

Flawed test imperils scores of cancer patients

By PETER GULLAGE

Thursday, October 6, 2005 Posted at 5:07 AM EDT

From Thursday's Globe and Mail

Hundreds of tissue samples from Newfoundland and Labrador breast cancer patients dating back to 1997 are being retested after major flaws in a laboratory test were uncovered

ST. JOHN'S — Newfoundland and Labrador breast cancer patients are in a frightening limbo as hundreds of tissue samples dating back to 1997 are being retested after major flaws in a laboratory test were uncovered.

The problem was discovered in May when a test for hormone receptors in the cancer cells of a patient who had fallen ill in spite of testing negative, gave a different result than earlier tests. The hormone receptor test determines if cells are stimulated by either estrogen or progesterone and indicates cancer-cell growth. The original test was negative, but in May, the patient's tissue tested positive, and as a result the province's breast cancer testing program was suspended.

"With 40 steps in the [testing] procedure, if you have a problem in any particular step, it can affect the results you get," explained Bob Williams, vice-president of quality diagnostic and medical services for the Eastern Health authority. "There are checks and balances in there, but in this case, in some of these cases, these things did not appear to work."

In July, the authority called on Toronto's Mount Sinai Hospital to test previously screened tissue and to take on the lab work for all new breast cancer patients. Health-care officials say they can't be precise about the number of people affected. Mount Sinai is testing 30 per cent of the hundreds of tissue samples that came up negative since 1997. So far, 10 per cent of results have changed to positive.

A different result "may have implications for patient care and that's the issue that's discussed with the patient's treating physician and then treatment may be modified based on that," Dr. Williams said.

The troubles in the lab are a worry for breast cancer survivors who have to wait for news about the new tests on their tissue.

"My breast cancer pathology came back as estrogen negative but partially progesterone positive, so it is possible that there was an error in my pathology," said Gerry Rogers, a breast cancer survivor who turned her ordeal into an award-winning documentary.

"It's hard to know that maybe a mistake has been made."

Patients who test positive for hormone receptors may be offered Tamoxifen, a drug that interferes with estrogen and progesterone over a five-year treatment. Ms. Rogers wonders where her breast cancer tissue sample is in the process and whether it's too late to take the drug.

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"If the case were to be that in fact there was an error in the pathology, then the window of opportunity for the effectiveness of Tamoxifen in my case has kind of passed," she said.

Peter Dawe, director of the Newfoundland and Labrador chapter of the Canadian Cancer Society, warns that this "has the potential to be a big issue" for the province's health-care system and patients.

"It alters the treatment. You could be having an inadequate treatment based on a test result," Mr. Dawe said.

"There is a group that has the test result in question and our fear is that they should have received treatment and didn't."

Breast cancer patients in Newfoundland and Labrador face a frightening wait as hundreds of tissue samples dating back to 1997 are being retested following the discovery of major flaws in a laboratory test.

The problem was discovered in May, when a test for hormone receptors in the cancer cells of a patient who had fallen ill in spite of testing negative gave a different result than earlier tests.

The hormone receptor test determines if cells are stimulated by either estrogen or progesterone and indicates cancer-cell growth.

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Major flaws discovered in NL breast cancer tests

CTV.ca News Staff - Thursday, October 06, 2005

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Product Summary:

LACK OF PATHOLOGISTS: There is some troubling news for cancer patients in the province. Doctors who study their test results are in short supply and the numbers are getting smaller.

Tuesday, December 13, 2005 06:07PM Item # 06

CBC - TV News

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DEBBIE COOPER: There is some troubling news for cancer patients in this province. Doctors who study their test results are in short supply, and the numbers are getting smaller. The doctors are called pathologists. It's a problem that extends right across the country. Erin Sully reports on why there is a shortage and what it could mean for patients.

ERIN SULLY: Pathologists study disease. Cancer-related diseases take up ninety percent of their time, but there aren't enough doctors to do all the work, and it's going to get worse. Nearly one third of the pathologists now working in the province will retire or leave next year.

DR. DAN FONTAINE: Our pathologists are getting older, and it's not only restricted to Newfoundland. We've seen this across the country, and there are no young pathologists coming in to the system.

ERIN SULLY: Dr. Dan Fontaine works at the Health Sciences Centre in St. John's. He was the last pathologist to graduate from Memorial University, and that was three years ago. He says hospitals here are trying to recruit pathologists but no luck. The reason? Other provinces offer bigger salaries and lower workloads.

DR. DAN FONTAINE We've had two positions that have been available for twelve months and eighteen months of which we've had fourteen applicants. We were successful in recruiting one individual from those. There were nine offers made. The other eight completely refused as soon as they saw the salary.

ERIN SULLY: Too few pathologists means a longer wait for test results and more stress for cancer patients like Gerry Rogers who says waiting was the hardest part for her after she was diagnosed.

GERRY ROGERS: You know, you say should I be positive? I kind of feel something's wrong but maybe it's not. Sometimes the waiting is really, really long. It's tough.

ERIN SULLY: The cancer society says it's time to start addressing the issue, that it is not acceptable for cancer patients to wait for test results.

PETER DAWE: You'd see people clamouring to get services outside the province, to get it done quicker, and you see a deterioration of our cancer control system. Again, from a Cancer Society perspective, that's not acceptable.

ERIN SULLY: But it might not be possible for cancer patients to be tested outside the province. Hospitals elsewhere in Canada have their own backlog of work. Eastern Health Care is in negotiations with a private lab in Ottawa to take on the overflow, and, on January 17th, a case will be made to the government to get more money to recruit pathologists to Newfoundland and Labrador. Erin Sully, CBC News, St. John's.

Some breast cancer patients still waiting for results of retesting

**BEN
CURTIES**



The results are in, but Newfoundland's most famous breast cancer survivor is still wondering if her test was accurate.

Gerry Rogers, director and subject of the Gemini Award-winning documentary *My Left Breast*, says her doctor is almost certain the tests carried out to help determine her course of breast cancer treatment were among those sent back by the Eastern Health Board to Toronto's Mount Sinai Hospital for review.

But information is hard to come by.

"They haven't told me anything," Rogers tells *The Independent*. "Nobody has contacted me about anything. But when I saw my oncologist in late December, she said 'Gerry, looking at the test results that are coming back and looking at your initial test results, I'm 99 per cent sure that yours would be one of the ones that were falsely negative.'"

In May last year, Eastern Health, which oversees hospitals in the St. John's area, sent away test results (Canadian Cancer Society spokesman Peter Dawe pegs the number at 1,000) from as far back as 1997 after determining that between five and 20 per cent of the results may have been inaccurate.

The outcomes of the tests, which examine hormone receptors in breast cancer cells for estrogen and progesterone, help physicians determine the

course of treatment that a patient should undergo.

The last of the retest results came in last week, but Eastern Health officials have yet to issue a public statement on the issue, electing to wait until they have assessed the retests and notified

patients on an individual basis.

"I'm not sure what the strategy will be at that point until we get them all finished and I guess we'll decide at that point what we're going to do publicly," says Deborah Pennell, spokeswoman for Eastern Health.

When *The Independent* broke the story in October, Eastern Health officials said they had kept it quiet because they didn't want to cause mass hysteria.

But Rogers is angry that she had to learn about the testing errors from the media.

"I think as soon as they knew that something was wrong they should have told us immediately, rather than the information coming out because somebody in the media got wind of somebody who

See "Rumblings," page 2

'Rumblings and rumours' of legal action

From page 1

knew something," she says. "They should have done it immediately and explained what they did and didn't know, because we're not children. We're health-care consumers, and this is a system that we all own."

Instead, Rogers has been forced to wonder what might have been.

According to Dawe, a positive result on the test, called an ER/PR test for estrogen or progesterone receptors, means the patient could respond to a hormone therapy treatment such as Tamoxifen. The faulty tests showed false negatives.

"In clinical trials, Tamoxifen has shown some great results of improving survival rates of women with breast cancer," says the cancer society spokesman. "If you're positive, and you get tested and they say you're negative, you're missing the opportunity to get the hormone therapy."

The ramifications are not lost on Rogers, who could have been told about the five-year hormone treatment program six years ago.

"They might suggest now for me to take Tamoxifen, but it seems to me like closing the barn door after the horses are out," says Rogers, who has lost both breasts.

"I'm well now, but if something were to happen, you would think could this have been prevented?"

"I've had some friends who have been diagnosed and who have died, who maybe weren't supposed to die," she adds. "I'm not making any kind of informed medical pronouncement here, but I had friends whose pathologies indicated they had a pretty good chance for survival, and they died. They were early stages, with no lymph node involvement, and they were estrogen negative; they weren't on Tamoxifen. And then they got recurrences and died. I wonder if their pathology was wrong

too, you know?"

Pennell says it will take at least another month to know how many people may have been incorrectly treated.

"It's all relative," she says. "There's a lot of treatment options and people may have gotten treatment anyway. It's really hard to determine until we get down through every single case and take a look back."

"For some people, it's not going to mean anything," agrees Dawe. "They may have been offered Tamoxifen or some other treatment anyway. For some people, Tamoxifen may not have been an option no matter what, because there are some side effects. It's really individualized. Until I get some real good numbers I'm hesitant to talk about anything."

Eastern Health officials wouldn't discuss exactly what went wrong — though they have explained that new lab technology caught the errors and led to the retests.

The cancer society hasn't been told.

"Eastern Health should answer that, but from what we've been told it's a complicated process," Dawe says. "They haven't pinpointed exactly what went wrong. In any biological test there's going to be a certain amount of false negatives. It just happens that their rate is up around 10 per cent. They're trying to tighten up their quality control to the point that where they can say 'We're doing this test as well as anybody else.'"

Dawe says there have been lots of "rumblings and rumours" of legal action, but he's heard nothing concrete. Pennell says Eastern Health hasn't heard of any lawsuits either.

For Rogers, the errors would be a lot easier to swallow if they were explained.

"For the most part, people are not litigious," she says. "They just want to be treated with respect and fairness. By handling it this way, it makes people

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Gerry Rogers

angry enough to want to be litigious."

Rogers phoned Eastern Health when she found out the results were in, and was directed to a "patient liaison" voicemail. She hadn't heard back prior to *The Independent's* press deadline. She says the silence is unfortunate, considering how well she has been treated by Eastern Health in the past.

"I've feel that I've had exemplary care," she says. "Every step of the way I've been treated with compassion and respect, and this is totally disrespectful."



Gerry Rogers lost her breasts to cancer.

ER/PR MAY 15-27, 2007

CBC RADIO CORNER BROOK MORNING SHOW 6-8AM Tuesday, May 15, 2007**CBC RADIO LABRADOR MORNING SHOW 6-8AM Tuesday, May 15, 2007****CBC RADIO ST JOHN'S MORNING SHOW 6-8AM Tuesday, May 15, 2007**

INACCURATE TESTING FOR CANCER PATIENTS: Court documents show that Eastern Health got many more medical test results wrong than it reported months ago. Last December Eastern Health announced some of the results of a review of all hormone receptor tests in this province, dating back to 1997. The test helps determine what treatment a patient receives after they've been diagnosed with breast cancer. Eastern Health said after the tests were redone in Ontario, treatment changed for more than 100 patients. But it wouldn't say how many of the tests came back with results that were different than the original tests. Now court documents obtained by CBC show that almost three times as many tests were wrong. [Reporter "Mark Quinn"; "Geri Rodgers", filmmaker; "Peter Dawe", Canadian Cancer Society"; "Dr. Craig Alwright(sp?)", pathologist] AIRED: 7:12 DURATION: 4:00 REPORTER: DOROTHY KING

CBC NATIONAL NEWS, THE CURRENT: May 15, 2007*Faulty Test Results – Patient*

Last summer we told you about mistakes that were made at a pathology lab at the largest hospital in Newfoundland and Labrador, run by the Eastern Regional Health Authority.

The mistakes were severe and resulted in the mistreatment of dozens of cancer patients. In one case, after undergoing a double mastectomy and chemotherapy, a woman found out she didn't have breast cancer at all. And today, court documents obtained by CBC Radio, reveal just how widespread other initial errors were. At issue is a test for hormone receptors. A positive test means estrogen is feeding the cancer tumour, and so many women who test estrogen/progesterone receptor positive are given a hormone therapy called tamoxifen to stop the estrogen. Tests show women who take tamoxifen for five years have a reduction in second cancers.

After tissue samples from the Nfld lab were re-tested at Toronto's Mount Sinai hospital, the documents reveal that forty-two percent of the patients tested for estrogen/progesterone receptors had received the wrong results -- they got false negatives -- and this may have adversely affected their course of treatment.

Gerry Rogers is one of the women affected by the mistakes made at that Newfoundland pathology lab. She has portrayed her own fight with breast cancer in the award winning

Newsworld National Film Board feature called "My Left Breast", and is an advocate for women living with breast cancer. She joined us from our St. John's studio.

Faulty Test Results – Association

We asked the Eastern Health Integrated Regional Authority of Newfoundland and Labrador for an interview on this matter. But an official with the board says that no one can comment as the matter is before the courts. To shed some light on how pathology and laboratory medicine works in Canada, we were joined by Jagdish Butany. He is the President of the Canadian Association of Pathologists and we reached him this morning at his office in Toronto.

Breast Cancer Tests—Bioethicist

Philip Hebert knows that mistakes are part of pathology. But as a family doctor he must also treat patients with a devastating cancer diagnosis quickly and effectively. In addition to his practice, Dr. Hebert chairs the Research Ethics Board at Toronto's Sunnybrook Hospital and is author of *Doing Right. A Practical Guide to Ethics for Physicians and Medical Trainees*. He was in our Toronto Studio.

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CBC RADIO NEWS AT 7:00AM Tuesday, May 15, 2007**CBC RADIO NEWS AT 8:00AM Tuesday, May 15, 2007**

MISDIAGNOSIS REPORTED: Court documents reveal that Eastern Health had many more medical tests results wrong than it reported months ago. [Reporter "Mark Quinn"; "Peter Dawe", Canadian Cancer Society; "Dr. Craig Alwright(sp?)", pathologist; "Geri Rodgers", cancer survivor] AIRED: 7:00 A.M. DURATION: 2:00 REPORTER: NANCY WALSH

FALSE TESTING FOR BREAST CANCER PATIENTS IN NL: Tamoxifen therapy is one of the most successful treatments for women diagnosed with breast cancer but hundreds of women in Nfld and Labrador were mistakenly denied this life saving treatment. ["Vic Adobia", reporter; "Geri Rodgers", patient; "Peter Dawe", Canadian Cancer Society; CBC National News 7:30] AIRED: 7:30 AM DURATION: 3:00 REPORTER: JUDY MADRIN

VOCM RADIO OPEN LINE Tuesday, May 15, 2007

TRAVEL FOR HEALTH CARE: "Marg" calling to talk about invasive by-pass surgery. She says that she didn't realize how far some of these patients had to travel to get this surgery, as people as far as Buchans and the Northern Peninsula have to travel sometimes 13 hours or more to St. John's for the surgery. AIRED: 11:27 AM DURATION: 03:00 REPORTER: RANDY SIMMS

CBC RADIO ON THE GO AT 4:00 PM Tuesday, May 15, 2007

CONCERN OVER INACCURATE TEST RESULTS: CBC has learned that hundreds of women in Nfld and Labrador who might have been eligible for a potentially lifesaving breast cancer treatment were denied the drug due to faulty test results. Tamoxifen blocks hormones that promote the growth of cancerous cells. Hormone receptor tests determine whether a woman is eligible for that treatment. But in that province we now know that at least one-third and possibly half of the negative tests between 1997 and 2005 were wrong. That means hundreds of women who could have benefited from the drug treatment didn't get it. "Geri Rodgers" is one of those women. "Ross Wiseman" is this province's minister of Health and Community Services. AIRED: 04:07 PM DURATION: 15:00 REPORTER: TED BLADES

ROSSITER GIVES HOUSE UPDATE: Mike Rossiter discusses the happenings in the House of Assembly today. Topics included the controversy with Eastern Health over false testing for cancer patients and Liberals super weekend. AIRED: 05:23 PM DURATION: 05:00 REPORTER: TED BLADES

CBC RADIO EVENING NEWS AT 5:00PM Tuesday, May 15, 2007

CONCERN ABOUT CANCER TESTS IN NL: Court documents reveal there are serious problems with treatment tests for breast cancer. ["Vic Adobia", reporter; CBC National News 4:30 P.M.] AIRED: 04:36 PM DURATION: 02:00 REPORTER: Marcia Williams

PROVINCIAL GOVERNMENT ADDRESSING EASTERN HEALTH SCANDAL: The provincial government is scrambling to try to restore confidence in the health care system over a controversy involving the Eastern Health Care Corporation. ["Mike Rossiter", reporter; "Ross Wiseman", Health minister; "Lorraine Michael", NDP leader] AIRED: 05:01 PM DURATION: 02:00 REPORTER: JACINTA WALL

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VOCM RADIO NEWS AT 5:30PM Tuesday, May 15, 2007

GOVERNMENT REASSURES WOMEN: Government says women should be confident in the quality control measures put in place in light of the hundreds of false breast cancer test results discovered by Eastern Health. ["Jennifer Tulk", reporter; "Dwight Ball", Liberal Health critic; Health Minister "Ross Wiseman"] AIRED: 5:35 PM DURATION: 03:00 REPORTER: AUDREY WHELAN

CBC TV HERE & NOW AT 6:00 PM Tuesday, May 15, 2007

CANCER PATIENTS QUESTIONING EASTERN HEALTH: Many cancer patients in the province are questioning how reliable Eastern Health is. ["Mark Quinn", reporter; Geri Rodgers, cancer patient; "Peter Dawe", Canadian Cancer Society; "Dr. Craig Allred", pathologist; "Deanne Fleet", reporter; "Lorraine Michael", NDP leader; "Dwight Ball", Liberal Health critic; Dr. Cara Lang, Eastern Health; "Ross Wiseman", Health minister] AIRED: 06:00 PM DURATION: 06:00 REPORTER: COOPER/CROWE

CBC RADIO EVENING NEWS AT 6:00PM Tuesday, May 15, 2007

PROVINCIAL GOVERNMENT ADDRESSING EASTERN HEALTH SCANDAL: The provincial government is scrambling to try to restore confidence in the health care system over a controversy involving the Eastern Health Care Corporation. ["Mike Rossiter", reporter; "Ross Wiseman", Health minister; "Lorraine Michael", NDP leader] AIRED: 06:01 PM DURATION: 02:00 REPORTER: JACINTA WALL

NTV EVENING NEWS AT 6:00PM Tuesday, May 15, 2007

CRITICISM OF EASTERN HEALTH: It's come to light that Eastern Health drastically underestimated a problem it had with breast cancer testing in December of 2005. ["Geri Rodgers", cancer patient; Health Minister "Ross Wiseman"; "Peter Dawe", Canadian Cancer Society] AIRED: 6:01 PM DURATION: 03:00 REPORTER: HUTTON/WISEMAN

CABLE 9 OUT OF THE FOG Tuesday, May 15, 2007

DAWE ON EASTERN HEALTH CONCERN: Roger speaks with Peter Dawe, executive director of the Canadian Cancer Society in NL about a concern over the false reports from breast cancer tests by Eastern Health. AIRED: 7:41 DURATION: 10:00 REPORTER: HOLMES/SAMPSON

ER/PR MAY 15-27, 2007

VOCM NIGHT LINE Tuesday, May 15, 2007

EASTERN HEALTH WITHHELD CRITICAL INFORMATION: Host Preamble – The Minister of Health today told the House of Assembly that 40% of women had information about faulty breast tests withheld on legal advice. Faulty hormone receptor tests disqualified scores of women in Newfoundland and Labrador from receiving potentially life-saving treatment for breast cancer. The error rate for a controversial series of tests completed over an eight-year period is much higher than expected. AIRED: 8:24 DURATION: 01:00 REPORTER: LINDA SWAIN

IMPACTED BY FALSE DIAGNOSIS: "Minnie" is one of the women affected by the misdiagnosis. Over 300 women were affected. Many women made decisions that they would not have made. She had her second breast removed to prevent the cancer from coming back. It has been eight years and there is very little she can do. Eastern Health has made it worse. She still does not know what went wrong. It seems they were more interested in covering their own butts than saving women. She said she has had a number of issues with health care. She said she is disappointed with the three Conservative Members of Parliament from this province. She has lost her faith in the Conservative Party of Canada. AIRED: 8:25 DURATION: 07:00 REPORTER: LINDA SWAIN

DOCTOR WITHHELD DIAGNOSIS FOR MONTHS: "Rose Marie" is responding to the issue of Eastern Health Care not passing on details of false reports. She said that in May of 2005 she was tested for major headaches. She was told that nothing was found. It turns out that she had a brain aneurism. She was not told for months about it. She talked about her experience with health care. AIRED: 8:41 DURATION: 07:00 REPORTER: LINDA SWAIN

EASTERN HEALTH RUNNING FOR COVER: Filmmaker "Gerri Rodgers" talks about the way Eastern Health has handled the issue of false test results for breast cancer screening. She tried to get a hold of someone for 8 months. She went to John Ottenhimer and said if she didn't hear from someone in 24 hours, she would make a big fuss. Eastern Health finally called her and said they didn't call her because they didn't want her to worry. 43 percent of the test have come back that they were wrong. Her results were wrong. Newfoundland and Labrador had the highest rate for breast cancer fatality. She questions if the two are linked. Are the pathology labs to blame? Is there a possibility that there were false positives? AIRED: 11:07 DURATION: 09:00 REPORTER: LINDA SWAIN

ER/PR MAY 15-27, 2007

CTV NEWS WEBSITE: May 15, 2007 7:58 PM ET**CTV NATIONAL NEWS May 15, 2007***Affidavit: cancer patients given wrong treatment*

More than 300 breast cancer patients in Newfoundland and Labrador did not receive proper treatment because of incorrect test results, according to an affidavit filed in the province's Supreme Court.

In 2005, the Eastern Health Authority asked Toronto's Mount Sinai Hospital to review 2,000 hormone receptor tests dating back to May 1997, after oncologists found conflicting results in breast tumour samples. According to the affidavit, signed by the authority's risk management consultant Heather Predham, 763 women were given the tests. Of that number, 317 received the wrong result.

Gerry Rogers was diagnosed with cancer in 1999 and lost both of her breasts. She is now one of 47 women suing pursuing a class-action lawsuit against the health authority because of the tests. "There are some women I know who are quite devastated," Rogers told NTV News on Tuesday. "What it has done is basically shaken their faith and trust in the medical system."

Hormone receptor tests determine if a patient is estrogen- and/or progesterone-positive, in which case they may benefit from hormone therapy like Tamoxifen. "There was a group of people out there whose treatment was going to change and they really needed to ensure that happened, and that needed to be

communicated and well understood," said Health Minister Ross Wiseman.

"I appreciate, as well, where they're coming from with respect to the litigation." The 47 women launched their lawsuit last year. Opposition health critic Dwight Ball accused the government of not doing enough to fix problems with the tests or informing the public.

"We think that the public had a right to know," he said. "And we see this government right now with Eastern Health putting the litigation process above the treatments that were necessary."

Peter Dawe, head of the province's Cancer Society, said hormone receptor tests are notoriously complicated. But he still found the number of incorrect results by the authority extremely worrying. "A 42 per cent error rate is almost like flipping a coin," he said.

The authority has refused to discuss the test results while the case is before the courts, but Dawe said the public should be educated about the findings. "Two years ago, we had people contacting us just hysterical -- I mean, literally panicking -- and we went through that process with dozens of people," he said.

With a report from NTV News and files from The Canadian Press

ER/PR MAY 15-27, 2007

CBC NEWS WEBSITE: May 16, 2007 | 9:51 AM NT*Minister defends Eastern Health*

The Newfoundland and Labrador government is scrambling to restore confidence in the provincial health-care system over a controversy involving Eastern Health. Eastern Health said in December that 763 breast cancer patients who had been given hormone receptor tests since 2005 could expect a 10 per cent error rate. The tests determine what kind of treatment for breast cancer a woman receives. On Monday, CBC News revealed that 42 per cent of the test results, involving 317 patients, were wrong. Court documents show that Eastern Health knew in December that the margin of error was higher than was expected. "I understand and appreciate the dilemma they found themselves in and trying to balance the responsibility of the patients who needed change and the responsibility of protecting the interests of the company in the event of a litigation," Health Minister Ross Wiseman said in legislature.

The disclosure of the 317 inaccurate tests would have been more informative, said Wiseman. But he believes Eastern Health has learned its lesson and improved its hormone receptor testing program. "And we shouldn't see a repeat of what we saw last year."

Wiseman said.

Wiseman said just before the December announcement, a statement of claim and an application for a class action lawsuit were filed on behalf of 40 of the 317 women whose tests results were inaccurate. Eastern Health decided to keep the full information about inaccurate tests quiet on the advice of its lawyers, he said. The health of women should have come before any potential lawsuit, said NDP Leader Lorraine Michael. "I think it's immoral. I think it's unethical. Certainly, my confidence in the system is shaken by it. If I were a woman dealing with breast cancer, I think I would not want to deal with our system here in Newfoundland and Labrador."

CTV NEWS WEBSITE/ CANADA AM May 16, 2007 8:14 AM ET*Affidavit: cancer patients given wrong treatment*

More than 300 breast cancer patients in Newfoundland and Labrador did not receive proper treatment because of incorrect test results, according to an affidavit filed in the province's Supreme Court. In 2005, the Eastern Health Authority asked Toronto's Mount Sinai Hospital to review 2,000 hormone receptor tests dating back to May 1997, after oncologists found conflicting results in breast tumour samples. According to the affidavit, signed by the authority's risk management consultant Heather Predham, 763 women were given the tests. Of that number, 317 received the wrong result. Gerry Rogers was diagnosed with cancer in 1999 and lost both of her breasts. She is now one of 47 women pursuing a class-action lawsuit against the health authority because of the tests.

Hormone receptor tests determine if a patient is estrogen- and/or progesterone-positive, in which case they may benefit from hormone therapy like Tamoxifen. "I was appalled at what happened. I heard about the problem with the pathology through the media and any woman who's had breast cancer, that's how we heard about it," Rogers told CTV's Canada AM.

Rogers indicated she had tried to contact health authorities for over eight months and was not provided with any information regarding her condition through this period. Rogers suggested that doctors were not informed either as her own physician was asking her for information on the matter. "The other thing that was kind of alarming was in Newfoundland and Labrador, we have the highest mortality rate for women with breast cancer. Is that linked?" Rogers said.

The 47 women launched their lawsuit last year.

Opposition health critic Dwight Ball accused the government of not doing enough to fix problems with the tests or informing the public. "We think that the public had a right to know," he said. "And we see this government right now with Eastern Health putting the litigation process above the treatments that were necessary."

Peter Dawe of the Canadian Cancer Society, said hormone receptor tests are notoriously complicated. But he still found the number of incorrect results by the authority extremely worrying. Dawe feels the lawsuit should prompt a wider investigation into how breast cancer testing is handled. "I think the pressure has to be on the system in each jurisdiction to say this is a problem," Dawe told CTV's Canada AM. "There is going to be a certain error rate in this particular test, that's my understanding. Is everything being done to keep that a bare minimum?"

Error rate of N.L. cancer tests alarms advocates

Last Updated: Tuesday, May 15, 2007 | 8:05 AM NT

[CBC News](#)

Faulty hormone receptor tests disqualified scores of women in Newfoundland and Labrador from receiving potentially life-saving treatment for breast cancer, court documents show.



Eastern Health announced in 2005 it was retesting samples from hundreds of women.
(CBC)

The documents also show the error rate for a controversial series of tests completed over an eight-year period is much higher than expected.

For almost two years, the Eastern Health regional authority has been grappling with erroneous hormone receptor testing. A class action lawsuit has been filed over the tests, which have involved hundreds of women.

When testing began in 2005, Eastern Health predicted that about 10 per cent of the tests would be wrong. But an affidavit filed by Eastern Health as a response to the lawsuit shows the error rate is actually much higher.

Of 763 patients who tested negative, 317 turned out to have been given wrong results.

"It looks like there was upwards of 42 per cent of the tests results were actually wrong, and that's a pretty startling number," said Peter Dawe, executive director of the Canadian Cancer Society.

"My initial reaction was that I was surprised that the numbers were so high."



Gerry Rogers said she was disturbed to learn of the error rate in hormone receptor tests.
(CBC)

Dawe and other cancer advocates have been lobbying for more information about the hormone receptor tests since the summer of 2005, when Eastern Health arranged with Mount Sinai Hospital in Toronto to retest samples.

According to a February 2007 affidavit signed by Heather Predham, assistant director of quality and risk management with Eastern Health, of the 317 patients with wrong results, 104 patients required a change in treatment.

Of those, 96 were prescribed Tamoxifen, a drug therapy considered one of the best options for blocking the hormones that promote cancerous cell growth.

Gerry Rogers, a St. John's filmmaker who is one of the more than 40 women involved in the class action suit, said she was deeply disturbed by the findings.

"When people are sick and you've had cancer, people are so afraid, you're just so afraid — you automatically think you're going to die," said Rogers.

"So you need to have faith and trust in the medical system, in your doctors, and I really have a lot of respect and trust in the doctors who have taken care of me. But it kind of shakes your foundation when you know it's still a bit of a crapshoot and then this stuff happens," she said.

Eastern Health is not commenting on the testing while the matter is in court. A judge is expected to decide later this month whether the class action lawsuit will proceed.

Eastern Health is not releasing the results of tests that were redone for 176 patients who died since their original tests.

Eastern Health apologizes

*Should have disclosed
more on faulty tests:
Tilley*

BY STEVE BARTLETT

THE TELEGRAM
AND THE CANADIAN PRESS

Eastern Health regrets not disclosing everything about faulty tests that help determine breast cancer treatment.

During a media briefing Friday George Tilley, CEO of the health authority, apologized for not providing all the details of a report into the tests.

He also expressed regret for the confusion caused by the decision to withhold the information.

"It's great to be a Monday-morning quarterback now," he said, "but I confess to you that we didn't (provide full detail). And I apologize for it."

In June 2005, new equipment determined a patient's original hormone-receptor test was wrong.

More patients were then retested with the same result.

Eastern Health decided to review all 2,709 estrogen and progesterone receptor tests back to 1997.

It was discovered tests for 317 people were wrong.

See REGRETTED, page A2

But in December 2006, when Eastern Health released the initiative's outcome, it focused only on the 117 of those patients whose treatment had changed.

Tilley said he regretted the decision not to reveal the extent of the problem.

Gerry Rogers, a patient who later discovered her test result was wrong, said the apology is the first step in healing the emotional wounds patients have suffered.

"I'm happy that finally Eastern Health has come out and at least issued an apology, but it's not enough," said Rogers, who made the Gemini Award-winning documentary "My Left Breast" on her ordeal with breast cancer.

"They have to start speaking directly to people who have been involved ... and it still doesn't explain what has gone wrong"

Peter Dawe of the Canadian Cancer Society would have preferred full disclosure from the get-go, but said he thought Tilley was sincere.

"I think they honestly know that they made a huge mistake in their communication process," he said, "and I really hope they learn from it."

Health Minister Ross Wiseman said it was important for Eastern Health to get the information to the public. Over the past few days, he said, "partial pieces of information" have led to a lot of speculation and "a lot of unnecessary anxiety."

NDP Leader Lorraine Michael wasn't as impressed. She said it didn't seem like Tilley provided much new information. She doesn't think details

will be forthcoming without a judicial inquiry, something for which she and the Opposition Liberals have been calling. Tilley welcomed the idea of an inquiry during the briefing.

Premier Danny Williams has said the province is seeking legal advice on the best way to review the issue.

During the briefing, Eastern Health's Dr. Nash Denic said the authority's hormone-receptor testing is now as good as Canada's best labs — 100 per cent of the results are consistent with Mount Sinai in Toronto.

Dawe said that is "absolutely vital to people moving forward who are going to, unfortunately, end up with breast cancer."

At least 36 of the women who had faulty tests have passed away, although it is unclear how many died from cancer. It is unknown, Tilley said, how many would have benefited from hormone therapy.

He committed to a review of the deceaseds' tissue samples if it would alleviate the concerns of their family.

Tilley stressed the issue is not about breast cancer screening that the hormone receptor tests are done after a diagnosis.

"At no time has there been any question with regards to accuracy of mammograms or biopsies that we would use to assist in diagnosing breast cancers."

Arguments in a class-action lawsuit against Eastern Health by a number of the women affected by the false tests are set to be heard this week.

'Out there'

CIHRT Exhibit P-0015 Page 21

Eastern Health breaks silence on inaccurate breast cancer results

STEPHANIE
PORTER



Eastern Health broke a yearlong silence this week, addressing the media about the results of their decision to re-test nearly 1,000 breast cancer specimens to address possible inaccuracies.

Eastern Health says 117 breast cancer patients were "identified as requiring treatment changes," as a result of the new tests and subsequent case reviews. There is no one issue or

mistake that led to the changes, according to the organization; rather, it was "a systems problem."

The exact number of incorrect results was not released, due in part to a pending class-action suit against the health authority. Meantime, the number of registrants in the class action is growing steadily, with lawyer Ches Crosbie reporting at least three new participants in the past week — raising the total to more than 40.

When *The Independent* broke the story of the inaccurate tests in October 2005, there was a flurry of media appearances by hospital officials. Since then, spokespeople have repeatedly

turned down requests for interviews, deferring any public statements until all test results were in and all patients contacted.

"We were criticized for not being out there in the public," cancer program clinical chief Kara Laing tells *The Independent*. "But we felt that we had to take the time and the energy we had and we had to focus it on the patients and that we couldn't really spend a lot of time out in the broad public arena.

"Until we had the opportunity to meet with and decide what we were going to do with

See "We've made," page 8

'I hope I never have to do it again'

OHRT Exhibit P-0015 Page 22

From page 1

every single one of the patients — although we knew there was the whole element of the public trust — at the time, our main focus was on the patients."

At issue are the outcomes of seven years' worth of estrogen and progesterone receptor (ER/PR) testing, done at the laboratory at the Health Sciences Centre in St. John's.

The tests, conducted on tissue samples from breast cancer tumours, are used to guide oncologists in determining the best therapy for the patient after surgery.

A positive test result means the patient may respond to hormone therapies, such as the drug Tamoxifen — which is taken by mouth and generally thought to carry less side effects than chemotherapy. A negative test result means hormone therapy is not an option.

...

The ER-PR test is not an exact or simple procedure. In 2004, a new semi-automated system, called Ventana, was installed in the Health Sciences Centre laboratory. It replaced the Dako System, a more complicated, manual procedure, involving more than 40 steps.

Nash Denic, chief pathologist of the laboratory program, gave media representatives a tour of the labs last week. From room to room, machine to machine — from watching tiny samples being taken from a kidney tumour to looking through a microscope at treated tissue — he explained the procedure.

"I want to show you the complexity of doing the test," he says. "I hope I don't leave you more confused than before."

Eight million tests are completed in the lab every year, says Denic, of which between 300 and 400 are ER/PR.

Even with the new, more automated system, there are a number of steps, and the end result is a matter of judgment — different doctors may look at the final sample and offer slightly different results.

What constitutes a positive result is also changing. At one time, if fewer than 30 per cent of cells were positive, it would be considered a negative result. That benchmark has fallen in recent years, to 10 per cent, and even down to one per cent — today, an oncologist may decide to use hormone therapy to treat a cancer with any sign of positivity.

"Ten years from now, we might be saying 90 per cent of tumours are positive, where now we say it's 75," says Laing. "The testing may get better, the antibodies may get better. What we know about things is changing all the

time."

...

With all the media coverage this week, lawyer Ches Crosbie — who has filed the application to be certified as a class-action — has received three more registrations from women wanting to be part of the class action suit. That puts the total "in the 40s," he estimates.

"I guess this reminded them of the whole situation," he says. "Well, they're members (of the lawsuit) anyway, in the sense that they're in unless they opt out when notice is given after certification," he says. "But people have been indicating an interest in being in the class."

The suit is being filed on behalf of women (and men) who fall into three categories. First, a large class of people whose retests did not result in any changes — but the process caused the women unnecessary stress and anxiety. That class could be 1,000 or more.

Secondly, he represents those whose initial test were shown to be incorrect, or who may have been offered a treatment that was not ideal, which may have affected the outcome of their cancer.

Third — and this may not be strictly related to the results of the ER/PR tests — Crosbie represents a small group of women who may have had unnecessary surgery.

Myrtle Lewis, who was profiled in *The Independent* last July, had both breasts and a number of lymph nodes removed seven years ago, and underwent months of debilitating chemotherapy. Last summer, she says, her doctor revealed that the review of her file indicated her cancer may not have been as invasive as originally believed — indeed, she may never have needed the double mastectomy. She's not the only one.

"I was contacted by a lawyer for a woman in the same position this week, so that makes three, I guess, who I've been told about," says Crosbie.

"Three people whose pathology was misread as being cancer and who received a mastectomy — but it wasn't cancer in that sense, it was cancer in situ (similar to precancerous cells)."

The problem is wider than the reading of the ER/PR tests, he says.

"It's a problem with pathology and quality control in pathology. And we're arguing that there effectively wasn't any."

Eastern Health is not commenting on the lawsuit.

...

Laing was part of the eight-person "tumour board" (two oncologists, two surgeons, two pathologists, a representative from the quality department and one support person) tasked with reviewing

the complete file of every patient whose specimen was sent to Toronto for retesting — many of whom may now be involved in the lawsuit.

The board met every Thursday night for months, slowly working through the paperwork, charts, and files.

"It was a stressful time because we were worried about our patients," says Laing. "I don't think I would have changed how things happened or unfolded, but it was a lot of extra work."

"It wasn't something that you could just say, 'everybody do this for two months or six months until it's all sorted out,' because this needed to be done in addition to the regular day-to-day work and new patients ... I hope I never have to do it again."

Oscar Howell, the new vice-president of medical services for Eastern Health, says the past year has been "pretty stressful for (medical staff), as it was for cancer patients." He keeps his tone optimistic though, touting advances in cancer diagnosis and treatment, and the strength of the doctors — if not the quantity.

"We do have a shortage of pathologists now, and that concerns me greatly, and we are trying to recruit additional pathologists," he says.

"If there's good that came out of it, it's that this will allow us to make this part of the lab the best it can be ... and if we can take the learning from this and extrapolate that back through our entire laboratory, I would hope that we would make it so good we will attract a lot more people."

Looking back on the media presentations and interviews she participated in this week, Laing says she found the process "difficult," adding that she found the tone "demanding, accusatory, like there's some big thing we're hiding from everybody."

Laing maintains there is no big secret being protected from the public's always critical — and often cynical — eyes.

"(We've) made the lab better," she says. "We have a core group of people doing things in the lab; you now have stability in the oncology workforce. You now have people who are paying attention, not just to this, but to all things that are happening — so if things start to appear out of sync, you can look at it now."

"It really was a systems problem and we've done everything we can to fix the problem and we hope other labs learn from this."

The lab at the Health Sciences Centre will start conducting ER/PR tests again in an estimated two months.

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From the beginning: the chronology

GHRT Exhibit P-0015 Page 23

May 2005: The first evidence surfaces that an estrogen/progesterone receptor (ER/PR) test had given a false negative, according to Eastern Health. An oncologist was treating a breast cancer patient, and "given the nature of this woman's cancer, her age and other factors, the oncologist requested the test be repeated," states Eastern Health. The new test, using updated technology, converted to a positive result.

Five more negative patients are retested — all also converted.

June 2005: Medical staff decide to retest all negative results from 2002 to determine if the cases were isolated. All labs in the province are asked to send specimens to St. John's for retesting.

Over the next two months decisions are made to retest all ER/PR negative patients as far back as 1997, and that an external laboratory — Mt. Sinai Hospital in Toronto — should conduct the tests, according to Eastern Health. Almost 1,000 specimens would be sent off.

Early October 2005: The first set of results arrive from Mt. Sinai, according to Eastern Health. As results become available, patients are contacted, one by one.

October 2, 2005: *The Independent* learns about the retesting, and brings the story to the public's attention for the first time. Other local and national media follow.

Dr. Kara Laing, cancer program clinical chief with Eastern Health, speaks with *The Independent*. "The reason we haven't gone public with this is we don't have all the answers," she said. "The last thing you want to do or we want to do is make people afraid ... is to cause some sort of mass hysteria."

Eastern Health purchase advertising to inform the public of the retesting. Patient relations officers begin calling all patients who had been retested.

(In an interview this week, Laing says there were "hundreds of patients contacts and encounters," and many times that number in incoming phone calls. "There was a lot of anxiety, a lot of phone calls, a lot of meetings to be arranged — not just breast cancer patients who had a change, but all the breast cancer patients ... then there were other cancer patients calling in, 'should I be concerned? Does this affect me?'")

October 2005: According to Eastern Health, a tumour board is set up to review the complete medical file of every patient that had been retested, as

the results arrive.

The external review process of the laboratory at the Health Sciences Centre begins.

January 29, 2006: A spokeswoman for Eastern Health confirms to *The Independent* the retest results are in — but declined to make a public statement until all patients had been contacted.

"I think as soon as they knew that something was wrong, they should have told us immediately," filmmaker and breast cancer survivor Gerry Rogers told *The Independent*. "They should have done it immediately and explained what they did and didn't know, because we're not children. We're health-care consumers, and this is a system that we all own."

February 5, 2006: A follow-up story in *The Independent* reports on what appears to be the first attempt by a breast cancer patient to sue Eastern Health over the ER/PR test results.

A lawyer filed a statement of claim on behalf of Michelle B. Hanlon of Mount Pearl, alleging the cancer that cost her both breasts and later spread to her lungs, liver and brain could have been stopped or slowed if she had received the correct ER/PR test result.

Although more lawsuits are predicted, an Eastern Health spokesperson confirms, "as of right now at this moment in time, (Hanlon's) is the only lawsuit that I'm aware of."

February-May 2006: Armed with all the retest results, the tumour board makes a "concentrated effort ... to review results, write recommendations and conduct disclosures," according to Eastern Health. The organization allows the subsequent six months to offer all patients an opportunity to discuss with their physicians.

"My clients feel there are many women out there who are upset and feel that they'd like to do something legally or they'd like to have a remedy or they'd like to know what happened."

Myrtle Lewis

July 30, 2006: *The Independent* publishes a story about Myrtle Lewis, a breast cancer survivor, and her lawyer, Ches Crosbie. In the late-'90s, Lewis had both breasts and 11 lymph nodes removed, and underwent months of chemotherapy, which she says stripped her of energy, compromised her immune system, and left her sensitive to sunlight and many chemicals.

On July 5, she was contacted by the hospital and went in for a meeting. She was told medical staff had determined her cancer was "in situ," a less invasive and more localized form of breast cancer than her original diagnosis. Her specimens were among the hundreds that were retested.

Lewis joined a number of other women who are part of a class action lawsuit against Eastern Health, filed by Crosbie.

"My clients feel there are many women out there who are upset and feel that they'd like to do something legally or they'd like to have a remedy or they'd like to know what happened," he says.

"It's a problem with pathology and quality control in pathology. We're arguing that there effectively wasn't any."

Oct. 13, 2006: Ches Crosbie files papers asking for certification as a class. At least 39 women have signed on to be part of the suit.

November 2006: Eastern Health completes its quality review process.

Dec. 11, 2006: For the first time in more than a year, Eastern Health representatives speak to the media. A technical briefing is provided, as well as a tour of the immunohistochemistry lab.

Oscar Howell, vice-president of medical services says 939 negative tests were sent to Mt. Sinai for retesting. Although the conversion rate is not released, he does state that, after all files had been reviewed, 117 patients "had been identified as requiring treatment changes." In some cases, a changed ER/PR result was the cause of the change; in other cases, there were other factors involved.

Dec. 15, 2006: The defendant's (Eastern Health) materials are due to be filed in court. A date will then be set for the argument to determine if the case will be certified as a class action and proceed as such.

— Stephanie Porter

Newfoundland launches inquiry into faulty cancer tests

BY TARA BRAUTIGAM ST. JOHN'S

In a bid to restore public confidence in its beleaguered health-care system, the Newfoundland and Labrador government announced yesterday it will establish a judicial commission of inquiry to determine why more than 300 patients received the wrong results from botched breast cancer tests.

"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," provincial Health Minister Ross Wiseman told a news conference.

"In the interests of openness and transparency, we feel that this is the only way to be able to make a full public disclosure of what exactly took place here, and more importantly, what can we learn from this."

The independent commission will be established by the

provincial cabinet under the Public Inquiries Act and will have the authority to subpoena witnesses.

Cabinet is expected to appoint a commissioner and set the terms of reference within the next several days. The commission would examine, among other things, what went wrong with the tests, why the problem wasn't detected sooner, and whether authorities responded in an appropriate and timely manner, Mr. Wiseman said.

"A lot of good can come from this," said Gerry Rogers, a patient who later discovered her test result was wrong and made the Gemini Award-winning documentary *My Left Breast* on her ordeal with breast cancer.

"This has been a long time coming and I think that this is really necessary in terms of clearing up any confusion. There are so many people who are afraid, who aren't clearly

understanding what's going on."

In August, 2005, the Eastern Health Authority arranged for Mount Sinai Hospital in Toronto to redo more than 2,000 hormone-receptor tests going back to May, 1997, after oncologists discovered inconsistent results in breast tumour samples.

From October, 2005, to February, 2006, the authority received the results of the retests. While the 317 patients whose treatments were changed were notified soon after of the results, the rest of the 763 weren't.

At least 36 patients in Newfoundland and Labrador who received the wrong test results have died, though it remains unknown how many died as a result of their cancer.

George Tilley, CEO of Eastern Health, apologized Friday for the "confusion" that ensued when the organization failed to fully disclose what it knew

about the widespread inaccuracies with the hormone-receptor tests.

The tests are considered critical in evaluating a breast-cancer patient's treatment because, if patients are found to be estrogen- and/or progesterone-positive, they may respond to hormone therapy such as Tamoxifen.

If not, they may be given other treatments, such as chemotherapy.

At least 80 patients are in the process of launching a class-action lawsuit against Eastern Health. The suit will be argued in a St. John's court.

Medical experts acknowledge there is a degree of uncertainty in assessing the test results, but Eastern Health officials including Mr. Tilley say they're unable to explain how so many tests in the province were wrong.

In a separate controversy that has beset the provincial health authority, Mr. Tilley an-

nounced the suspension of a radiologist whose work at the Burin Peninsula Health Centre was questioned by staff in February.

"Some staff called to say they weren't comfortable that some of the procedures he was using were consistent with standard practice, and that some of the decisions or interpretations that he was making were inconsistent with what they felt was the right outcome," Mr. Tilley said. "We've definitely seen some evidence of some errors, and I guess we've got to check now whether that was isolated or whether in fact it's more widespread."

The authority is now conducting a review of 6,000 reports the radiologist conducted on 3,500 patients since he was hired in November. He has been suspended since May 10, but Mr. Tilley said he could resume duties pending the outcome of the review.

NEWS



Last updated at 8:29 AM on 24/05/07



Lawyer Richard Rogers is looking after a handful of the cases involving breast cancer testing, including that of his sister Gerry Rogers. — Photo by Jamie Baker/The Telegram

Family matters 🚗

Rogers family tackles personal, legal issues associated with breast cancer controversy

JAMIE BAKER

The Telegram

After nearly 20 years as a lawyer, Richard Rogers is used to representing victims. But he never thought his own sister, outspoken breast cancer survivor Gerry Rogers, would be one of them.

Richard is among the handful of lawyers representing breast cancer patients who have been affected by faulty hormone receptor tests carried out by Eastern Health between 1997 and 2005.

Gerry is one of the best recognized breast cancer patients in the province, highlighted by her ground-breaking film about her own ordeal, "My Left Breast."

Now, she's one of Richard's clients.

"This, for me, is so close to home," Richard admits when asked about balancing his role as a lawyer and as a brother.

"I'm used to representing underdog victims against big groups or corporations. Now, I'm representing my own sister in a similar capacity ... it's really strange."

Eastern Health recently apologized after it was revealed that 317 out of 763 tests carried out over the eight-year period were done in error.

On Wednesday, St. John's lawyer Ches Crosbie was in court seeking certification for a potentially massive class action against Eastern Health (See story, page A2).

With statistics indicating that, by 2020, one in three Canadians will be diagnosed with cancer in their lifetime, Gerry says it is crucial the current case results in an improved system that patients can trust.

"I want to know what happened — this is not about revenge," she says, using the word "disappointment" to summarize how she feels about the way the testing issue was handled by Eastern Health.

"They have spoken to the media, they have spoken to the MHAs. Now they need to speak to us, the women who are affected," she says.

"We need clarity and transparency. This is our health-care system, not somebody's corporation."

Richard remembers being in provincial court, working a case, when he learned of his sister's breast cancer diagnosis some 10 years ago.

"My mother told me about it, and said it was serious enough they had to do surgery right away," he recalls. "That was very unnerving because we're a very small, close-knit family."

It was the first time someone in his family would meet cancer head-on.

But it would not be the last.

Mother, sister diagnosed

After Gerry's diagnosis, she encouraged their mother and sister to get tested. The results from those tests showed both women were advanced to the point where they, too, were developing breast cancer.

"All of them had their breasts off," Richard says. "It all happened very quickly."

While his sister is well-versed in matters surrounding the plight of women facing breast cancer, Richard said he is happy to add the title "legal advisor" to his ongoing "supportive brother" role.

"Anybody who knows who I am knows I'm a really touchy-feely-type lawyer, so some people in this kind of suit often find that to be a bit more supportive," he says.

Richard had previously dealt with specific women's health issues, such as litigation involving women who had suffered side-effects associated with having silicone breast implants.

But he suggests nothing could likely compare to the pending breast cancer testing matter.

"We're not talking about people that have suffered some moderate side-effect. We're talking, in some cases, about life or death," he says. "Imagine all the people who were given a clean bill of health and were wrongly treated, or the people who didn't have cancer at all who were put on chemotherapy."

In addition to court action, the province has also announced there will be a judicial inquiry into the matter to find out what went wrong.

Richard believes such an inquiry could carry explosive potential.

"What if it goes beyond the 1997 to 2005? What about other cancers?" he says. "As it stands now, the government should have a healthy fear with an inquiry because the liability exposure could be even greater than what they believe it is right now."

Standardized labs needed

Gerry says, if nothing else, the controversy shows it is high time labs become standardized across Canada, much like they are in Europe.

Although she uses the word "compassionate" to describe the care she received throughout her battle with breast cancer, she also insists the testing problems shows that governments need to pay more attention to health care as a whole.

"I hope this will be the wake-up call as to how important our health-care system is," she says bluntly. "We need more resources, more money, more personnel and more training directed into our health-care system."

"Our health-care system has been chipped away. Some of the things we are seeing now are a symptom."

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