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Statement of Claim

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IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION

BETWEEN:

VERNA DOUCETTE **PLAINTIFF**

AND:

EASTERN REGIONAL INTEGRATED HEALTH AUTHORITY **DEFENDANT**

Brought under the *Class Actions Act,* SNL 2001, c. C-18.1

STATEMENT OF CLAIM

The Parties

1. The proposed representative Plaintiff Verna Doucette was born on January 20, 1955. She resides at PO Box 227, Port au Port, Newfoundland and Labrador, A0N 1T0. She brings this action on her own behalf, and on behalf of a class of similarly situated persons pursuant to the *Class Actions Act*, such class to be defined in the Plaintiff's application for class certification.

2. The Defendant, Eastern Regional Integrated Health Authority, is an authority constituted by the *Regional Integrated Health Authorities Order* under the *Hospitals Act*, Regulation 18/05, to manage and control the operation of, and was at all materials times responsible for the operation, supervision and management of the General Hospital, Health Sciences Centre, St. John's, its employees, agents and servants, including its laboratory staff ("the Hospital").

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Errors in Test Results

3. Patients who are diagnosed with breast cancer receive what are referred to as ER (estrogen) and PR (progesterone) receptor tests. These tests determine whether the type of tumor needs hormones, such as estrogen or progesterone, to grow.

4. A positive test result means that the cancer may respond to therapies which block the action of hormones on the tumor cells, such as the drug Tamoxifen.

5. Medications such as Tamoxifen are given to patients as additional or adjuvant therapy, following primary treatment after diagnosis of breast cancer. Tamoxifen is taken by mouth.

6. If Tamoxifen is contraindicated or not tolerated, an Aromatase inhibitor (Anastrozole) may be used in post menopausal patients.

7. If testing determines that a cancer is ER and PR negative, the patient may be given chemotherapy as adjuvant therapy.

8. In early 2005, treating oncologists noticed that the health of breast cancer patients was not responding as expected to treatment regimes indicated as appropriate, based on laboratory results showing the presence or absence of estrogen and progesterone receptors (ER and PR).

9. Oncologists requested that the lab at the Health Sciences Centre have their patients' breast cancer tissue samples retested, and some inconsistent results in breast tumor samples were discovered.

10. The Defendant decided to retest all the ER/PR receptor test results since 1997. It temporarily halted testing by its own lab and sent about 1000 previously collected tissue samples to Mount Sinai Laboratory in Toronto to ensure accuracy and that patients were

receiving appropriate treatment. The Mount Sinai retesting showed an error rate of at least 10-20%.

11. The Defendant decided not to advise patients or the public of the retesting, and class members learned of the retesting through the news media in October 2005, causing consternation, mental distress, and concern among patients as to whether they had received appropriate therapy.

12. In the course of reviewing laboratory performance, the Defendant discovered that a number of women who were diagnosed with invasive cancer actually had only pre-invasive cancer. These patients were over treated with chemotherapy and excessive surgery, accompanied by long-term morbidity including lymphedema, as a result.

Representative Plaintiff – Verna Doucette

13. On March 22, 2002, Ms. Doucette had an open biopsy of a lump in her right breast which was diagnosed as an infiltrating ductal carcinoma. The tissue specimen was sent to the laboratory of the Defendant, and was diagnosed as an infiltrative ductal adenocarcinoma of moderate differentiation (Grade 2) with lymph channels and perineural invasion negative. Four axillary nodes out of four were negative for tumor. The size of the tumor was estimated to be up to 3 to 5 centimeters, and classified as a pT2. Subsequent testing has showed no evidence of metastatic disease. At the time of her diagnosis of breast cancer, Ms. Doucette was 47 years old.

14. By letter dated February 3, 2006, Dr. K. Laing, Clinical Chief, Cancer Care Program, Bliss Murphy Cancer Centre, St. John's, which program and centre is under the responsibility of the Defendant, advised Ms. Doucette's treating physician that the previous test reporting Estrogen receptors as negative and Progesterone as less than 5% on retesting at Mount Sinai Hospital in Toronto, were now reading Estrogen receptors 60% and Progesterone 30%. A physician review panel recommended that Ms. Doucette

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be offered Tamoxifen or, if this were not tolerated or were contraindicated, then Aromatase inhibitor (Arimidex).

15. At the time of breast cancer diagnosis, Ms. Doucette's oncologist advised that chemotherapy was indicated on the basis of negative ER/PR status. Ms. Doucette followed the advice of her oncologist and commenced a planned six cycle course of chemotherapy.

16. By about November 4, 2002, Ms. Doucette's treating physicians decided that her developing chest problems may have been triggered or worsened by the chemotherapy, and the chemotherapy was discontinued after four cycles.

17. Subsequent investigation determined that the immune suppression effects of chemotherapy had activated an old tuberculosis infection in the left lung upper lobe. Pneumonectomy, or surgical removal of the lung, has been considered, as there has been great difficulty in controlling the patient's chest infections since chemotherapy.

18. In addition to receiving inappropriate therapy with serious health effects of the therapy, the representative Plaintiff has been denied appropriate therapy for four years. Tamoxifen therapy is appropriate for up to seven years after diagnosis.

Fault or Negligence of Defendant

19. The Defendant is corporately liable to the Plaintiff in tort of negligence, and the particulars of the Defendant's fault or negligence are as follows:

(a) failure to adequately supervise technical personnel during a meticulous and labour-intensive testing process;

(b) failing to adequately train testing personnel in the requirements of the testing process;

(c) failing to have appropriate control of the quality of the stain;

(d) failing to encourage or require specialization among the pathology medical staff;

(e) failing to implement a quality assurance program, eg. through periodic review for conformity with statistical norms, or quality control audits;

(f) failing to inform patients of the change in their ER/PR testing status in a timely and appropriate manner.

20. The Defendant is also vicariously liable for the acts or omissions of its employees and agents, as set out above. The representative Plaintiff specifically does not allege vicarious liability with respect to the employed pathology staff, licensed by the Newfoundland and Labrador College of Physicians and Surgeons. The negligence alleged with respect to medical professional involvement is entirely corporate.

21. The Defendant has a contractual relationship for the provision of medical services to the Plaintiff and other patients. A major or important part of the contractual relationship was to provide the Plaintiff and class members with piece of mind. An implied term of that contractual relationship is that the Defendant would employ properly trained and supervised personnel in the testing process, and that it would have a proper quality assurance program, proper internal controls, and ensure an appropriate level of expertise and specialization among the pathology medical staff charged with ultimate responsibility for interpretation of the testing, in the exercise of its contractual duties arising out of the testing, diagnosis and treatment of patients.

22. Another implied term of the contractual relationship was that the Defendant would promptly and appropriately notify the Plaintiff and other patients of the discovery of testing errors and of the decision to embark on retesting of tissue samples, in a manner calculated to minimize the worry and concern that patients would feel.

23. The nature of the contractual relationship is such that the parties contemplated that the Defendant's breaches of contractual duty set out herein would entail mental distress by the Plaintiff and other patients.

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24. The representative Plaintiff repeats the foregoing and says that the Defendant has violated duties of disclosure of a fiduciary nature, existing between the Defendant and its patients.

Damages

25. As a result of the Defendant's breaches of its obligations, the Plaintiff and class members have suffered foreseeable loss, including:

(a) pain, suffering, and loss of quality and enjoyment of life;

(b) mental distress, frustration, anxiety, displeasure, vexation, attention, aggravation, upset and inconvenience;

(c) past and future loss of income and earning capacity;

(d) past and future cost of care;

(e) loss of consortium and loss of guidance, care and companionship; and

(f) out-of-pocket expenses.

Relief Requested

26. The Plaintiff claims the following relief:

(a) an order certifying the proceeding as a class proceeding;

(b) general damages;

(c) special damages;

(d) the costs of providing appropriate notice to class members and administrating this proposed class action for their benefit;

(e) interest pursuant to the provisions of the *Judgment Interest Act*, R.S.N. 1990, c. J-2;

(f) such further and other relief as this Honourable Court deems just.

DATED at St. John's, in the Province of Newfoundland and Labrador, this 7th day of July, 2006.

CHES CROSBIE BARRISTERS
Solicitors for the Plaintiff whose address for service is:
169 Water Street, 4th Floor
St. John's, NL A1C 1B1
Per: Chesley F. Crosbie, Q.C.

TO: THE DEFENDANT
Eastern Regional Integrated Health Authority
Waterford Bridge Road
St. John's, NL

ISSUED at St. John's, in the Province of Newfoundland and Labrador, this day of July, 2006.