

## Summary of Decision Upholding FDA's Proposal to Ban Use in Poultry of Baytril

On March 16, 2004, an Administrative Law Judge for the Food and Drug Administration (FDA) upheld FDA's proposal to ban use in poultry of Baytril, a fluoroquinolone antibiotic nearly identical to Cipro. In a strongly worded opinion, the Judge rejected Bayer Corporation's challenge to the proposal, moving the process one step closer to removing Baytril from the market (Bayer still has the opportunity to appeal to the FDA Commissioner). The proposed ban focuses on Baytril's impact in undercutting the effectiveness of fluoroquinolones in treating *Campylobacter*, the leading bacterial cause of severe food-borne illness in the U.S. The Judge concluded that "[p]oultry is a significant source of fluoroquinolone-resistant *Campylobacter* in humans" and that "[f]luoroquinolone-resistant strains of *Campylobacter* have a greater potential to adversely affect human health than do fluoroquinolone-susceptible strains of the bacterium." (Decision, p. 65.) Accordingly, the Judge concluded that **"Bayer has not shown Baytril use in poultry to be safe."** (Decision, p. 66, emphasis added.)

In ruling against Bayer, the Judge noted that Bayer's arguments were **"inconsistent."**

"Bayer presents [a particular] study to make a case that poultry are a source of *Campylobacter* and that the withdrawal of Baytril will lead to additional cases of diarrhea from *Campylobacter* derived from poultry sources. At the same time Bayer argues that chicken is not a source of *Campylobacter* and seeks to discredit the evidence that poultry is a major source of [*Campylobacter*-related disease]. **In any event, the evidence of record is insufficient to support a finding of any significant benefit to human health as a result of Baytril use in poultry.**" (Decision, p. 63, emphasis added.)

In addition, the Judge **rejected Bayer's arguments that withdrawal of Baytril would lead to more human illness, terming those arguments "not reliable."** (Decision, p. 62, emphasis added). The Judge noted that Bayer's argument rests on an analysis by a consultant, Dr. Louis Anthony Cox (also known as Tony Cox), and concluded that Cox's analysis used a **"combination of faulty microbial load distribution with an unsubstantiated dose-response relationship** to find a human health benefit for [Baytril]." (Decision, p. 62, emphasis added).

The Judge also sharply criticized Cox for mis-quoting the scientific literature:

**"This witness admits to altering quoted material from published articles.** He contends that editing quoted material is fair as long as it does not change the context and admitted that this is the way he quotes other sources throughout his testimony. He further indicates that his use of quotation marks does not necessarily mean that the quoted words can be attributed to another source, and goes so far as to attempt to justify the indiscriminate use of quotation marks in his sworn testimony by claiming it was merely to emphasize important concepts." (Decision, p. 14, emphasis added; references to transcript and exhibit page numbers omitted.)

The Judge went on to state:

**"There can be no justification for excerpting the substance of material from publications and presenting it in quotes** attributed to that publication. If a witness is merely referring to the substance of a portion of a published article relied on, the use of quotation marks is totally inaccurate and misleading. Under the circumstances, **this witness' credibility is severely compromised and his testimony cannot be relied on.**" (Decision, p. 15, emphasis added.)

The Judge also rejected arguments by Bayer's ally, the Animal Health Institute (AHI), that withdrawal of Bayer from the market would have a substantial economic impact. According to the Judge, "the exhibit AHI cites to as showing that the withdrawal would have such an influential effect, was stricken in its entirety from the record. It was stricken because it was **found to be altogether unreliable**, and not just on the issue of economic effects of Baytril's withdrawal." (Decision, p. 41, emphasis added.)

*The complete text of the March 16, 2004, decision is available at*  
<http://www.fda.gov/ohrms/dockets/dailys/04/mar04/031604/00n-1571-idf0001-vol389.pdf>.