

COUNTRY CANADA (transcript)  
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# WHAT'S IN THE BEEF ?

**REG SHERREN:** Hi. I'm Reg Sherren. Welcome to a brand new season of Country Canada. We begin here in Ottawa where, among other things, it's the government's responsibility to ensure the safety of the food you eat. Yet some of the government's own scientists say that's not happening. They say serious health concerns are being ignored or dismissed. You're about to meet one of them.

**UNIDENTIFIED:** Ready, one, two, three!

**UNIDENTIFIED:** Let's go (inaudible)...

**SHIV CHOPRA:** Ah, don't go in the field.

**SHERREN:** Surrounded by his grandkids, this is when Dr. Shiv Chopra is happiest. He can forget about the day-to-day demands of his job. He can stop being a scientist and just play.

**CHOPRA:** Whoa! (Laughs)...

**UNIDENTIFIED:** (inaudible)...

**SHERREN:** But in those quiet times, his mind drifts. He remembers his work, his public responsibility to keep the food we eat safe for his grandchildren and for all of us, and he wonders why his job has become so difficult. They call you a trouble maker.

**CHOPRA:** Well, they call me a trouble maker, but many other people in Canada call me a hero.

**SHERREN:** What happened in this particular case?

**CHOPRA:** In this particular case, that drug should not have been approved.

**SHERREN:** There's been a big change in what we eat. Fifty years ago beef cattle were not routinely injected with antibiotics or growth hormone.

(SOUND OF CATTLE)

**SHERREN:** Now growth hormones implanted behind the ear can put an extra 40 kilograms on the average beef cow. That's roughly ten percent of its body weight. Drugs can fatten the cow for slaughter in less time. That's good business for the farmer. Today injections and implants are a regular part of the business of raising food. Any drug that may end up in our food must be safe... for the animal, and for us.

**CHOPRA:** Boneless is fine.

**UNIDENTIFIED:** How about drumsticks?

**CHOPRA:** Three should be fine.

**UNIDENTIFIED:** Three?

**SHERREN:** Dr. Shiv Chopra is one of the government scientists evaluating those veterinary drugs. He's a microbiologist with nearly 40 years' experience. His decisions are enormous. Public safety is on the line. So are billions of dollars in revenue for drug companies.

**CHOPRA:** It's the job of scientists like me to assess and make a recommendation whether the application complies with the law or not. It's simple.

**SHERREN:** You are essentially supposed to be the front line, if you will.

**CHOPRA:** I am the front line and the bottom line and the only line.

**SHERREN:** And he's got a problem. This is an antibiotic called tylocin. Some ranchers use it to help treat or prevent disease. Tylocin can also help animals grow faster using less food. It's been available in Canada for a number of years now. You don't even need a veterinary prescription to get it. So it seemed like a routine approval when the drug's manufacturer asked Health Canada to approve the use of tylocin in conjunction with growth hormones already available on the market. It turns out that approval was anything but routine.

**CHOPRA:** It came to my attention because of my particular expertise, designated duty in antimicrobial resistance. And I said there's a problem here. We need to look at it.

**SHERREN:** Since 1969 Chopra has been a government watch dog. And his passionate work ethic has brought him notoriety, including a Governor General's Award for a lifelong commitment to human rights. His passion has also led to battles, both public and private, with his bosses. Chopra has been reprimanded and suspended. He's been through court, testified at government hearings, all, he says, to protect the public.

**CHOPRA:** My science has never been questioned by anyone in the department.

**SHERREN:** In 1999 Chopra has questions about the tylocin hormone application. New research suggests tylocin may lead to bacteria resistance to human antibiotics. This resistance could cause untreatable, potentially fatal infections, especially in children. He wants more data from the drug makers, human safety data.

**CHOPRA:** In this particular case there was no data. The company said approve it, we've already had approval for some other uses and now we want to use this drug in combination with hormones which are implanted in animals to prevent abscesses.

**SHERREN:** Canada's food animal drug industry is approaching a half billion dollars a year in sales. Big business with big investments. A drug company will spend on average \$250 million and 15 years getting a new animal drug ready for the market. And there's no payback unless the government approves that drug for use.

**JEAN SKOTZNICKI:** We want timely reviews, we want consistent reviews...

**SHERREN:** Jean SKOTZNICKI is a lobbyist for the animal drug companies, the Executive Director of the Canadian Animal Health Institute. She says it takes a long time to get a new drug approved in Canada, twice as long as the United States or Britain. Delays mean lost revenue for the drug maker. Lost revenue is bad for business.

**SKOTZNICKI:** There are pressures on the system, yes. We're asking for a robust review process, timely reviews process with current guidelines. So I think if there's pressure that's the type of pressure you're seeing companies put... in our institute... put on government regulators.

**CHOPRA:** The pressure is not put directly by the companies on me or my colleagues. It comes indirectly by the pharmaceutical company lobbies on the Prime Minister, the Ministers, the... the Privy Council and whatever.

**SHERREN:** And that trickles down to your supervisor?

**CHOPRA:** And then that comes down to my level.

**DIANNE KIRKPATRICK:** Hi. I'm Dianne Kirkpatrick.

**SHERREN:** Dianne Kirkpatrick is Chopra's boss, the Director General of the Veterinary Drug Directorate. She says there's no pressure.

**KIRKPATRICK:** The only complaint that we receive from industry when making submissions is could we do them a little quicker. But it's, you know, a decision. Come up with a decision, do your reviews.

**SHERREN:** Is that not pressure?

**KIRKPATRICK:** No pressure at all. It's not...

**SHERREN:** So that doesn't trickle down in fact?

**KIRKPATRICK:** No. No, that certainly doesn't trickle down.

**SHERREN:** But Chopra tells a different story. In the late 1990s government scientists assess a hormone designed to increase milk production. RBSC has been used in the US for years, but Chopra doesn't believe sufficient safety data has been provided for the Canadian review. He refuses to sign off, even though years earlier the Chief of the Human Safety Division told the drug maker human safety requirements had been met. In the end, approval is stopped and Chopra exonerated, but it takes a Senate committee, a Labour Board hearing and a federal court case.

**CHOPRA:** I felt very good because I felt vindicated in Canada. I felt greatly honoured in Europe because, as a result of what happened in Canada, the European Union banned it, even though their commission gave sanction to approve it.

**SHERREN:** Two years later another drug in use in the US is under review here. Baytril is an antibiotic for chickens and cows. But Canadian scientists believe Baytril may cause antibiotic

resistant bacteria in food animals, which could pass to humans. The resulting infection may not be treatable because Baytril is much like a common human antibiotic. Chopra's assessments keep Baytril out of Canada's food supply. But the drug maker writes to the Health Minister and his Deputy Minister expressing 'extreme frustration with your department's handling of our submission.' The government denies pressure is put on its scientists, however Chopra's final report claims several incidents of harassment, coercion and slander from within the department against three specific drug evaluators connected to the Baytril assessment.

**CHOPRA:** If I'm told approve this drug because it's already approved by the US, I don't need to look at the data, that's where the buck stops, because if I do that then I will be lying.

**SHERREN:** Following the RBSC scandal Chopra and 200 Health Canada scientists write the Health Minister concerned about safety standards. After the Baytril review Chopra and five other scientists write their professional association regarding 'the many years of pressure and harassment that we have been facing to pass various products.'

**CHOPRA:** I am a confirmed whistle blower. Whistle blower is like the referee, simply saying, 'You're playing foul; don't. Stop.' Don't ask me to bend the law. I cannot bend the law.

**SHERREN:** Chopra had kept two potentially dangerous drugs out of the Canadian food supply. But he was about to battle his own bosses again, and lose. That story when we come back.

## TV COMMERCIAL BREAK

**REG SHERREN:** Welcome back to Country Canada. Back in the spring of 2002, scientists entrusted with keeping Canada's food supply safe are worried. An animal drug banned in several countries because of human health concerns is under new review here. The government places its most tenured evaluators on the case, but their recommendations are dismissed by senior managers.

**DIANNE KIRKPATRICK:** I think we made a... I know we made a good, solid decision.

**SHIV CHOPRA:** We don't know what... we don't know where to turn to now.

(SOUND OF CATTLE)

**SHERREN:** Drug maker Alanco wants government approval for a new cattle medication, an injectible pellet mixing an antibiotic with growth hormones. But government drug evaluator Dr. Shiv Chopra is worried about antimicrobial resistance. He's not the only one concerned.

**DR. GERARD LAMBERT:** It was a controversy (inaudible)...

**SHERREN:** Dr. Gerard Lambert, another experienced government scientist, 30 years with Health Canada. Lambert has European data showing one of the growth hormones to be mixed with tylocin may cause cancer and nourish tumours. It's already banned in Europe. Lambert wants specific human safety data from the drug maker, but his boss says not.

**LAMBERT:** We consider that there was no... it was not a finished (inaudible)... there was no data to support that.

**SHERREN:** Kirkpatrick, the head of the entire department, hears the same argument from Chopra: Don't approve without additional data. Essentially your supervisor's telling you she has a scientific difference of opinion.

**CHOPRA:** It's not a scientific difference of opinion because there is no data. If there were data and there's a scientific difference of opinion, then of course we can sit and discuss. You cannot discuss on something nothing. If there are no data, what can you discuss? That's precisely what we... why we asked for a meeting.

**SHERREN:** Instead the file is assigned to a pair of relative newcomers in the Health Department. On May 6th, 2002 they recommend to approve the implants saying, 'One can assume tylocin should not cause an increase in tylocin-resistant bacteria in the food animals.' The approval comes despite their own comment, 'No in-animal residue data were submitted, and therefore no definite conclusion could be made.'

**CHOPRA:** The law says data satisfactory to the Ministry shall be provided. And my colleagues said there are no data. And if there are no data, nobody can approve. Nobody should approve. And... and we... in fact we told the department, the Director General, you... this is wrongdoing. You don't have that authority.

**KIRKPATRICK:** I'm aware that there was a difference of opinion and...

**SHERREN:** So are they... are they wrong?

**KIRKPATRICK:** Well, in this case, what I would say is that their views were taken into account and, notwithstanding their views, the overwhelming evidence is that the product can be used safely if used in accordance with the label directions.

**SHERREN:** The tylocin hormone implants become the latest in a number of controversial animal drugs available in Canada. European inspectors came to Canada in the fall of 2000 to evaluate the control of drug residues in food animals. They found six growth hormones being used on livestock here which were banned in Europe because of links to cancer, among them revelor-H, approved by Health Canada in 1997, again against the advice of the government's own scientists. The European inspectors also found what they considered a lax government system of checking food animals for drug residues. Some suggest Europe banned growth hormones to keep out North American beef, but study after study suggests hormones pose a potential health risk. And a growing body of evidence links bacterial resistance in animals to resistance in humans. For that reason the World Health Organization asked all countries to ban tylocin as a growth promoter.

**LAMBERT:** And now we come out with an antibiotic and hormones and we combine it, and we don't (inaudible)... it's mind boggling. It's... I cannot... And we are... it's... it's not acceptable.

**SHERREN:** Is there any guiding policy on the approval of drugs with antimicrobial cross-resistance?

**KIRKPATRICK:** What we're doing is we've mounted a very substantive effort to look at the whole issue of antimicrobial resistance, and for example...

**SHERREN:** But is there an existing policy?

**KIRKPATRICK:** ...we... No, we don't have a... we don't have a policy that I can hand you and say here's the policy.

**SHERREN:** Why not?

**KIRKPATRICK:** We have guidelines. Because it's a very complex issue and what...

**SHERREN:** It's been around for a while, though.

**KIRKPATRICK:** It has.

**CHOPRA:** They call it risk management. In other words, to make profit let us take risk, and we will wait 20 or 30 years. If cancers occur, reproductive disorders occur, if people... too many people die from antimicrobial resistance, then we will think about it. Then we will manage it.

**SHERREN:** The tylocin implant approval produces a blizzard of memos and e-mails through Chopra's department. Several scientists are dismayed by what they see as a lack of evidence. Tensions increase when, the next day, Lambert is demoted as Acting Manager and replaced by one of the scientists who approved the implants.

**LAMBERT:** They... because I lack judgment.

**SHERREN:** (inaudible)...

**LAMBERT:** Yeah, that maybe I lack judgment for my career, but I don't lack judgment for health, for science.

**SHERREN:** And Kirkpatrick defends her position to her own staff in this confidential memo issued just days after the approval: 'This decision is also consistent with conclusions reached in other countries, for example, by the US Food and Drug Administration.' The manufacturer says tylocin hormone implants are widely used in the United States with no controversy. This fall Canadian cattle producers will also have the implants. They and the consumers who will soon eat the meat are unaware of the months of scientific hand-wringing that happened behind closed government doors.

**CHOPRA:** Either she's right or I'm right. And now the Minister or the Deputy Minister has to make a choice.

**SHERREN:** When there is a difference of scientific opinion within your... your department, who ultimately makes the decision?

**KIRKPATRICK:** Well, it depends. And it depends on...

**SHERREN:** In this case, who made the decision?

**KIRKPATRICK:** In the end, it was my decision as I have responsibility for issuing what is tantamount to the approval for a use of a veterinary drug.

**CHOPRA:** She got herself appointed as Director General. She has a BSc in physical chemistry. She's not a veterinarian, she's not a microbiologist, she's not a biologist. All of those things.

**SHERREN:** What degrees does Ms. Kirkpatrick hold? We don't know. The Health Department will not tell us. So you feel confident that you have the competency level to make these sort of scientific determinations?

**KIRKPATRICK:** I certainly wouldn't claim to be able to make them on my own. Again, that's why we have a very extensive breadth of competency...

**SHERREN:** Well, let me put it to you this way.

**KIRKPATRICK:** Let me answer.

**SHERREN:** You have two senior tenured scientists in your department that have serious health concerns about approving tylocin. Why not err on the side of caution?

**KIRKPATRICK:** If anything, as always, comes up that would bring new evidence to that position, we would consider it and we would make decisions accordingly thereafter.

(SOUND OF A HORN)

**UNIDENTIFIED:** Three cheers for West Carleton! Hip-hip...

**CHILDREN:** Hooray!

**UNIDENTIFIED:** Hip-hip...

**CHILDREN:** Hooray!

**UNIDENTIFIED:** Hip-hip...

**CHILDREN:** Hooray!

**SHERREN:** Chopra says there's now a growing list of drugs in Canada's food system that make him uneasy.

**CHOPRA:** Nothing is going to happen to you tomorrow, or maybe even a year's time. But over long term you may get cancer, there will be reproductive disorders in... in your children and grandchildren.

**SHERREN:** When you look at your grandchildren, what do you think about what you see going on?

**CHOPRA:** I feel even more helpless than ordinary Canadians do because I'm a knowledgeable person. I know what's involved. I cannot even take care effectively for the truth.

**SHERREN:** Health Minister Anne McLellan declined to be interviewed for this story. Instead she deferred to her senior managers, saying they could provide any of the information required on the running of her department. Don't go away. We'll be right back.