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Regulators say they're under pressure to give all-clear to poultry antibiotic blamed in U.S. for surge in resistant germs

BY KRISTA FOSS

A controversial antibiotic, which may compound the growing problem of drug resistance in humans, is causing a flap behind the scenes at Health Canada's already beleaguered Bureau of Veterinary Drugs.

Shiv Chopra, a senior evaluation scientist with the bureau, claims he and his colleagues have spent years fighting departmental pressure to approve Baytril (enrofloxacin), an antibiotic of the fluoroquinolone class that is used in Europe and the United States to treat bacterial infections in poultry and cattle.

Fluoroquinolones are a popular and important class of antibiotics used to treat a broad range of infections in humans.

But now that chickens are treated with these same antibiotics in the United States, the germs they carry and sometimes pass on to humans — including campylobacter, a leading cause of food-borne illness — are becoming resistant to fluoroquinolones.

According to the U.S. National Antimicrobial Resistance Monitoring System, a national surveillance program operated by the Center for Veterinary Medicine, the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, campylobacter resistance

to fluoroquinolones did not increase until 1996 and 1997, just after the approval and use of those drugs in poultry.

South of the border, fluoroquinolone-resistant campylobacter infections in humans reached 13.6 per cent by 1998 and rose to 17.6 per cent in 1999. Without effective treatments, campylobacter infections can be deadly for the elderly and those with weakened immune systems.

In Canada, Bayer Inc., which manufactures Baytril, first sought approval for the drug here in 1995. The company says it has complied with all requests to clear up safety issues, yet according to Dr. Chopra, it has been held up by a departmental fight over its safety.

"All the scientific data was submitted in 1995 and we have met all the requirements requested of us in terms of that data," Bayer spokeswoman Karen Schwartz said.

As a result of the internal fight over Baytril and other drugs, seven of the bureau's scientists, including Dr. Chopra, are asking their union, the Professional Institute of the Public Service of Canada, to demand an investigation by the Senate into the way the bureau regulates drugs used to treat animals eaten as food and whether or not the department is hiring and

promoting unqualified people.

Dr. Chopra said the scientists feel that they have exhausted all other bureaucratic, legal and political channels to get those issues addressed.

"We have said to our union that there continues to be pressure on us to pass drugs of questionable safety," he said.

According to Dr. Chopra, a fellow drug evaluator was threatened with disciplinary action when he insisted that Bayer Inc. provide the bureau with more data on human safety.

Further, he said important files on Baytril disappeared from the bureau in 1999 and 2000. And Dr. Chopra said his managers met many times with Bayer about the drug, without being briefed by the scientists, like himself, who were doing the evaluation.

"It is a major example of departmental pressure being exerted on staff," said Dr. Chopra. "We are saying that there are two classes of drugs, hormones and antibiotics, [that] should not be in our food supply. . . . Now we're ready to take that concern to a higher level."

A Bureau of Veterinary Drugs spokeswoman dismissed the accusations out of hand.

"The dissension isn't related to how drugs are approved. Any dissension relates to the interpretation of data; it's not uncommon for there to be many different interpretations of data," Diane Kirkpatrick, an interim executive with the bureau, said.

Dr. Chopra said he asked to look

at the data that Bayer submitted to the U.S. Food and Drug Administration when it received approval of Baytril in 1998; his request was refused.

Dr. Chopra has butted heads with department officials before. A gag order was placed on him and another Health Canada scientist, Dr. Margaret Haydon, after they spoke out several years ago about departmental pressure to approve a bovine growth hormone the safety of which they questioned. The Federal Court of Canada last year upheld their right to speak.

Earlier this year, Dr. Haydon was suspended for 10 days for questioning the government's decision to ban imports of beef from Brazil.

The chicken antibiotic has already stirred up controversy south of the border.

Last October, the FDA proposed to ban the use of two leading fluoroquinolone antibiotics for poultry, including Baytril.

Abbott Laboratories willingly withdrew its product, but Bayer has challenged the proposed ban and continues to sell its antibiotics to farmers.

Baytril has been used in Canada: In 1988, it was approved as an antibiotic to wash turkey eggs, and it has been a standard antibiotic treatment for cats and dogs.

Mrs. Kirkpatrick of the veterinary drug bureau said last week that Bayer withdrew the drug as a turkey egg wash in Canada voluntarily in 1998. Bayer could not confirm whether the drug was still used at all on Canadian farms.