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NLIS 3

Health and Community Services

May 22, 2007

**Minister to Announce Details on Review into ER/PR Testing in Eastern Health**

The Honourable Ross Wiseman, Minister of Health and Community Services, will hold a news conference today (Tuesday, May 22) at 12:30 p.m., to announce details on an independent review of the estrogen and progesterone receptor (ER/PR) breast cancer testing system at Eastern Health. The news conference will be held in the Media Centre, Ground Floor, East Block, Confederation Building.

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2007 05 22

10:55 a.m.

NLIS 5  
Health and Community Services  
May 22, 2007

### **Government to Undertake Judicial Commission of Inquiry on Estrogen and Progesterone Receptor Testing for Breast Cancer Patients**

In order to maintain confidence in the provincial estrogen and progesterone receptor (ER/PR) breast cancer testing system at Eastern Health, the Honourable Ross Wiseman, Minister of Health and Community Services, today announced that the Provincial Government will undertake a Judicial Commission of Inquiry on estrogen and progesterone receptor testing for breast cancer patients.

On Friday, Eastern Health CEO George Tilley apologized for the confusion that has ensued over this issue and stated that 'at no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for ER/PR' and that 'Eastern Health has acted and will continue to act in the best interest of our patients.'

"Government recognizes it is of the utmost importance for those directly involved and the general public to understand what happened to ensure that this situation does not reoccur," said Minister Wiseman. "Through an independent review, we will endeavor to get those answers. It is critical that patients and their families are assured that government takes this matter very seriously and that any questions they have are addressed in an open and transparent manner."

A Judicial Commission of Inquiry will be established by the Provincial Cabinet under Section 3 of the *Public Inquiries Act, 2006*. Cabinet will appoint a commissioner, set the terms of reference for the inquiry and authorize an appropriate budget. Once the commissioner's report is completed, it will be submitted to the Minister of Health and Community Services and will be released publicly.

The review will address six key questions:

1. What went wrong with the ER/PR tests that resulted in a high rate of conversions when re-tested?
2. Why was the problem with the tests not detected until 2005? Could it have been detected at an earlier date? Were the testing protocols during that period reasonable and appropriate?
3. Once detected, did the responsible authorities respond in an appropriate and timely manner to those categories of people who needed re-tests and those who were being tested for the first time?
4. Once detected, did the responsible authorities communicate in an appropriate and timely manner with the general public about the issues and circumstances surrounding the change in test results and the new testing procedures?

5. Are the testing systems and processes currently in place reflective of "best practice"?
6. Does Eastern Health currently employ an effective quality assurance system to provide maximum probability that the testing problems will not reoccur?

The Commissioner will provide recommendations as necessary and appropriate to address the questions for the inquiry as identified above. The minister will announce further details regarding the Commission of Inquiry, including the appointment of a commissioner.

Minister Wiseman added, "I look forward to receiving the commissioner's report which will answer the many questions that have arisen with respect to this issue."

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### **Backgrounder – ER/PR Testing for Breast Cancer Patients**

- This issue is not about breast cancer screening. At no time has there been a question of accuracy of mammograms or biopsy results to diagnose breast cancer.
- Estrogen and progesterone testing (ER/PR) takes place after a breast cancer diagnosis to determine whether cancer cells have estrogen or progesterone receptors. Breast cancers that are either ER-positive or PR-positive (or both) may respond to hormone therapy, such as the drug Tamoxifen. Hormonal therapy, chemotherapy and radiation are considered to be adjuvant therapies. The aim of adjuvant therapy is to decrease breast recurrence rates and improve overall survival rates. Adjuvant therapies are generally additional treatments given after potentially curative surgery.
- Eastern Health first became aware of a problem with ER/PR test results in May 2005 and immediately conducted an internal review. In July 2005 it made a decision to retest all negative ER/PR tests done between May 1997 and August 2005 to ensure that if there was one patient who could benefit as a result of a change in their test result and subsequent treatment change that it was important that this be done. Eastern Health also suspended their own testing at that time.
- The process to retest and conduct external and internal reviews in the lab took about one year to complete. Once test results came back, the results were assessed to determine if a recommended treatment change was necessary. The assessments were conducted by a panel of experts in cancer care, including oncologists,

pathologists and surgeons. The first test results were received by Eastern Health in October 2005. All test results were received by February 2006.

- There were a total of 939 patients with ER negative reports. Of the 763 patients reviewed, 317 patients had a change in result. Of that number, 117 of the patients had a resulting change in treatment. A further 176 patients, of the total 939, originally reported as negative are deceased.
- Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:
  - That their tissue had been retested and there was no change in the original results;
  - That their tissue had been retested and that Eastern Health was recommending a change in their treatment; or
  - That although there was a change from their original test result, no change in treatment was recommended.
- There was full disclosure to patients and their families once test results became available. Unfortunately, test results came back at different times and there was a delay in the retesting process which led to some patients feeling they were not informed in a timely fashion. Ultimately, Eastern Health's primary concern was notifying all affected individuals.
- Eastern Health held a media briefing in December 2006. At the time the focus was on the 117 patients who had a change in test result and a change in treatment plan and this was communicated to the media. Unfortunately, the media were not provided with the number of test results that had changed (317).
- Eastern Health has committed to retest results for the 176 patients who are deceased and to ensure that all patients' families are contacted for follow up.
- Eastern Health apologized on Friday for the confusion created by not disclosing all of the information to the media in December. Although the media were not informed, the 317 patients who were directly impacted were informed of their individual circumstances.
- Eastern Health has implemented a number of measures to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training. In addition, as a measure of quality control, a random sample of tests are sent to Mount Sinai to ensure the accuracy of Eastern Health test results. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007.

2007 05 22

1:30 p.m.

NLIS 4  
Executive Council  
May 30, 2007

### **Provincial Government Prepares for Commission of Inquiry and Announces New Task Force on Health System**

Premier Danny Williams announced today that Robert Thompson will effective immediately assume the role as Secretary to Cabinet for the Management of Health Issues. In this role, Mr. Thompson will chair a task force on the management of adverse health events and the related dissemination of public information. This task force will extend beyond hormone receptor testing and will examine how the health system identifies, evaluates, responds and communicates in regard to adverse events in the health system which may compromise the health of patients in Newfoundland and Labrador.

In this position, Mr. Thompson will assume responsibility for preparing the provincial government for full and open participation in the upcoming Commission of Inquiry on Hormone Receptor Testing.

"The revelations of the last two weeks have no doubt affected public confidence in how the health system in our province operates and how the public is kept informed on issues of importance," said Premier Williams. "As such, today I am announcing that we have appointed the province's most senior public servant to provide leadership in the management of adverse health events, and to also work to ensure that government's participation in the Commission of Inquiry is fully accountable and transparent."

Mr. Thompson will undertake all preparations for the inquiry from the province's perspective and will make recommendations to Cabinet on how government can respond to issues raised by the inquiry.

"I look forward to Mr. Thompson's leadership in his new role and am confident that his work will assist in helping to restore faith in our health care system," added the Premier.

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### **Biography**

**Robert Thompson**  
**Secretary to Cabinet for Health Issues**

Robert Thompson has served for the last three and a half years as the Clerk of the Executive Council and Secretary to the Cabinet. Prior to that he served as Deputy Minister of the departments of Health and Community Services, and Tourism, Culture and Recreation. In his career with the provincial government, he has also served as Assistant Secretary to Cabinet for Economic Policy and has held management positions with the Intergovernmental Affairs Secretariat, the Department of Education, the Department of Career Development and Advanced Studies, and the Department of Rural, Agricultural and Northern Development.

Mr. Thompson is a graduate of Memorial University of Newfoundland (Political Science), with graduate studies at York University (Public Administration) and Memorial University (Business Administration). He serves as a Director of the Canadian Policy Research Networks, and he is the Chair of the Board of Directors of Shallaway: Newfoundland and Labrador Youth in Chorus. He has served on the boards of Canada Health Infoway Inc., the Canadian Tourism Commission, the Atlantic Canada Tourism Partnership, the Special Celebrations Corporation, the Credit Union Stabilization Fund and the St. John's Downtown Development Corporation. Mr. Thompson resides with his wife, Wanda, and their daughter, Emily, in St. John's.

2007 05 30

10:30 a.m.