



No. L050414  
Vancouver Registry

**IN THE SUPREME COURT OF BRITISH COLUMBIA**

BETWEEN:

MARGARET BIRRELL

Plaintiff

AND:

PROVIDENCE HEALTH CARE SOCIETY dba PROVIDENCE HEALTH CARE and dba ST. PAUL'S HOSPITAL and dba THE B.C. EAR BANK, and VANCOUVER COASTAL HEALTH AUTHORITY dba VANCOUVER GENERAL HOSPITAL and dba VANCOUVER HOSPITAL and dba THE B.C. EAR BANK, and THE UNIVERSITY OF BRITISH COLUMBIA dba THE B.C. EAR BANK, and JOHN DOE.

Defendants

Brought under the *Class Proceedings Act*

**STATEMENT OF CLAIM**

**The Parties**

1. The Plaintiff, Margaret Birrell, resides at 608 – 1445 Marpole Street, Vancouver, British Columbia. The Plaintiff received an ear tissue transplant with tissue and bone supplied by the British Columbia Ear Bank (the "B.C. Ear Bank"). She brings this claim on her own behalf and on behalf of all other persons who received transplants with tissue and/or bone supplied by the B.C. Ear Bank.
2. The Defendant, Providence Health Care Society is incorporated under the laws of British Columbia and has a registered office at St. Paul's Hospital, Room 582 Burrard Building, 1081 Burrard St., Vancouver, British Columbia V6Z 1Y6. It is an organization that owns, manages and operates several health care facilities in Vancouver, British Columbia including St. Paul's Hospital, the location of the B.C. Ear Bank.

3. The Defendant, the Vancouver Coastal Health Authority is a provincial health authority that operates several health facilities in Vancouver. It is a corporation created pursuant to the *Health Authorities Act*, R.S.B.C. 1996, c. 180 and has a business office located on the 10<sup>th</sup> Floor, 601 West Broadway, Vancouver, British Columbia V5Z 4C2. The first location of the B.C. Ear Bank was at the Vancouver General Hospital which is now called Vancouver Hospital and is operated by the Vancouver Coastal Health Authority.
4. The Defendant, the University of British Columbia is a corporation created pursuant to the *University Act*, R.S.B.C. 1996 c.468 and has a business office located at 2329 West Mall, Vancouver, British Columbia V6T 1Z4. The University of British Columbia's Division of Otolaryngology was, at material times, involved in the operation of the B.C. Ear Bank.
5. The Defendant, John Doe is the entity that has legal responsibility for the liabilities of the Shaughnessy Hospital. The B.C. Ear Bank was previously located at the Shaughnessy Hospital. The Shaughnessy Hospital is now closed. The Plaintiff is not presently aware of the identity of the entity that has legal responsibility for the liabilities of Shaughnessy Hospital.

### **The B.C. Ear Bank**

6. The B.C. Ear Bank is a transplant tissue bank that opened in or about 1974 and was first located at the Vancouver General Hospital.
7. On a date which is unknown to the Plaintiff, the B.C. Ear Bank was moved into the Shaughnessy Hospital in Vancouver, British Columbia which is now closed. Responsibility for the B.C. Ear Bank was transferred to St. Paul's Hospital in or about 1993 and was physically relocated to St. Paul's Hospital in or about 1995.

8. The B.C. Ear Bank was at various points in time operated as a joint enterprise by the University of British Columbia's Division of Otolaryngology and the hospital Defendants: Vancouver General Hospital, the Shaughnessy Hospital and St. Paul's Hospital. The exact dates on which responsibility for the B.C. Ear Bank was passed from one hospital Defendant to another are unknown to the Plaintiff.
9. The B.C. Ear Bank collected, processed, and stored bone and tissue obtained from donors and distributed this tissue and bone to hospitals and physicians across Canada and in the United States for transplant purposes. The materials distributed included, without limitation: ossicles (ear bones), tympanic membranes (ear drums), tympanic membranes with bone attached, ear bone plugs, temporal bones, costal cartilage, dura mater, and pericardium. Dura mater is a Class IV medical device pursuant to the *Medical Device Regulations* of the *Food and Drugs Act*, R.S.C. 1985, c. F-2 which is the highest risk classification assigned to a medical device. It requires a licence to distribute. The defendants failed to obtain the requisite licence.
10. Over 6,000 individual pieces of tissue and bone have been distributed by the B.C. Ear Bank to an estimated 80 hospitals and individual physicians across Canada and the United States for transplant into humans.

### **The Events**

11. Reviews conducted on the operations of the B.C. Ear Bank by Health Canada in late 2002 uncovered health and safety concerns related to the tissue and bone being distributed by the B.C. Ear Bank. The reviews revealed that the tissue and bone at the B.C. Ear Bank had not been consistently processed in accordance with basic safety requirements and were not safe for transplant.
12. Health Canada's review of the records maintained by the B.C. Ear Bank regarding the tissue and bone collected, processed and distributed by the B.C. Ear Bank found that the records were incomplete and insufficient. The documentation failed to confirm that

screening and other procedures were conducted on donors or on tissue and bone to prevent the transmission of such infectious diseases as Human Immunodeficiency Virus (“HIV”) type I and II, Hepatitis B, Hepatitis C, Syphilis, Human T-Cell Lymphotropic Virus (“HTLV”) type I and II, and Creutzfeld Jacob Disease to transplant recipients. These diseases are potentially life threatening and incurable. In addition, they may have a long latency period requiring medical testing and monitoring to determine if they have been contracted.

13. An internal review of the documentation kept at the B.C. Ear Bank by Providence Health Care was conducted at about the same time as the Health Canada review. It revealed that tissue and bone was collected from at least 2,800 different donors. Medical records to determine if the donors had infectious diseases existed only in cases of cadaveric donors who were previously patients of St. Paul’s Hospital. Providence Health Care’s review of the available donor records indicated that 40 donors tested positive for Hepatitis B. Over 100 pieces of tissue and bone from these infected donors were distributed and it has been confirmed that some of this infected material was transplanted into humans.
14. Without records for all donors, it is impossible to determine how many more donors of the over 6,000 pieces of tissue and bone distributed by the B.C. Ear Bank had an infectious disease. Some of the tissue and bone was collected by dissecting cadavers from Coroner’s cases and it is likely that these donors were never tested for infectious diseases. There is also a risk that tissue and bone collected from infected donors cross-contaminated tissue and bone from other donors through co-mingling of materials during processing and storage at the B.C. Ear Bank
15. In February of 2003, Health Canada directed St. Paul’s Hospital to issue a recall of all tissue and bone distributed by the B.C. Ear Bank. Health Canada also advised St. Paul’s Hospital to notify hospitals and physicians to contact transplant recipients of tissue and/or bone distributed by the B.C. Ear Bank for appropriate patient follow up and testing for infectious diseases. In addition, Health Canada alerted hospitals, tissue banks and health care professionals across Canada of the results of its investigation of the B.C. Ear Bank

and recommended that recipients of the tissue and/or bone be tested for infectious diseases.

16. In or about 1994, the Plaintiff received an ear tissue transplant with tissues and bones supplied by the B.C. Ear Bank. In January of 2005, the Plaintiff received a letter from her physician informing her of the documentation problems at the B.C. Ear Bank and advising her that she should undergo testing for HIV, Hepatitis B and Hepatitis C.

### **Liability and Damages**

17. At all material times, the Defendants owed a duty of care to the Plaintiff and to other persons who received transplants with tissue and/or bone supplied by the B.C. Ear Bank to ensure that the tissues and bones had been properly screened, sterilized and tested before distribution.
18. The Defendants were negligent in their operation and supervision of the B.C. Ear Bank by distributing tissue and bone from the B.C. Ear Bank without confirming that the tissue and bone had been properly screened, sterilized and tested.
19. The Defendants failed to maintain accurate, complete and legible records relating to the tissue and bone at the B.C. Ear Bank.
20. The Defendants knew or ought to have known that the standard of care applicable to the B.C. Ear Bank was high since it was distributing tissue and bone for transplant into humans.
21. The Plaintiff pleads and relies on the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and its associated regulations for the standard of care applicable to the collection, processing, storage, and distribution of tissue and bone for transplant into humans.

22. The Defendants are vicariously liable for the negligence of their employees, servants and agents.
23. The particulars of the Defendants' negligence and breach of duty include, without limitation:
- a) failure to screen tissue and bone collected from donors for infectious diseases;
  - b) failure to properly sterilize tissue and bone;
  - c) failure to test tissue and bone for infectious diseases;
  - d) failure to investigate the suitability of donors before collecting tissue and bone that was intended for transplant into humans;
  - e) failure to conduct any or any adequate review of medical history and health risk factors for infectious disease in donors;
  - f) failure to obtain and maintain donor questionnaires for the purposes of donor screening;
  - g) failure to ensure that all donors had the appropriate testing for infectious diseases;
  - h) failure to meet the basic safety standards of practice for preventing the transmission of infectious diseases;
  - i) failure to conduct timely reviews of screening procedures used on donors;
  - j) failure to conduct timely reviews of the sterilizing and testing conducted on tissue and bone;
  - k) failure to adequately train, inspect, and supervise staff in the collection, processing storage, and distribution of tissue and bone;
  - l) failure to employ competent personnel to collect, process, store and distribute tissue and bone;
  - m) failure to obtain a licence to distribute dura mater;
  - n) failure to maintain accurate, complete, legible records related to the tissue and bone collected by the B.C. Ear Bank;
  - o) failure to maintain accurate, complete, legible records related to the health status of the donors providing tissues and bones to the B.C. Ear Bank;

- p) failure to recognize that the B.C. Ear Bank's procedures for recording data were inadequate; and
  - q) failure to properly instruct employees, servants and agents at the B.C. Ear Bank to evaluate and record information related to the donated material.
24. The Defendants knew or ought to have known that the negligence alleged above could cause serious injury, loss and damage to person who received transplants of tissue and/or bone from the B.C. Ear Bank.
25. As a result of the Defendants' negligence, the Plaintiff and all other persons who received transplants with tissue and/or bone supplied by the B.C. Ear Bank have suffered loss and damages which were foreseeable by the Defendants. The particulars of the loss or damages include:
- a) pain, suffering, loss of quality and enjoyment of life, and loss of life expectancy;
  - b) damages for past and future loss of income;
  - c) damages for loss of earning capacity and future loss of opportunity;
  - d) damages for nervous shock, stress and anxiety after being informed of the risk of infection and the need for medical testing and monitoring;
  - e) damages for past and future cost of care; and
  - f) special damages and expenses including medical expenses.
26. For many years prior to the Health Canada investigation, the Defendants were aware of the substandard operations of the B.C. Ear Bank but the Defendants placed their own interests above the health and safety of the transplant recipients. The Defendants' conduct was reprehensible and is deserving of sanction by the Court through the award of punitive damages.

**Relief Sought**

27. The Plaintiff claims on her behalf and on behalf of all recipients of tissue and/or bone supplied by B.C. Ear Bank:
- a) an order certifying this action as a class proceeding under the *Class Proceedings Act*,
  - b) R.S.B.C. 1996, c. 50;
  - c) general damages;
  - d) special damages;
  - e) punitive damages;
  - f) interest pursuant to the Court Order Interest Act, R.S.B.C. 1996, c.79;
  - g) costs of this action pursuant to s. 37(2) of the *Class Proceedings Act*, R.S.B.C. 1996. c.50; and
  - h) such further and other relief as this Honourable Court may deem just.

PLACE OF TRIAL: Vancouver, British Columbia

DATED at Vancouver, April 11, 2006

  
Counsel for the Plaintiff