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Product Summary:

NEWS CONFERENCE: Right now we want to take you live to St. John's Newfoundland.
Friday, May 18, 2007 12:30PM Item # 01
CBC - Newsworld

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Standing Order: YES
Breast Cancer Testing - All Media - HCS
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NANCY WILSON: Right now we want to take you live to St. John's Newfoundland. Officials with the local health authority are reacting to the story of flawed testing on breast cancer patients. The incorrect results left some patients thinking they didn't have breast cancer when in fact they did. As a result some of them were steered away from helpful drug treatments such as Tamoxifen. There is a possible class-action lawsuit in the works. Let's listen in live.

GEORGE TILLEY: Breast cancer patient might benefit from hormonal therapy. So at no time has there been any question with regards to accuracy of mammograms or biopsies that we would use to assistant in diagnosing breast cancer. Next let me say that has President, Chief Executive Officer of Eastern Health I apologize for the confusing that is ensued over this issue. I take full responsibility for the organizations actions in talking about this issue and we are steadfast in our attempt to clarify the situation and to ensure there's no more confusion about who is affected and what it all means. At no time did Eastern Health withhold any personal information from any patent in impacted by our decision to retest for estrogen and progestin receptors, more commonly known as ERPR. It is important to stress here and for you to know that we contacted each and every patient who was affected by this test review, making sure that they receive all of the information and support that they required. Further more once we become aware of the potential issues with the ERPR test we immediately suspended our own in house testing program and began using the service of an out of province facility. In 2005 when we discovered some inconsistencies in a small number of ERPR tests we made an organizational decision to go back and review all of the ERPR test results back to 1997. We did this because we know that

hormonal therapy may still be of some benefit to a breast cancer patient who was diagnosed that time ago. We felt that even if there was one possibility to benefit a patient then we had an obligation to go back and test all patients regardless of the consequences. It took us about a year to complete all the retesting and then to conduct reviews in our laboratory. This took us much longer then we had anticipated and I know that clearly that added to the stress levels of our patients and their families. However, I noted that we relied upon the services of an external laboratory outside of the province and their ability to meet their original commitment failed and they had some of their own issues in terms of workload that caused ours to be delayed. Additionally as test results came back to us it was necessary to assess all of the results that we received and to determine if there was a change in the result and of there was whether there would be a recommended change in the treatment of those individual patients. These assessments were conducted by a panel of experts in cancer treatment using the best available knowledge in cancer treatment and diagnoses and before we talked about the results of our findings to the public we felt we had an obligation to contact each and every patient who was involved in the retesting to tell them one of three things: either that their tissue had been retested and there was no change in results, that their tissue had been retested there was a change in results and that there was a recommendation for change in treatment, or lastly that although there was a change in results on review by the expert panel there was no recommendation for a treatment . . . plan. The process was never considered a research project. It was never considered a quality assurance exercise. It was all about this organization doing or re-doing a test to provide every treatment opportunity to our patients. And in December we issued an assessment of the review to the media and many of my colleagues at the table today participated in that. We did so at that point in time because we felt the public at large deserved to know as much as we could tell them about the results. And let me explain these numbers. There were nine hundred and thirty nine patients with ER negative reports. Of the seven hundred and sixty three patients that we reviewed, three hundred and seventeen of them had a change in result. Of these, one hundred and four had a resulting change in treatment. An additional thirteen patients were added to those one hundred and four because although the results changed the definition of what was negative did, meaning that hormonal therapy was now considered an alternative for those patients. So at that time, in December, we focused in on the one hundred and seventeen patients who's treatment plans changed. And I acknowledge at that time that we did not identify the additional patients who had a change in test result but did not have a change in treatment plan. We believed that the decision to focus in on the one hundred and seventeen patients was the right one because from our perspective, it was the critical piece of information. Now that being said, given the discussions over the past several days, in many ways emanating from not having that number revealed at an earlier date, I regret the decision that we didn't simply refer to it earlier. And I apologize for the confusion that that caused. So that group, the total group of three hundred and seventeen who's results changed appears to be the source of much confusion. And I need to stress that this is not a new group of patients and in fact includes the one hundred and seventeen that we had publicly indicated

required a treatment plan. And I also appreciate that this issue is undoubtedly causing great anxiety for the patients suffering from cancer and their family members and we sincerely regret that. Unfortunately, we simply do not know how many of the patients who are now deceased, going back to 1997, may have benefited from hormonal therapy. We are committed to being responsive to all of our patients and their families and if a systematic review of the tissue samples of these patients would help to alleviate all or any concerns, then I'm committed to ensuring that this is completed and that the family members are contacted for follow up. This has clearly been a learning experience for this organization but I must reiterate that Eastern Health has acted, and will continue to act, with the best interest of our patients in mind. They are our first priority and patient safety is important to us. Our staff and physicians have been and will continue to be available to any and all patients and families who are impacted by this review and I would certainly encourage any patient or family member with questions to contact our client services staff, any of our physicians, or other healthcare providers. And I now open up the floor to questions.

UNKNOWN REPORTER: It's public knowledge that the method used for hormone receptor tests is, there's a subjective degree to it. But how do you explain for the magnitude of the errors that happened in this province?

GEORGE TILLEY: We saw a change in results for three hundred and seventeen patients. And as you point out, there is an element of uncertainty in this particular test and it's quite well-known both nationally and internationally. When we first became aware of this and decided to suspend treatment, our physicians and technologists spent a great deal of time looking inside the organization, looking at the procedure for that test. We also sought the input of technologists, a technologist and a physician more independent of the organization, to come and give us an objective assessment as to what we do and how we do it... I recall that the comments of the physician were that he considered us to be in the middle of the pack in terms of laboratory services with regards to ERPR. And to be quite frank with you, we're not satisfied with being in the middle of the pack, we are interested in becoming amongst the top laboratories for this procedure in the country. Having said that, the individual, individuals who are not able to point to a technique, a person, a discipline that had done anything that would suggest that errors would occur. And unfortunately, because of that, we have to look at this problem in terms of what can we do to make improvements in the system to restore our comfort and the public's confidence in that procedure. So what we have spent a great deal of time doing is looking at other centers in the country for whom we, us and others feel that they have centers of excellence, to look at what they've done and implemented it here.

UNKNOWN REPORTER: Mr. Tilley, you said you were apologizing for the confusion but what do you think you did that added to this confusion?

GEORGE TILLEY: We made a conscious decision to focus in on patients who had a change in results and also, because of that, had a change in their treatment plans. The concern that's been talked about over the last couple of days is whether we were inappropriately neglecting reference to the other group of patients who had results change but there was no change in their treatment plan. And by us neglecting to provide that, we seem to have caused some confusion, we certainly had confusion amongst public who contacted our organization. There was concern particularly regarding whether this applied to cancer diagnosis in the first place. There was also concern amongst individuals that we had contacted back in 2006 about this procedure. So we felt that by us omitting that figure, we may in some way of added to this problem.

UNKNOWN REPORTER: Why didn't you opt for full disclosure when people were asking...

NANCY WILSON: We're watching a news conference in St. John's, Newfoundland. Local health officials apologizing to women and their families for any anxiety or confusion that resulted from faulty hormone tests that were conducted for women and a false negative was reached in some cases and as a result, women who had breast cancer were not diagnosed with breast cancer and they then had no access to hormone treatments like Tamoxifen. We know that this story spanned from 19, in the late 1990's, to 2005. Since then, more than three dozen women have died, presumably of breast cancer, but officials saying that they cannot connect the dots to the point where the faulty hormone receptor test is the reason that they died. So that is the latest in an ongoing story that certainly has shocked authorities in Newfoundland. We'll continue to follow that story throughout the day on NewsWorld and beyond.

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