

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

Judge rules against FDA a second time on subtherapeutic use of antibiotics

For a second time in less than 3 months, Judge Theodore H. Katz, United States Magistrate Judge, Southern District of New York, has ruled against the Food and Drug Administration in a lawsuit concerning the subtherapeutic use of antibiotics in animals. Both cases were brought by the Natural Resources Defense Council (NRDC) along with several other groups.

In the March 22, 2012 case which we examined on March 30, 2012 (<http://agpolicy.org/weekcol/609.html>), Judge Katz “determined that the...Food and Drug Administration (FDA, Agency) unlawfully withheld agency action by failing to implement withdrawal proceedings pursuant to the Food, Drug, and Cosmetic Act (FDCA)...for certain uses of penicillin, oxytetracycline, and chlortetracycline in food-producing animals.”

In that order the Judge wrote “specifically, the Commissioner of the FDA...must re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing. If, at the hearing, the drug sponsors fail to show that use of the drugs is safe, the Commissioner must issue a withdrawal order.”

The judge was clear that he was ordering the FDA to complete a regulatory process it began 35 years earlier, but was not ordering the FDA to come to any particular conclusion with regard to the withdrawal of authorization for certain uses of these antibiotics in food-producing animals.

In the June 1, 2012 memorandum opinion and order (<http://www.nylj.com/nylawyer/adgifs/decisions/060612katz.pdf>), Judge Katz writes, “the issue presently before the Court involves the FDA’s response to two Citizen Petitions, filed in 1999 and 2005, respectively. Both Petitions requested that the FDA begin withdrawal proceedings for all non-therapeutic uses of medically-important antibiotics food producing animals.” While the petitions were filed in 1999 and 2005, the FDA took until 2011 to deny the petitions choosing instead to pursue a strategy of voluntary compliance by the industry with Draft Guidance #209.

After spending 20-some pages showing that the court had jurisdiction over the case, Judge Katz said, “in the instant case, the Agency failed to address the Petitions on their merits. The Agency did not evaluate the science presented in the Petitions or assess the

safety of the relevant drugs.

“Although the Administrative Record for the 1999 and 2005 Citizen Petitions is more than three thousand pages in length and contains numerous scientific studies of the risks of antibiotic resistance from the use of antibiotics in food-producing animals, the Agency did not address or even mention the scientific evidence in its responses. Further, in its tentative responses to the Citizen Petitions, the Agency stated that” [f]or legal, scientific and resource reasons, withdrawal actions for the petitioned drugs need to be considered on a drug by drug basis.

“Data and information will need to be reviewed and analyzed for each drug. Thus the petitions can only be granted or denied on a drug by drug basis as reviews are completed and resources permit. II Rec. at 52, 124.) However, the Agency issued its final responses, denying the Petitions, without presenting any evidence—in the denial letters or in the Record—that these drug by drug analyses had been completed or ever undertaken.

“There is no evidence in the Record that the Agency performed any risk or safety assessments of the petitioned drugs at all. The Agency simply refused to evaluate the drugs’ safety on the grounds that if withdrawal proceedings were required they would ‘take many years’ and ‘impose significant resource demands.’

“Denying the Petitions on the grounds that it would be too time consuming and resource-intensive to evaluate each individual drug’s safety, and withdraw approval if a drug was not shown to be safe, is arbitrary and capricious. The Agency did not discuss or appear to consider the controlling statute’s governing criteria and overall purpose whether the drugs at issue pose a threat to human health and, if so, the obligation to withdraw approval for such health-threatening drugs....The fact that withdrawing approval may be costly or time-consuming is not a sufficient justification, under the FDCA, for the Agency to abdicate its duty to ensure that the use of animal drugs is safe and effective.”

Judge Katz goes on to note, “the FDA is refusing to follow the statutory mandate of withdrawal proceedings on the ground that such proceedings are not effective because they take too long. Yet, the Petitions at issue have been pending for thirteen and seven years, respectively. The position that instituting withdrawal proceedings—what the statute mandates—is

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too time consuming is both ironic and arbitrary. Had the Agency addressed the Petitions in a timely fashion, withdrawal proceedings could have been commenced and completed by now.”

On the matter of the safety of these antibiotics, Judge Katz writes, “the Agency has all but made a finding that the subtherapeutic use of antibiotics in food producing animals has not been shown to be safe. In the course of this litigation, the Agency has conceded that ‘the phenomenon of antimicrobial resistance exists, [that] antimicrobial resistance poses a threat to public health, [and that] the overuse of antimicrobial drugs in food-producing animals can contribute to the development of antimicrobial resistance’....The Agency has also stated that it ‘has reviewed the recommendations provided by...various published reports and, based on this review, believes 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’....

“Accordingly, the Court finds the Agency’s denial of the Petitions to be arbitrary and capricious.

“For over thirty years, the Agency has been confronted with evidence of the human health risks associated with the widespread subtherapeutic use of antibiotics in food-producing animals, and, despite a statutory mandate to ensure the safety of animal drugs, the Agency has done shockingly little to address these risks. Now, in responding to this litigation and two Petitions that have been pending for years, requesting that the Agency comply with its statutory mandate, the

Agency has refused to make any findings and instead intends to adopt a voluntary program that is outside the statutory regulatory scheme.

“The adoption of voluntary measures does not excuse the Agency from its duty to review the Citizen Petitions on their merits. The Agency must evaluate the safety risks of the petitioned drugs and either make a finding that the drugs are not shown to be safe or provide a reasoned explanation as to why the Agency is refusing to make such a finding....

“For the foregoing reasons, Plaintiffs’ [NRDC et. al] motion for summary judgment on their third claim for relief is granted and Defendants’ [FDA] motion for summary judgment is denied. The Court remands the matter to the Agency for further proceedings consistent with this Opinion.

“The Court emphasizes that it is not compelling the Agency to reach a certain conclusion. The Court simply finds that the Agency’s proffered grounds for denying the Petitions were arbitrary and capricious.”

Katz is once again ordering the FDA to determine whether the use of certain antibiotics in food-producing animals is safe and consistent with overall public health objectives with regard to the problem of the spread of antibiotic resistant bacteria.

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