

Safe Milk

1998

In 1997, Health Canada quietly proposed to make major cuts to its Protection Branch (the agency that ensures the safety of our food and medicine), which would have put Canadians at risk. The Council learned of the plan and leaked it to the media - causing embarrassment for the government and reinstatement of funds by the Minister. But other threats have persisted. Throughout most of the 1990s - before taking on genetically engineered foods - the Council helped ensure our children's safety by running a successful campaign to prohibit the use of dangerous Bovine Growth Hormone (BGH) in dairy cattle.



Back off BGH: Keep Canadian Milk Safe

Dairy cows, farmers and milk consumers may soon find their lives disrupted by powerful transnational drug companies who want to push recombinant Bovine Growth Hormone (BGH) onto Canadians. BGH is a genetically-engineered drug injected into dairy cattle to increase milk yield.

Cows on BGH suffer from a higher incidence of udder infections, reproductive disorders, lameness, burn-out and premature death. And the intense use of antibiotics to deal with these side-effects raises the question of unsafe residues in milk and immune deficiency problems for humans. The risk intensifies as tariffs come down and milk spills into Canada from the U.S., where antibiotic testing is inadequate.

By-products found in BGH milk have also been linked to serious human health problems, including breast cancer.

The federal government, under intense pressure from citizens, farmers, and dairy processors has stalled off approving BGH. Concerned about a drop in dairy sales, the government called on Monsanto, the manufacturer of the drug, to submit further data on the dangers of BGH.

The government's call for more studies, instead of a complete moratorium and an independent examination of BGH's impact on human and animal health, was a way to avoid setting a precedent for broader evaluations of other genetically-engineered foods that could be pushed into Canadian kitchens soon. To keep BGH out of our food system permanently, concerned Canadians have to continue to pressure their MPs and the ministers of Health and Agriculture to strike a moratorium.

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Background

The giant chemical and biotechnology company Monsanto first asked Health Canada for approval to sell its version of recombinant Bovine Growth Hormone (BGH) over ten years ago. BGH is a genetically engineered hormone that boosts milk production in dairy cattle. It is not yet approved for use in Canada, and there has been widespread opposition among Canadians who do not want this drug to enter our milk supply.

Since the Monsanto application was filed ten years ago, Health Canada scientists within the Human Safety Division of the Bureau of Veterinary Drugs have been reviewing the application, and are still not convinced that its safety is proven.

Earlier this year, Health Canada established two external panels to provide "independent advice" on BGH. The panels are looking at the possible human health effects of BGH use and at the animal safety and efficacy, respectively. The reports of these two panels are to be released very soon.

Health Canada says that these panels are supposed to help instill public confidence in the safety of the milk supply. They are also to provide independent advice in cases when there is lack of consensus among the Department scientists and when there is substantial controversy in the international scientific community about the safety and efficacy of a veterinary drug.

Health Canada's policy guide explicitly states that, when using external panels, all committee members must comply with the department's conflict of interest policy in order to "ensure the integrity, objectivity and impartiality of Health Canada's decision-making process and to contribute to public confidence.". The policy states that it is not sufficient to merely avoid actual conflicts, but "also avoid any situation which might cause the public to doubt the objectivity of government action." The guidelines for members of Health Canada advisory committees further states that "a decision maker must not have material interest in the result" and that one "*not create a reasonable apprehension or suspicion of bias* that could be attributable to the decision maker" (emphasis added). This policy applies both to the panels as a whole, and to the individual members.

In the case of BGH a review of the records reveals numerous violations of this policy in regard to the two external panels. These include a number of contradictions in the process, potential conflicts of interest, and bias or reasonable perception of bias.

Are the external panels impartial, objective and credible?

There is a major question around the panel on animal safety and efficacy. This seven-member panel is under the aegis of the Canadian Veterinary Medical Association. The CVMA can hardly be said to be impartial on the issue of BGH.

In 1994, the CVMA issued a public statement stating that "The CVMA is of the view that the use of BGH in cows to increase milk production poses no threat to human safety." The statement goes on to acknowledge that intensified dairy management may be required to minimize disease and asserts that veterinarians will be able to provide services to dairy farmers to maintain dairy herd health. A media report also documents the CVMA's support for the use of BGH and its claim that there is no threat to human safety.

Dr. Ian Dohoo, chairperson of the panel on animal safety and efficacy, was questioned about this 1994 CVMA public statement on BGH before the Senate Committee on Agriculture and Forestry in October, 1998. Dr. Dohoo claimed that the CVMA public statement "did not represent the official position of the CVMA" and that it was "inadvertently included as a position statement" back in 1994. Yet the CVMA web site continued to include reference to the position statement on BGH until it was removed from their home page shortly after the Oct. 29 hearings.

How independent, objective and impartial are the individual members of the panels?

Animal Safety Panel

The Canadian Animal Health Institute (CAHI) is a trade association which represents companies that develop and manufacture pharmaceuticals, feed additives and animal pesticides. The CAHI also has a history of supporting the use of BGH. They testified at the 1994 Commons Committee hearings on BGH, concurring with proponents of the product. Monsanto is a member of CAHI.

Dr. Dohoo, is listed as an Associate Member with the Canadian Animal Health Institute (CAHI) in their annual directory for 1997. Dr. Dohoo has not listed this associate membership status on his résumé as provided to the Council of Canadians and has stated to The Council of Canadians researcher, when contacted, that he has never been a member of the CAHI. It is not known whether Dr. Dohoo has disclosed his affiliation with CAHI to Health Canada, as required under conflict of interest guidelines.

Professor Ken Leslie, is another member of the panel on animal safety. He is a professor at University of Guelph with specific interest in dairy cattle, and is involved in numerous research projects. Some of his research is funded by the pharmaceutical company Elanco, which was one of the companies who initially sought a license to market BGH products in Canada. Monsanto and Elanco have come to a profit sharing agreement on the sale of BGH related products. Professor Leslie commented on the relationships between many members of this panel and industry, saying "I doubt you will find people with this kind of expertise without ties to industry".

Dr. Patricia Dowling, a veterinarian and another member of the animal safety panel, delivered a CBC Radio "Commentary" on Nov. 9th 1998, on the use of antibiotics in livestock. When BGH is used in dairy cattle, antibiotic use is increased, posing one of the controversial aspects of BGH use. Thus antibiotic use in livestock is critically linked to the issue of BGH approval.

In her commentary, Dr. Dowling failed to make the distinction between widespread "prophylactic" use of antibiotics in animal feed and occasional therapeutic use of antibiotics to cure a sick animal. As a veterinarian, she surely understands the distinction, but in her commentary she used statements based on a confusion of the two scenarios to argue against a proposed ban on the widespread use of antibiotics in animal feed. She closed with a message that individuals must take responsibility for their own health - a message that, in this context, tends to excuse Health Canada and industry from their rightful responsibilities.

Dr. Dowling went out of her way to comment publicly on a controversial subject closely related to the approval of BGH. Health Canada's policy states that a conflict of interest is created when committee members make public statements "which could be perceived as impairing their ability to address an issue in an impartial and objective manner."

(Ironically, Health Canada has been on record curbing the rights of their own scientists to speak publicly on these matters, as they did with Shiv Chopra earlier this summer when he was invited to speak on the topic of genetically engineered foods.)

Presenting these ties and statements made by the CVMA and the members of the panel on animal safety and efficacy is not intended to impugn their professional reputations or their

commitment to public service. Our intent is to point out that there is a reasonable apprehension or suspicion of bias inherent in the proceedings.

Panel on Human Safety

The Chair of the five-person panel on human safety, Dr. Stuart MacLeod, admitted that he and most of his panel members have worked for most of the major pharmaceutical companies over the years - a view confirmed by panel member Dr. Gerald Marks.

Under questioning, Dr. Macleod revealed to the Senate Committee on Oct. 29th 1998 that his wife had worked for 15 years for Searle Canada, a wholly-owned and operated division of Monsanto.

Dr. MacLeod is also Vice President of Clinical Affairs with a company called Innovus - a business that assists pharmaceutical companies in getting their products to market - including obtaining Health Canada approval. Innovus boasts they have "comprehensive internal resources with our network of prominent investigators, academics and strategic alliances..." Innovus would not reveal to The Council of Canadians the identities of their clients.

Dr. Rejeanne Gougeon is a nutritionist on the human safety panel whose résumé lists her work as a consultant for Monsanto on BGH and food biotechnology since 1993 to the present. She has also conducted research work funded by CAHI, on BGH and its impact on the wholesomeness of milk. Her published summary in The Journal of the Canadian Dietetic Association repeats her support for BGH. She has also made her opinions on BGH and related issues known through various media interviews.

Again, we emphasize that these examples run counter to Health Canada's management policy on conflict of interest for external panel members and they collectively leave a reasonable perception of bias inherent in the proceedings. These statements are not intended to reflect negatively on the professional reputations of the individual panel members, but rather to express concern for the process that they are in.

Why do the panels exist at all?

Health Canada states that the use of external panels is justified when departmental scientists do not reach consensus on an issue. This "lack of consensus" rationale is documented in Health Canada's terms of reference for BGH panels, in documents obtained under Access to Information and it is reiterated in a leaked memo from the Prime Minister's office, dated September 21st 1998. This memo states that the Bureau of Veterinary Drugs committee preparing the so-called Gaps Analysis report could not reach a consensus.

Yet the scientists *did* reach a consensus - as documented in the original version of the Gaps report, signed by all four scientists assigned to the file. They agreed that the files showed that "the manufacturer of this product did not subject it to *any* of the normally required long-term toxicology experimentation or tests for human safety " (emphasis added). After pressure was exerted by Health Canada Management, two members agreed to make some changes - thus producing a "second" report, signed only by two of them.

At the Sept 22nd 1998 Senate hearings, this matter was discussed and it was made clear by Dr. Thea Muller, one of the scientists, that the "two" reports not only complemented each other but were identical in the fundamental scientific respects. There was no lack of consensus.

It had been a long-standing idea within management at Health Canada to refer this matter to external panels - pre-dating the lack of consensus. Access to Information documents obtained by Ottawa researcher Ken Rubin, on behalf of the Council of Canadians, indicate that Health

Canada officials were preparing to defend the rationale for external panels as early as December 1997 - long before the report referred to by the PMO was under preparation.

Conclusions

The external panel review process for BGH has been fundamentally flawed.

The external panels have been established based on a false premise. The Health Canada scientists reviewing this drug agreed unanimously in April of this year that the safety of BGH had not been proven. Yet that unanimous report was not accepted by management at Health Canada.

The work of the scientists has taken place amidst allegations that Monsanto tried to bribe Health Canada into approval of BGH, a mysterious incidence of stolen files and even stranger follow-up on the theft, and what the scientists describe as "an atmosphere of coercion and harassment." The scientists were not even allowed free access to the files on this case in the normal course of their duties and were forbidden to speak publicly on this, or related, matters.

Operating in a relatively small and specialized field, it is extremely difficult to find expertise that is not in some way connected with the industry in question. In this case, the panels are clearly not free of the perception of bias. One panel operates under the aegis of an organization whose support for BGH is a matter of public record. Both panels have members who have worked with related industry. One member has directly worked for the drug company in question (Monsanto), one receives funding from a company with a profit-sharing agreement, one member has a spouse who worked for 15 years for a company that is a subsidiary of Monsanto. Panel members have spoken in favour of BGH, or on closely related subjects.

The panels also have an extremely limited time-frame and are commenting on limited information and data reviews. At the end of October the human safety panel had received only seven of forty volumes of research which Health Canada has in its possession. That committee is expected to report next month.

The health and safety of all Canadians, and the quality of our food safety system, is too important to risk to part-time study from individuals who may have a conflict of interest. Health Canada must have the capacity to provide research independent of industry, and the public must have confidence that the scientific research will reach decision makers, unfiltered by vested interests. Only the rigorous research of independent scientists will create this public confidence.