

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

### FDA issues more “guidance” seemingly disregarding court antibiotic ruling

On April 11, 2012 the U.S. Food and Drug Administration (FDA) announced that it was “taking steps to protect public health.”

As the FDA explained, “Antimicrobial resistance occurs when bacteria or other microbes develop the ability to resist the effects of a drug. Once this occurs, a drug may no longer be as effective in treating various illnesses or infections. Because it is well established that all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, it is important to use these drugs only when medically necessary.”

What surprised us in this announcement was FDA’s statement that it was taking “three steps to protect public health and promote the judicious use of medically important antibiotics in food-producing animals.”

Unlike Sen. Sam Ervin who cannily described himself as an “old country lawyer” during the Senate Watergate Hearings, we are not even country lawyers. But as a couple of “old agricultural economists,” we were expecting that any FDA press release concerning antibiotics would either state that the FDA was complying with Judge Theodore Katz’s order “to complete mandatory withdrawal proceedings for the relevant penicillin and tetracycline [use authorizations]” or that the FDA was appealing the judge’s order.

This is where the not-a-country-lawyer thing comes into play. Perhaps someone will be able to explain to us why we are wrong in our understanding of Katz’s order. It seems to us that the FDA did just exactly what Katz told them would not comply with the requirements of the law.

As we wrote in a previous column, close to the end of his order, Judge Katz reviewed 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to choose a different course of action in lieu of withdrawal proceedings, such as that embodied in the [FDA] 2010 Draft Guidance.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 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’).”

It is that 2010 Draft Guidance (#209) on “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals” that the FDA issued in final form on April 13, 2012 <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>. And in their announcement, the FDA did not even give a nod to Judge Katz’s order or how their action on Guidance 209, let alone the newly issued Guidance #213 <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> fit into the court’s ruling. In addition the FDA published a “Veterinary Feed Directive; Draft Text for Proposed Regulation” in the Federal Register <http://www.gpo.gov/fdsys/pkg/FR-2012-04-13/pdf/2012-8844.pdf>.

While the Veterinary Feed Directive requires a veterinary prescription for the use of antimicrobials in food-animal feed, it references Draft Guidance number 209 and 213. Both of those documents contain the following, “FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word ‘should’ in Agency guidances means that something is suggested or recommended, but not required.”

Perhaps some explanation for the FDA action can be found in a New York Times article (<http://www.nytimes.com/2012/04/12/us/antibiotics-for-livestock-will-require-prescription-fda-says.html?hpw>) by Gardiner Harris where he writes, “The reason for the reliance on voluntary efforts is that the F.D.A.’s process for revoking approved drug uses is lengthy and cumbersome, officials said. The last time the F.D.A. banned an agricultural use of a medically important antibiotic against the wishes of its maker, legal appeals took five years. In this case, hundreds of drugs are involved, each with myriad approved uses in various animals.

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before F.D.A. could restrict all of these uses on its own,’ Ms. Rogers [of the Pew Campaign on Human Health and Industrial Farming] said.”

Still—and perhaps someone can explain how we have misinterpreted what Katz wrote—it appears to us that the voluntary efforts the FDA is depending upon do not comply with the Judge’s order.

We do not think this play has reached its final act; look for more action on the use of antibiotics in

food-animal feed in the coming weeks and months.

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