of contributing to the ineffectiveness of human drugs.

The [change in FDA policy](#) resulted after five years and three versions' worth of testimony, public comment and regulatory drafting, involving input from the animal-health industry and food activists. Not a regulation with force of law, the guidance is instead an explanation of FDA's "way of thinking" about how a drug's safety profile should include the issue of potential resistance in human-disease-causing bacteria. It explains a science-based process drug makers

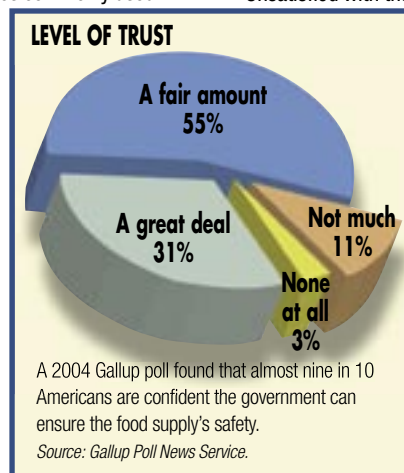
may use when they seek FDA's approval to market any new drug for food animals. The process is designed to help assure consumers that the drug's use in animals will not create a risk of untreatable diseases in humans.

Unsatisfied with the speed at which products were

being taken off the market after the guidance was finalized, the activist group [Environmental Defense](#) led April's petitioners in claiming seven classes of drugs in feed now no longer meet FDA's criteria for a safe drug.

Their deliberate attempt to confuse the complex issue of risk management — apparently in an attempt to build support for a [thrice-failed blanket Congressional ban](#) — illustrates the use and

misuse of what's come to be known as "the precautionary principle." It's a political device designed and now typically used by environmental protectionists to turn the blunt instrument of government against scientific outcomes that don't support their cause. This government by the frantic, of the frantic and for the frantic ignores the benefits of any practice like antibiotic feeding and focuses solely on chasing away unproven risks, no matter how absurd the result.



The law of unintended

costs: Risk-assessment expert [Tony Cox](#) has modeled the [expected human-health impacts](#) of ending the use of one antibiotic, virginiamycin, in animals. Continuing to use the drug as it's currently used, he predicts, is likely to cause 0.27 additional human cases annually of *Enterococcus faecium* infections resistant to streptogramins and vancomycin — two antibiotic classes commonly used to treat the infection.

In contrast, banning the drug's use in animals can be expected to cause an additional 6,660 annual cases of human food poisoning caused by *Campylobacter*, as the higher bacterial loads in the animals would increase the risk of contamination.

Source: Cox LA Jr. *Rapid Risk Rating Technique for risk-benefit assessments of antibiotics used in food animals.* Invited presentation, ASM General Meeting, New Orleans, La., May 2004.



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For the Record: Some straight talk about antibiotic use in food production

Antibiotics prevent animal disease and improve meat, milk and egg production. Protecting the ability to use these important, safe and proven tools remains absolutely necessary to meet the world's growing demand for affordable protein. ALPHARMA Inc., Animal Health sponsors this educational series to provide you facts to help set the record straight.

Questions or comments? Contact Steve Kopperud at skopperud@poldir.com