

**MINISTERIAL STATEMENT
ACTION PLAN TO ENSURE SAFE CARE AT B.C. TISSUE BANKS**

Check against delivery

VICTORIA – Mr. Speaker, I rise to make a ministerial statement on the investigation into the operation of the B.C. Ear Bank.

A news conference was launched in Vancouver a short time ago to provide details around a Health Canada investigation into the operation of the B.C. Ear Bank at St. Paul's Hospital in Vancouver. The review, which is still ongoing, has uncovered health and safety concerns that our government takes very seriously.

To some degree, these concerns boil down to poor record-keeping and a lack of clear documentation to show that appropriate screening of tissue donors and sterilization of tissue took place.

While we have been advised by experts at Health Canada and our provincial health officer that the risk to patients potentially impacted by this situation is extremely low, the damage to the credibility of all of those responsible for safeguarding our public health-care system over the past two decades is real. In fact, it is clear to both myself, my health-care colleagues and to the Premier that these issues undermine the public's faith in the operation, management and regulation of tissue banks not only in B.C., but across the country.

This is not acceptable to me, to the Premier or to our government as a whole. And I know it is not acceptable to the people of British Columbia.

I want to make it clear today that we will take every action necessary to ensure British Columbians have full confidence in the ability of our public health system to deliver safe, high-quality care and that their health and safety will be protected now and in the future. But before I explain the elements of our action plan, I'd like to clarify some of the history around the B.C. Ear Bank and the chain of events that led us here today.

The B.C. Ear Bank has been in existence since 1974, first operating out of Vancouver General Hospital before moving into the former Shaughnessy Hospital in Vancouver. Responsibility for the bank was transferred to St. Paul's in 1993, and it relocated to the actual hospital site in 1995. It served as a combination teaching lab and transplant tissue bank under the medical direction of the University of B.C.

The B.C. Ear Bank collected, processed, sterilized and stored bone and tissue. The bank then sent these materials to hospitals across the country who requested them for both teaching purposes and for use in transplant operations on patients suffering from hearing loss.

I understand that in September of 2002, administrators at Providence Health Care first became aware of concerns around quality control and standards of practice at the bank and began to gather the facts. By the first week of October, Providence had launched a more formal internal investigation and advised Health Canada of its concerns. Health Canada subsequently launched its own review.

At that time Providence suspended the B.C. Ear Bank's operations, and no tissue or bones have been collected or shipped since that time. But I'm advised there is evidence of concerns relayed between clinicians associated with the bank as far back as the early 1990s, and again in 1998. I have also been made aware that broader concerns around the operation and regulation of tissue banks in this country are long-standing within the medical community. In fact, in recent days I have been advised by health experts that for years they have lobbied the federal government for a stronger regulatory framework in Canada and clear standards to ensure patient safety is protected.

As far back as the release of the Krever inquiry report in 1997, Health Canada began looking at the risk of disease transmission from tissue transplants, and while the debate around standards has dragged on, the potential risk to British Columbians and patients across the country has remained.

On Feb. 7, Health Canada approached the provincial health officer, Dr. Perry Kendall, with preliminary results of its investigation, and Dr. Kendall launched a formal assessment to determine the level of risk to patients arising from Health Canada's concerns. Dr. Kendall immediately informed the deputy minister, who contacted me. Since that time we have been working closely with Health Canada to assist and advise in the planning of the notification and recall strategy that has been announced today.

Once the risk assessment was complete, the Premier was given a verbal telephone briefing about the issue on Feb. 14, and both he and I were clear with our officials of the need for immediate action to ensure full co-operation with Health Canada's investigation, and appropriate notification of both patients and providers. The Premier also directed me to initiate a plan of action over the weekend to ensure the situation was fully investigated, with paramount concern at all times for public health and safety. The Premier was clear that this information must be released this week – in a manner that was responsible and mindful of patients' needs.

On Monday, I met with the Premier, Dr. Kendall and ministry staff to discuss the situation. It was agreed Dr. Kendall would develop a course of action, which I am sharing with you today.

Dr. Kendall's action plan includes the following steps.

- One, that we call on Health Canada to launch a comprehensive review to ensure a clear and accountable regulatory and accreditation framework for tissue banks across the country.
- Two, that we direct the B.C. Transplant Society, through the Provincial Health Services Authority, to prepare a plan to assume responsibility for quality control and regulatory compliance for all tissue banks operating in B.C.
- Three, that we request the B.C. College of Physicians and Surgeons to review the practice of doctors involved with the B.C. Ear Bank and develop professional guidelines for tissue bank physicians.

- Four, that we appoint an independent expert team to review the circumstances leading to this investigation and assess the activities of other tissue banks in the province. The team would be expected to make public recommendations to government and the B.C. Transplant Society to ensure the issues identified by Health Canada never occur again.
- Finally, Dr. Kendall recommends the expert team also review the role of the University of British Columbia in overseeing clinical research relating to tissue transplants and ensure appropriate transition plans are in place when research programs are transferred into clinical practice.

Our government accepts these recommendations fully and will take action on each and every one. At the request of the Premier, I am also writing to the federal Health Minister to ensure an independent, comprehensive investigation is undertaken on this entire matter and to encourage the swift implementation of any other measures they deem necessary, to expedite this process and ensure the health of patients is protected. Clearly it is a matter of national importance, and it is appropriate in this circumstance that the federal government, through Health Canada, take a leadership role on these matters while our own action plan is being implemented.

I want to make it perfectly clear that all of these actions do not preclude any other measure we believe may be necessary in the coming days and weeks to restore the public's confidence in our public health system. The health and safety of patients is paramount, and we will continue to work closely with Health Canada, our health authorities and our stakeholders to ensure the highest standards of patient care are in place and clear lines of accountability are drawn.

As this process continues, Providence Health Care has asked 87 hospitals across Canada and in two U.S. cities to return tissue and bone distributed by the B.C. Ear Bank. Physicians at these hospitals who used the materials are being asked to inform their patients about these problems and provide whatever clinical followup they deem medically necessary.

Let me repeat – the risk of transmission to patients who received these products is extremely low, and there have been no reports to date of disease transmission attributed to any patient who received tissues processed or distributed by the B.C. Ear Bank.

In fact, Dr. Kendall has advised the actual risk of disease transmission attached to the close to 6,000 tissue samples identified in this investigation is about one in 100,000 – and even though documents don't exist in every case, there is clear information that sterilization of tissues did take place.

While we are fortunate the risk to patients is extremely small, we cannot afford to be complacent. I can assure you today – this government must and will take action.

For more information, visit www.providencehealthcare.com online.

1 backgrounder(s) attached.

Visit the province's Web site at <http://www.gov.bc.ca/> for online information and services.

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