Note: fluoroquinolone - a potent antibiotic - contains a fluorine molecule. This antibiotic depletes the body of these essential vitamins: B-1, B-2, B-3, B-6, B-12, Biotin, Inositol, and vitamin K. In addition, this antibiotic destroys the friendly gut bacteria acidophilus bifidum - the loss of which can lead to overgrowth of surviving antibiotic resistant bacteria pathogens, yeast and molds - leading to a condition known as dysbiosis which can mimic mild to severe flu like symptoms. - CW

Lawmakers' help for drug firm tests limits

FDA calls letter-writing efforts on behalf of Bayer illegal
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The Washington Post: http://www.washingtonpost.com/wp-srv/front.ht
Updated: 2:41 a.m. ET April 30, 2005

The German pharmaceutical giant Bayer suffered a serious setback last year when a federal administrative law judge backed a proposed ban on a drug used to fight poultry infections at factory farms. The judge cited growing scientific evidence suggesting that the practice was reducing the effectiveness of antibiotics vital to human health.

Facing defeat in a three-year legal battle, Bayer sought help in a new arena Congress. In a letter written in the office of Rep. Charles W. "Chip" Pickering Jr. (R-Miss.), and with the assistance of a Bayer lobbyist who was a longtime Pickering friend, 26 House members argued that the poultry medicine was "absolutely necessary to protecting the health of birds." It called on Lester M. Crawford, acting commissioner of the Food and Drug Administration, to set aside the judge's decision regarding the class of drugs. The Bayer product is known as Baytril.

Lobbying letter violates rules
The Baytril case provides an unusual look at an attempt by lawmakers to influence the executive branch's handling of an important public health issue involving parochial economic interests and complex science. In stepping in, the congressmen entered a murky area and overstepped legal limits on their involvement, FDA officials said. While members of Congress frequently write to agencies as part of regular oversight, they are not supposed to intervene in formal, trial-type proceedings.

Less than a month after the July 22, 2004, letter, the FDA informed the legislators in writing that their attempt to sway Crawford violated federal rules intended to shield him and other decision makers in similar quasi-judicial proceedings from outside pressure. They admonished the lawmakers that they were "not allowed" to communicate with Crawford because the lengthy public record of testimony and documentary evidence was closed.

Pickering, who is vice chairman of the House Energy and Commerce Committee, which has jurisdiction over the FDA, strongly defends the letter. A statement from his office said he "acted under legislative branch rules, representing his constituents and defending their interests." The

congressman, it added, "believes the medicine discussed in the letter is vital to maintaining the jobs and businesses in Mississippi based on poultry, and he stands by the content of the letter."

Closed record, open question
Crawford, now awaiting confirmation as FDA commissioner, is still considering Bayer's formal appeal of the judge's decision upholding the proposed ban. The FDA has declined to say whether he saw the congressmen's letter. Baytril is still being used in the poultry business.

Federal rules require communications from outside channels, such as the lawmakers' letter, to be made part of the public record of the case so that all sides are aware of them. But in this case the letter was not placed in the public docket until December, more than four months after it was sent, because of what the FDA said was an "inadvertent oversight."

"They are weighing in on the side of parochial economic interests against the public health, and that's disappointing," said Margaret Mellon, director of food and environment programs at the Union of Concerned Scientists.

Antibiotic resistance
The October 2000 decision by the FDA's Center for Veterinary Medicine to withdraw approval for Baytril was a milestone in the agency's attempts to protect human health. It was the FDA's first formal withdrawal notice for an animal drug based on concerns that it could make human drugs less effective. The decision set the stage for current regulatory steps that could lead to bans on other animal drugs, such as penicillin and tetracycline.

Baytril is a fluoroquinolone antibiotic, among the strongest class available to treat humans suffering from food poisoning and a broad range of bacterial infections, including anthrax. When the FDA's veterinary division approved Baytril in 1996, public health advocates warned that it could lead to an increase in bacteria impervious to Cipro, Bayer's highly successful fluoroquinolone for humans.

In withdrawing approval, the CVM cited a study that found rising levels of fluoroquinolone-resistant bacteria in supermarket chicken and in people who prepared and ate chicken. Cipro-resistant bacteria, all but unknown in the 1990s, soared to 13 percent of the bacteria sampled in 1997. Follow-ups showed resistance rising to 20 percent in 2002 before dropping slightly in 2003.

The FDA's findings and proposed action were supported by the Centers for Disease Control and Prevention, the American Medical Association, the Union of Concerned Scientists, and two agencies at the Department of Agriculture.

Backlash at Bayer
None of the research pointed to Baytril as the sole culprit. Public health

officials had long recognized that the overprescribing of antibiotics increased resistance to the drugs in humans. But the data persuaded the FDA's veterinary regulators to propose banning Baytril and SaraFlox, a similar product from Abbott Laboratories. Abbott agreed to withdraw its product.

But Bayer contended the FDA data were so flawed that there would be repercussions for the entire animal-drug industry if they went unchallenged. Forty to 70 percent of U.S. antibiotics are used in agriculture.

Robert Walker, spokesman for Bayer's Animal Health Division in Shawnee Mission, Kan., denies that Baytril is a significant contributor to the spread of resistant bacteria, saying there are "a lot of other factors at play." He added: "We don't feel there's anything from a scientific standpoint that supports taking it off the market."

Bayer has argued that although only 2 percent of chickens were treated with Baytril, the industry would lose millions of dollars a year if it were removed as an option. The company noted that the incidence of human infections resistant to Cipro-type medicines has declined sharply. The congressmen's letter said cases in which Cipro did not work dropped from 3.28 per 100,000 in 1997 to 2.62 per 100,000 in 2001.

Bayer's appeal triggered a review that over the next 38 months produced thousands of pages of documents and days of testimony before FDA Administrative Law Judge Daniel J. Davidson. To wage the legal battle, Bayer HealthCare, the subsidiary that oversees animal drug production, hired McDermott, Will and Emery of Chicago, the world's 14th-largest law firm.

The Animal Health Institute (AHI), the main trade group of animal-drug makers, quickly joined Bayer in contesting the ruling.

Broiler industry stays in background

Bayer and AHI got little public help from the huge, vertically integrated retail chicken producers that are the main users of Baytril. While the broiler industry, as it is known, views Baytril as "a valuable medication that ought to be available," said Richard Lobb, spokesman for the National Chicken Council, many big companies that sell chicken under their own labels to customers in supermarkets were unwilling to publicly embrace the use of antibiotics.

"It's not something we're up there banging away on" in Congress, Lobb said.

Bayer and AHI pursued other avenues. AHI filed petitions with the FDA and the CDC under a new business-friendly law, the Data Quality Act, seeking a "correction" of the information the agencies were putting out about Baytril. And in 2002, AHI hired former senator Robert W. Kasten Jr. (R-Wis.), paying him $75,000 a year to facilitate contacts with top officials at the Department of Health and Human Services on the Baytril matter. The department was the

FDA's parent and was then led by former governor Tommy G. Thompson, a longtime Kasten political ally.

AHI was "writing letters and not getting answers back," Kasten said. He said he arranged meetings with "legal people around the secretary" and may have mentioned the matter to Thompson. He also recalled at least one meeting with Crawford, then number two at the FDA.

Separately, Bayer HealthCare hired lobbyist Wayne Valis to work with administration officials on the validity of the government data on fluoroquinolones. Valis recalled setting up one or more meetings with officials at the White House office that oversees regulatory issues, as well as with officials from the FDA and several other agencies.

Cash and catfish

Bayer was unsuccessful in getting the corrections it sought from the FDA or the CDC, however, and in March 2004, Davidson strongly backed the veterinary division's proposed ban in a 68-page decision. He said the evidence "does not establish that the social and economic benefits [of this class of antibiotics] outweigh the risks to public health."

Davidson cited recent studies of bacteria in chicken showing increased levels of drug resistance. A 1999-2000 sampling of retail meat in the Washington area also mentioned in his ruling found that 35 percent of the suspect bacteria was resistant to Cipro-type drugs.

By then, Bayer had already begun looking for help in Congress.

Christopher Myrick, a lobbyist hired by Bayer in early 2004, had a long-standing connection to Pickering. They both grew up in Jones County, Miss., and their families knew each other well, attending church and school together, according to the congressman's office. When Pickering whose father was a federal judge and former state GOP chairman decided to run for a House seat in 1995, Myrick was one of his first contributors.

Myrick, a former Senate staff member, has been counsel to pharmaceutical giant Wyeth/American Home Products Corp., and has held leadership posts on trade associations, including AHI, according to his résumé.

In March 2004, he attended a small Pickering fundraiser for drug company representatives at the 116 Club, a Capitol Hill favorite of southern lawmakers that serves home-style catfish on request, along with chicken, dumplings and crab.

The event raised $11,000, Pickering spokesman Brian Perry said. Lobbyists for Merck, Pfizer, Abbott Laboratories and Hoffmann-LaRoche chipped in, campaign finance records show. Myrick contributed $1,000, and two partners in his lobbying firm, Larson, Dodd, Stewart & Myrick, donated to Pickering

then or later in the year.

Myrick did not return a phone call seeking comment.

'Go the extra mile'

Bayer representatives met with Pickering's congressional staff on June 17 and 23, according to his office. Perry identified the participants as Myrick and Julie Spagnoli, Bayer HealthCare's new chief Washington representative. Bayer, he said, "produced verbiage" for the letter and "brought in a lot of the material."

"We put together a kit to educate members of the media on the issue. It's most likely that is what she [Spagnoli] shared with them," said Walker, the spokesman for Bayer's Animal Health Division. "But I must stress generation of the letter was not due to Bayer writing it."

Pickering's office said a senior House Democrat, Rep. Bobby R. Etheridge (N.C.), and members of the House Agriculture Committee were given a chance to make changes. In all, 18 Republicans and eight Democrats signed. Among them were the House's third-ranking Republican, Whip Roy D. Blunt (Mo.); John A. Boehner (Ohio), second-ranking Republican on the Agriculture Committee; and Nathan Deal (R-Ga.), who recently became chairman of the Energy and Commerce Committee's health panel.

Blunt's office explained his stance by saying, "The poultry industry is a $1.77 billion industry in Missouri's 7th District, creating nearly 16,000 jobs for Congressman Blunt's constituents."

Ten of the 26 signers, including Pickering, Etheridge and Blunt, received campaign contributions from Bayer 's political fund in 2003 and 2004.

Rep. Sherrod Brown (Ohio), ranking Democrat on the Energy and Commerce Committee health panel, said he learned of it only when told about it in March.

The lawmakers, who did not mention either Bayer or Baytril by name, urged Crawford to "go the extra mile" to ensure FDA action on fluoroquinolones was based on valid science. But last Aug. 17, the FDA responded that the Code of Federal Regulations prohibited such contacts at that stage. The code, however, specifies no criminal penalties.

In defending the decision to send the letter while Crawford was reviewing the case, Pickering's office cited a 1970 advisory opinion of the House ethics committee saying a member may contact a federal agency to "call for reconsideration of an administrative response which he believes is not supported by established law, federal regulation or legislative intent."

Lawyers specializing in ethics issues say Congress's oversight duties give

members considerable leeway to contact officials, but there are limits during formal proceedings such as those the FDA is conducting. The House Ethics Manual states, "Since 1976, the Government in the Sunshine Act has prohibited anyone from making an *ex parte* communication to an administrative agency decision-maker concerning the merits of an issue that is subject to formal agency proceedings."

Such an intrusion amounts to "unfair and undue congressional interference in a judicial proceeding," said Stanley Brand, a former chief counsel of the House.

Donald Kennedy, a former FDA commissioner, said: "I never received any letters like that when I was in the position of making a quasi-judicial decision, and should not have. It is clearly improper."