

## PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

# Does the use of subtherapeutic levels of penicillin in animal feed meet “responsible and judicious use” standards of the AVMA?

The American Veterinary Medical Association (AVMA) issued a press release in response to the order of Judge Theodore Katz of the US District Court, Southern District of New York, that ordered the FDA to “re-issue a notice of the proposed withdrawals” “of approval of all subtherapeutic uses of penicillin in animal feed...and, with limited exceptions, all subtherapeutic uses of oxytetracycline and chlortetracycline [the two forms of tetracycline under consideration] in animal feed” providing the relevant drug sponsors with the opportunity to request hearings (see <http://agpolicy.org/weekcol/609.html>).

In its press release ([http://www.avma.org/press/releases/120328\\_antibiotics-in-food-production-pf.asp](http://www.avma.org/press/releases/120328_antibiotics-in-food-production-pf.asp)) the AVMA “reaffirmed its support of the responsible use of antibiotics in food animals after a federal court ruling demanded that the U.S. Food and Drug Administration (FDA) start proceedings to withdraw approval of certain uses of antibiotics used in food production.”

“The AVMA acknowledges the growing concern regarding antimicrobial use and resistance in animals and people, and supports the judicious use of antimicrobials to maximize public and animal health benefits while minimizing risks,” said AVMA Chief Executive Officer Dr. Ron DeHaven. “The judicious use of antimicrobials plays a key role in preserving the health of our nation’s food animals and the safety of our nation’s food supply. Many agree that there is a need for greater veterinary oversight of antimicrobial use in food-producing animals, and the AVMA is currently working with the FDA [US Food and Drug Administration] to develop practical means to increase this veterinary oversight.”

“DeHaven cautioned, however, that any decision to withdraw approval or ban any antimicrobial uses should be based on solid science and risk-based assessment, and not on anecdotal reports and speculation.

“It is crucial that safe and effective antimicrobials remain available for use in veterinary medicine to ensure the health and welfare of animals and, consequently, the health of humans,” DeHaven said. “The AVMA will continue to work closely with the FDA to formulate a sound, science-based strategy to deal with this complex issue.”

While DeHaven can argue for continued work with the FDA and the use of a risk-based assessment, as a former high-ranking USDA APHIS (Animal and

Plant Health Inspection Service) official must know that Judge Katz is restricted to basing his ruling on the law.

To clarify that legal standard one first needs to understand the current FDA position on antibiotic use in food-producing animals.

In his ruling Katz wrote, “On June 28, 2010, the FDA released a non-binding Draft Guidance entitled *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (“2010 Draft Guidance”).... In the Draft Guidance, the FDA reviewed recent scientific studies on the risks posed by the subtherapeutic use of antibiotics in animal feed, including a 1997 World Health Organization expert committee report that ‘recommended that the use of antimicrobial drugs for growth promotion in animals be terminated if these drugs are also prescribed for use as anti-infective agents in human medicine or if they are known to induce cross-resistance to antimicrobials used for human medical therapy’.... After reviewing the scientific evidence, the FDA concluded that ‘the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health’.... The FDA announced two non-mandatory principles to guide the use of antibiotics in animal feed: (1) ‘[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health[;]’ and (2) ‘[t]he use of medically important antimicrobial drugs in food producing animals should be limited to those uses that include veterinary oversight or consultation’” (<http://nysd.uscourts.gov/cases/show.php?db=special&id=162>).

Close to the end of his order, Judge Katz reviews several legal issues including the following: “Upon a finding that the use of a drug under certain conditions has not been shown to be safe, §360b(e) (1) [the relevant legal citation governing FDA’s action] prescribes a clear course of conduct: issue notice and an opportunity for a hearing, and, if the drug sponsor does not demonstrate that the drug use is safe at the hearing, withdraw approval of such use. The statute does not empower the agency to choose a different course of action in lieu of withdrawal proceedings, such as that embodied in the [FDA] 2010 Draft Guidance. See *Pub. Citizen, Inc. v. Nat’l Highway Traffic*

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Safety Admin. . . . ([A]n agency ordered by Congress to promulgate binding regulatory requirements may not issue a nonbinding policy statement that encourages but does not compel action.) (citing Pub. Citizen v. Nuclear Regulatory Comm'n. . . .); Natural Res. Def. Council. Inc. v. Env'tl. Prot. Agency, . . . ("The agency charged with implementing the statute is not free to evade the unambiguous directions of the law merely for administrative convenience'.")

In the above quote, Judge Katz makes two points: 1) the FDA is not free to issue a "Draft Guidance" as a substitute or interim process in lieu of initiating the withdrawal proceedings and 2) the relevant statute

requires the drug company to show that a use is safe. In the absence of a showing of safety, the approval of the "subtherapeutic use of penicillin and tetracyclines" must be withdrawn.

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