



The University of Georgia

College of Agricultural and Environmental Sciences
Department of Poultry Science

July 19, 2004

Dr. Lester Crawford
Acting Director
Food and Drug Administration
5600 Fisher's Lane
Room 1471
Mailstop HF-1
Rockville, MD 20857

Dear Dr. Crawford:

I submitted testimony for the case between Bayer and the Food and Drug Administration regarding the use of enrofloxacin in poultry operations. In reviewing the ruling by the judge in the case, I was extremely disappointed in his evaluation of the information and the conclusions he reached after reviewing the testimony.

As a brief introduction, I am an Associate Professor at the University of Georgia in the Poultry Science Dept. I have extensive experience in poultry processing plant management prior to initiation of my position here at UGA. I have a large extension appointment and have worked with almost every major and minor poultry processor in Canada, the U.S., Mexico, and Central and South America. My area of expertise is poultry microbiology and I have been working in this area for 17 years.

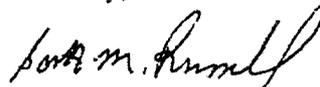
In my testimony, I presented evidence by reporting the results of a research study in which I asked the simple question "are flocks of chickens that have been untreated or unsuccessfully treated for airsacculitis significantly more contaminated with fecal material (resulting from torn intestines) and with *Campylobacter*"? The study was powerful in that it was replicated many times and microbiological samples were encoded and sent to a reference laboratory for evaluation. The results indicated that flocks of chickens that had untreated or unsuccessfully treated air sacculitis infections were significantly higher in fecal contamination and *Campylobacter*. To further support the study, I was able to obtain data collected by a very large local poultry processing plant, representing 32,000,000 birds over a two year period. This company collected data on air sacculitis, fecal contamination, and *Salmonella* prevalence. The data, which was analyzed by the Associate Department Head of Statistics at UGA, demonstrated a significant ($P = 0.0001$) relationship between air sacculitis and fecal contamination, and air sacculitis and *Salmonella* prevalence. All of this data was clearly presented in my testimony; however, the judge threw much of it out. His response was that this case was about *Campylobacter*, not *Salmonella*. As a scientist working in this area for many years, I strongly disagree with his assessment. Both of these pathogens are related to fecal contamination, which results from torn intestines. This case is about the mission of the Food and Drug Administration, which is to ensure the safety of the American food supply. The data contained within this testimony indicates that his ruling is in direct opposition to that which would be prudent in maintaining the safety of the U.S. food supply. I am absolutely convinced that withdrawal of enrofloxacin as a viable antibiotic for treatment of poultry would result in a concomitant increase in food-borne illness and would be ill advised. The study that was submitted by my colleagues as

testimony provides further evidence of this statement. Dr. Hofacre and others found that enrofloxacin was the only commonly used antibiotic that was effective for controlling air sacculitis. Again, in our study, flocks with high air sacculitis had significantly higher *Campylobacter* counts and *Salmonella* prevalence.

Moreover, testimony (stricken) was provided by the Vice President of McDonalds in which he stated that some poultry companies have discontinued using antibiotics and that there has been no adverse affect on the industry. This statement is not only false, but it is extremely misleading. The reason some poultry suppliers chose to discontinue use of antibiotics had nothing to do with food safety. It was a choice they made to maintain good relations with their major customers, such as McDonalds. McDonalds was putting pressure on these producers to discontinue using antibiotics. The reason McDonalds was putting pressure on poultry producers was because of pressure from special interest groups who have little or no understanding of the data that is constantly being produced by the scientific community. Thus, the fundamental reason for discontinued use was not scientific, but a response to a squeaking wheel. Special interest groups often have a narrow view of public safety. They want to impose their will based on unscientific beliefs which, in many cases, are in opposition to the public good. That is why the FDA is so important. It must be objective and evaluate the scientific data when making a decision in an unbiased manner. I believe it has not done so in this case. Additionally, the damage to the industry cannot be assessed immediately. It will take years for poultry companies to understand fully how these changes will impact them. For example, just after removing antibiotics from their feed, a major poultry producer (13 full-scale slaughter facilities) called me into 6 of their plants because they were having severe fecal contamination and the inspectors were writing excessive noncompliance reports. In fact, one plant was shut down while I was visiting. The intestines of these birds were visibly weaker than normal. In these instances, plant management will likely never make the connection between antibiotic withdrawal (which is a corporate decision and is only known to people who work with the growout operation) and weak intestines or fecal contamination. It is far too complex a process for these associations to be made by plant employees. Thus, the company never really has a clear picture of how antibiotic withdrawal affects their total process or food safety. I have had more calls this year to come and assist plants with excessive *Salmonella* prevalence than ever before. I am the only person in the U.S. who is doing this type of work. I believe that withdrawal of antibiotics may be contributing to this problem.

Finally, I am requesting that you bring together a panel of truly independent experts including scientists, poultry professionals, public health specialists, and attorneys to sincerely evaluate the scientific information in an objective way so that appropriate conclusions can be made. I appreciate your consideration in this matter and would be willing to provide any additional information that may be of assistance.

Sincerely,



Scott M. Russell, Ph.D.

Cc: FDA, Dockets Mgmt. Branch



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Scott M. Russell, Ph.D.
Associate Professor
The University of Georgia
Department of Poultry Science
Poultry Science Building
Athens, Georgia 30602-2772

Dear Dr. Russell:

Thank you for your letter of July 19 addressed to Dr. Crawford regarding the proposed withdrawal of the approval of enrofloxacin use in poultry. As described below, this matter is now pending before Dr. Crawford.

Under longstanding federal regulations governing the withdrawal of approval of a new animal drug, communications about this proposed withdrawal are not allowed between the Commissioner, officials advising the Office of the Commissioner, and persons outside the Food and Drug Administration (FDA). See Title 21 Code of Federal Regulations, Section 10.55(d)(1) (21 CFR 10.55(d)(1)). Therefore, Dr. Crawford is unable to respond to the specific issues regarding enrofloxacin that you raise in your letter. For your information, under these regulations, a copy of your correspondence and this response must be placed in the FDA docket and served on the participants. See 21 CFR 10.55(d)(3).

However, I am able to provide the following information on the regulatory process for FDA's formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. The FDA's formal hearings are conducted by an administrative law judge under regulations found at 21 CFR part 12. These regulations set out the procedures that FDA must follow when conducting formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of the New Animal Drug Application (NADA) 140-828, pursuant to Section 512(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act. That section requires that a new animal drug must be shown to be safe and effective for its intended uses. On October 31, 2000, CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register*. On November 29, 2000, Bayer filed a request for a hearing. The FDA Commissioner agreed and published a Notice of Hearing on February 20, 2002, in the *Federal Register*.

After submission of documentary evidence, written direct testimony, and joint stipulations by CVM, Bayer Corporation, the sponsor of the animal drug, and non-party participant Animal Health Institute (AHI), an oral hearing for cross-examination of witnesses was held between April 28 and May 7, 2003, with Administrative Law Judge Daniel J. Davidson presiding. The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the

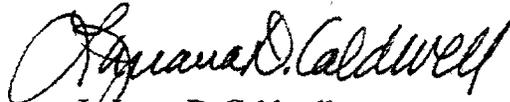
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administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

A public docket was established at the time the NOOH was published in October 2000. The record of the hearing, which includes the NOOH, referenced scientific studies, briefs, hearing transcripts, the initial decision of the administrative law judge, and subsequent filings by CVM, Bayer, and AHI, can be found in this public docket (Docket No. 2000N-1571).

I hope this information is helpful. Thank you for your interest in this issue.

Sincerely,



Lajuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)