



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

### **Ministry of Health Services Action Plan**

- Based on the recommendation of the provincial health officer, the Ministry of Health Services will take the following action regarding the B.C. Ear Bank:
  - Call on Health Canada to launch a comprehensive review to ensure a clear and accountable regulatory and accreditation framework for tissue banks.
  - Direct the B.C. Transplant Society, through the Provincial Health Services Authority, to prepare a plan for assuming responsibility for quality control and regulatory compliance for all tissue banks operating in B.C.
  - Direct the B.C. College of Physicians and Surgeons to review the practice of physicians involved with the B.C. Ear Bank and create professional guidelines for tissue bank physicians.
  - Appoint an expert team to review the circumstances leading to the B.C. Ear Bank investigation and assess the activities of other tissue banks in the province and make recommendations to government and the B.C. Transplant Society to ensure the issues identified by Health Canada never occur again.
  - Request the expert team review the University of British Columbia's role in overseeing clinical research relating to tissue transplants in B.C. and ensure appropriate transition plans and records are in place when research programs are transferred into the clinical practice of B.C. hospitals.
- The Minister of Health Services also will write the federal Minister of Health to ensure an independent, comprehensive investigation is undertaken on the entire matter and to encourage swift implementation of any other measures deemed necessary by Health Canada to expedite this process and ensure the health of patients is protected.

### **Health Canada Investigation**

- Health Canada is currently investigating the B.C. Ear Bank at St. Paul's Hospital after receiving information that tissues for transplantation may have been processed and distributed by the tissue bank in an unsafe manner.
- Health Canada has asked the hospital to mitigate potential risks by recalling tissue products and notifying physicians who have used tissues from the B.C. Ear Bank in transplantation. St. Paul's has complied with this request.

- Health Canada's risk assessment of potential disease transmission to recipients concluded the risk is low. The risk of contracting HIV, Hepatitis C and Hepatitis B from tissue distributed by the B.C. Ear Bank was assessed at 1/100,000.
- There has been no information to indicate any disease transmission from tissues processed and distributed by the B.C. Ear Bank.

### **Legislation Governing Tissue Banks**

- Health Canada has a clear mandate to regulate tissue banks under the Food and Drugs Act.
- There is no accrediting organization in Canada for tissue banks. Some Canadian tissue banks have sought accreditation voluntarily from the American Association of Tissue Banks, which accredits such facilities in the United States.
- Health Canada is developing standards for tissue banks and blood banks under the Canadian Standards Association. In January 2003, Health Canada issued a guidance document on "Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation."
- Health Canada held a national consensus conference on the safety of organs and tissues for transplantation in October 1995 to reach agreement on ways to reduce the potential risk of disease transmission through organ and tissue transplants.

### **Provincial Role**

- The Ministry of Health Services funds Providence Health Care, under which St. Paul's operates the B.C. Ear Bank, through the Vancouver Coastal Health Authority. The ministry does not have a mandate to regulate or license facilities such as tissue banks, which fall under the jurisdiction of Health Canada through the Food and Drugs Act.
- This government is taking steps to ensure the role of the ministry is one of stewardship and ensuring accountability from all its service providers. The performance contracts entered into by the province with all regional health authorities emphasize accountability and performance monitoring.

For more information, visit [www.providencehealthcare.com](http://www.providencehealthcare.com) online.

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