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Antibiotics Court Order Based On What Happened, And Didn't Happen, 35 Years Ago

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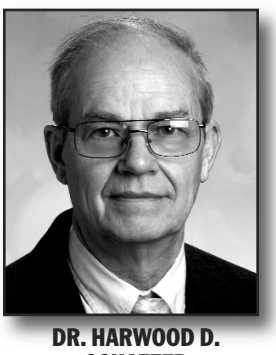

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On January 6, 2012, the Department of Health and Human Services, Food and Drug Administration (FDA) "published an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals," an action we wrote about in our January 20, 27, and February 3, 2012 columns. We do not know about others, but we certainly were not expecting any additional action on the use of antibiotics in food-producing animals in the near future.

But we were wrong; only this time the action was the result of a lawsuit and not an action by the FDA. Not only that, the action resulted not from a trial but rather a summary judgment by US Magistrate Judge, Theodore Katz of the United States District Court, Southern District of New York. As Judge Katz writes, in the case of *Natural Resources Defense Council, Inc., et al. (NRDC) v United States Food and Drug Administration, et al.* "the parties do not dispute the essential facts" (all quotes in this article are taken from the judge's Memorandum Opinion and Order filed March 22, 2012 and available at http://nysd.uscourts.gov/cases/show.php?db=special&id=162).

Both the NRDC and the FDA filed for a summary judgment and the court's decision turned primarily on matters of grammar and prior practice. Those interested in those issues are urged to consult the judge's order, pages 19-54. In this column, we focus our attention on the subject matter of the lawsuit and the action of the FDA required by the Court's decision.

As Judge Katz writes, "For over thirty years, the FDA has taken the position that the widespread use of certain antibiotics in livestock for purposes other than disease treatment poses a threat to health. In 1977, the FDA issued notices announcing its intent to withdraw approval of the use of certain antibiotics in livestock for the purposes of growth promotion and feed efficiency, which the agency had found had not been proven to be safe. The FDA issued the notices pursuant to [the appropriate statutes].... Although the notices were properly promulgated and over twenty drug sponsors requested hearings on the matter, the FDA never held hearings or took any further action on the proposed withdrawals.

"In the intervening years, the scientific evidence of the risks to human health from the widespread use of antibiotics in livestock has grown, and there is no evidence that the FDA has changed its position that such uses are not shown to be safe. In May 2011, after the FDA failed to respond to two Citizen Petitions urging the agency to follow through with the 1977 notices, Plaintiffs filed this action seeking a court order compelling the FDA to complete the withdrawal proceedings for antibiotics included in the 1977 notices."

After reviewing the history of the "use of antibiotics in food-producing animals, "Katz turns to the antibiotics that are the subject of the NRDC lawsuit: penicillin and two forms of tetracycline. In the 1950's the FDA properly authorized the use of these antibiotics in animals. "Since that time, penicillin has been used to promote growth in chickens turkeys and swine and tetracyclines have been used to promote growth in chickens, turkey, swine, cattle, and sheep.

"In the mid-1960s, the FDA became concerned that the long-term use of antibiotics, including penicillin and tetracyclines, in food-producing animals might pose threats to human and animal health. As a result in 1970, the agency convened a task force to study the risks associated with the use of antibiotics in animal feed."

"In 1972, the task force published its findings, concluding that: (1) the use of antibiotics in animal feed, especially at doses lower than those necessary to prevent or treat disease, favors the development of antibiotic-resistant bacteria; (2) animals receiving antibiotics in their feed may serve as a reservoir of antibiotic pathogens, which can produce human infections; (3) the prevalence of bacteria carrying transferrable resistant genes for multiple antibiotics had increased in animals, and the increase was related to the use of antibiotics; (4) antibiotic-resistant bacteria had been found on meat and meat products; and (5) the prevalence of antibiotic resistant bacteria in humans had increased.... The task force made several recommendations, including that (1) antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by the FDA, and (2) several specific drugs, including penicillin and tetracyclines, be reserved for therapeutic use unless they met safety criteria for non-therapeutic use....

"In response to the findings of the task force, the FDA (in this article we use "FDA" to designate the Food and Drug Administration or any of its units), in 1973, issued a regulation providing that the agency would propose to withdraw approval of all subtherapeutic uses of antibiotics in animal feed unless drug sponsors and other interested parties submitted data within the next two years "which resolve[d] conclusively the issues concerning [the drugs'] safety to man and animals...under specific criteria" established by the FDA."

The data the drug sponsors submitted to the FDA at that time did not, in the opinion of the FDA, establish that the use of these two antibiotics in feed is safe. As a result, the FDA "issued notices of an opportunity for hearing...on proposals to withdraw 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."

In response to these notices, "approximately twenty drug firms, agricultural organizations, and individuals requested hearings." After granting the request for the hearings, the FDA "Commissioner never set a date for the hearings on the [FDA's] proposal to withdraw approval of the use of penicillin and tetracyclines in animal feed." Though the FDA has continued research on antibiotic resistance as the result of the subtherapeutic use in animal feeds, it did not rescind the notices for the opportunity for hearing and has not concluded that their use is safe.

The NRDC case was filed to force the FDA, after 35 years, to proceed with the process of holding the hearings and unless the drug sponsors submitted data documenting the safety of the antibiotics in question withdrawing approval of the use of these antibiotics in animal feed.

It was this request to proceed with the process that Katz agreed to. "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 Court notes the limits of this decision. Although the Court is ordering the FDA to complete mandatory withdrawal proceedings for the relevant penicillin and tetracycline [use authorizations], the Court is not ordering a particular outcome as to the final issuance of a withdrawal order. If the drug sponsors demonstrate that the subtherapeutic use of penicillin and/or tetracyclines is safe, then the Commissioner cannot withdraw approval." Δ

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