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TERRY MILEWSKI: For many Canadians, a diagnosis of cancer is just the beginning of a fraught medical journey. Sometimes surgery is involved, sometimes painful procedures involving drugs, and radiation. No matter the prognosis, many take whatever treatment they believe will buy them more precious time with loved ones. But what if you found out that the journey had been unnecessary, that you didn't have cancer after all? And that the tests that put you on that course were faulty and just plain wrong? Well, that is the shocking news that some women in Newfoundland and Labrador have recently received. First some background. Between 1997 and 2004, tissue samples from about a 1000 breast cancer patients were tested at a pathology lab in the province's largest hospital. There were some concerns over possible inaccurate results. So the Eastern Regional Integrated Health Authority, that's the board that oversees the hospital, began sending thousands of samples out for retesting to Mount Sinai Hospital in Toronto. Well, the retest results were alarming. Mount Sinai determined that between ten and twenty percent of the original tests were inaccurate and one of the most dramatic errors was discovered in Myrtle Lewis's file. Last month, the 59 year old from Conception Bay South was told the harrowing diagnosis she received seven years ago was indeed inaccurate.

MYRTLE LEWIS: My family doctor called my husband and said she wanted to see me. And she said, Myrtle, she said, you got cancer in your right breast. She said you got a lump in your left breast. So she said I'm going to set up an appointment with, for the surgeons, she said, right away. I went to the surgeon, me and my husband, she talked to me and told me that I would have to have my right breast off and that we could discuss, me and my husband, before I decide what I do with the second one, right? I thought about my children, like I said, I thought about my family. She asked me what decision did I made, I said well I'm going to have two of them off. She said Myrtle, I'm glad you made that decision because she said three to six months down the road, you would have had that other one off anyhow. So I had my surgery on Friday, June 18th. Monday morning, my son came out to see me and I was ready for home. So I went home and I was pretty good while they were around. But then when they left and went home is when the pain started. I mean, I had, like I had a long mirror in my bathroom at the time. I'd go in, I'd get in the shower, I'd get out, I'd look at myself and I'd cry and I'd cry. And I used to say to myself then I got to get over this, this is something I got to fight. I got to beat this before this beats me. After that, they called me in into the cancer clinic and they sat down and they told me that I had to have six months of chemo because the tumor they took out of my breast was 1.5 centimeters. I do the chemo, I had the bag with me, before I get to the car, I'd be throwing up. I'd get home, I'd be in the bed three days. Then, I mean, I would just be getting over it when it was time to go back and get it again. I was six months like that. I mean, for seven years I was fighting the battle I had cancer and I was surviving it, I was a survivor. First thing, time I heard it on the news, and that was in February month. So I decided I was going to call the cancer clinic so I called. A week before the 5th of July they called me and they set up the appointment for the 5th of July. Never did I think when I went in and sat down to the oncologists that I was going to get the news I got. He looked at me and he said Myrtle, he said, we got good news and bad news. And he said the good news is you're not going to die of breast cancer because you didn't have it, you only had



pre-cancer cells. The bad news was he said I done, you done six months of chemo that you didn't have to do, you had eleven lymph nodes taken out of your right arm that you didn't have to have done. If somebody shot me and put a bullet in me I would still sit straight, I wouldn't have, I wouldn't have fell down. I mean, it just, I just couldn't believe it. I mean, if I knew I only had pre-cancer cells, do you think I would have had my two breasts off and... and have my dignity taken from me like I am? No self-confidence anymore. It hurt, you know, to know that... that somebody could make this mistake. I hope that this person or persons that made this mistake, I hope they feel good getting up in the morning, looking at their self. Because I sure don't feel good looking at myself.

TERRY MILEWSKI: That is Myrtle Lewis of Conception Bay South, Newfoundland, what a story. Joining me now is Ches Crosbie, the St. John's lawyer who filed a class action lawsuit on behalf of Myrtle Lewis and about half dozen women involved in breast cancer retesting. He's in our St. John's studio. Good morning.

CHES CROSBIE: Morning, Terry.

TERRY MILEWSKI: Mr. Crosbie, can you tell us a little bit about who your clients are and what kind of things they're claiming?

CHES CROSBIE: We brought the suit on behalf of what we thought would be three classes of women. Myrtle is in a class which we suspected existed but three people have come forward to our office now who are in basically the same position. In other words, they had received a diagnosis of breast cancer and received more extensive surgery than they ought to otherwise and... and also chemotherapy when they shouldn't have received that at all. And they've also had to live with, for some years in Myrtle's case, the concern that, you know, you've had breast cancer, you needed chemotherapy, they give you that because they think that some of the malignant cells may have escaped to other parts of your body, metastasized. And so they've also had to live with the fear that they may get a recurrence of cancer. And now it turns out not to be so. There are other, there are two other classes as well which I can describe to you.

TERRY MILEWSKI: Please.

CHES CROSBIE: Well, one is the larger class. What's happened is the health care facility here that looks after cancer for the province discovered because some women were not responding the way the treating oncologist thought they ought to. They went back and they looked at their pathology and discovered that they were getting readings that women were positive or negative for hormone receptor status. In other words, the cancer needed estrogen and progesterone to grow and based on that, particularly for the post-menopausal category of women, they determined whether someone would receive chemotherapy or would receive something less intrusive like Tamoxifen. And they were getting one treatment regime or another and not reacting the way that the oncologist thought they ought to. So from there it seems they discovered a much larger problem and ended up sending about a thousand specimens to Mount Sinai in Toronto for retesting. And this covers a period from 1997 basically to the present.

TERRY MILEWSKI: So how many women are we talking about in all? I mean, there must be many more than just the ones that you're representing.

CHES CROSBIE: Yes, there'd be about a thousand women in that, in that class of women who,



most of them now their receptor status has not changed. We estimate, however, about thirty to sixty women, this is only an educated guess but something like that, out of a thousand women that would appear received chemotherapy which lasts for four months, six months and is pretty unpleasant as I guess many of us know. Some of us have been through it, some of us know people who've been through it. And it seems they need not have received it in the first place. That's about thirty to sixty women, the larger class of a thousand people who found out in the news media that their specimens were being, tissue specimens were being retested. And had to live with the fear and uncertainty for some time before they had it confirmed one way or the other that their diagnosis remained unchanged or, or that it differed from what they'd received originally. And they had to live with the mental distress and loss of faith in the health care system that went with that and still have to live with that.

TERRY MILEWSKI: Now how exactly, do you know, how did these misdiagnosis happen? What went wrong at the lab?

CHES CROSBIE: We don't know exactly, although if we become certified as a class action, we'll have rights of discovery and we'd be able to find that out. But I've consulted with cancer specialists in pathology and oncology and reasonably sure that one of the main problems is that there's no proper system of quality control at the hospital.

TERRY MILEWSKI: How exceptional is this case then or are many others like it?

CHES CROSBIE: Well, Terry, I couldn't tell you that, I only know a bit about the one here in Newfoundland. It may be unusual, I hope it is. Here in Newfoundland, we also have a bit of an issue whereby our pathology people are paid less than they are elsewhere in the country. And that makes it more difficult to attract and retain top quality people. Now at the same time, we have many excellent people in pathology. But we're, we have a bit of a special situation whereby we have some people who haven't achieved their national examinations. And so there may be a breakdown in certain places with the... the standards that some of the pathologists have obtained and their competence in reading these samples.

TERRY MILEWSKI: All right maybe you could conclude by telling us what your clients are seeking exactly from this lawsuit and where we stand, what happens next with the case.

CHES CROSBIE: Well, the first thing we have to do is get certified basically. And after that, that means that people who might not otherwise be able to take claims, now Myrtle might have a claim that could stand alone without a class action, but there are others who couldn't proceed for a remedy and wouldn't have access to justice, unless they could aggregate their claims. And that's what a class proceeding is for. So if we're recognized as a class proceeding, then we go on, we do discoveries; we obtain, hopefully, the true facts of what went wrong here. And maybe one good thing coming out of all this is one of the recognized aims of the class action which is behaviour modification for defendants. Maybe some improvements will be made to the system on a permanent ongoing basis.

TERRY MILEWSKI: Mr. Crosbie, thanks very much. Ches Crosbie is a St. John's lawyer; he represents a number of Newfoundland and Labrador women who had their breast tissue samples retested by Mount Sinai hospital in Toronto.

TERRY MILEWSKI: As shocking as a misdiagnosis can be, my next guest says we should not be



all that surprised by these kinds of mistakes. Dr. Philip Hebert is a physician, a bioethicist and the chair of the Research Ethics Board at Toronto's Sunnybrook Hospital and he joins us in our Toronto studio. Good morning.

DR. PHILIP HEBERT: Good morning sir.

TERRY MILEWSKI: Dr. Hebert, what is your reaction to this case?

DR. PHILIP HEBERT: Well it's a terribly tragic case tied to sort of circumstances. Unfortunately, as you mentioned, it's not at all rare, this does happen from time to time. Pathology is not an exact science; it does require some work of interpretation and there are not always agreed upon standards when it comes to diagnosing particular malignancies.

TERRY MILEWSKI: So how common is it to find misdiagnosis of breast cancer for example?

DR. PHILIP HEBERT: Breast cancer in particular, I'm not sure exact statistics about that, but pathology samples generally, about ten percent of the cases have turned out to be a false diagnosis, not all resulting in harm of this magnitude, most don't result in harm of this magnitude. It may result simply in redoing a sample or retaking another tissue sample, but about one percent of the ten percent of cases result in the severe harm such as this case.

TERRY MILEWSKI: So if that's known, then how common is it to retest samples as they did in this case?

DR. PHILIP HEBERT: Well in the past it didn't used to be that common. Increasingly with quality assurance programs and people being aware of the errors being made and the consequences of it, it's now more common to retest samples than it used to be, but really it varies from institution to institution, province to province, country to country how often that's done.

TERRY MILEWSKI: Now is there anything specific about cancer screening specifically that might help us understand why these mistakes are made?

DR. PHILIP HEBERT: Only that cancer is not a thing separate from normal cells. Normal cells, cancer cells that is a gradation of irregularity and it isn't that there's a bright line that you can distinguish this normal cells from the abnormal and the normal from the cancerous so it's not always obvious how these diagnosis are made.

TERRY MILEWSKI: Now the retests so far have indicated that ten to twenty percent of some thousand patients in this case may have been misdiagnosed and I'm wondering how this rate of error compares to the national average when it comes to diagnosis generally, not just cancer.

DR. PHILIP HEBERT: Well we know that about one in thirteen patients, or about eight percent of patients, are harmed on account of medical care. So really the ten percent or so is not that different than what we're seeing already in medical care generally in Canada. Nobody has looked at pathology as a whole in Canada, but certainly the statistics from this one small thing, sample from Newfoundland, is similar to what's been found in other countries. About ten percent rate of error is not at all unusual. Twenty percent is a little high, but ten percent is pretty. . .



TERRY MILEWSKI: So what's an acceptable rate? Is there an acceptable rate?

DR. PHILIP HEBERT: Well of course there is an acceptable rate. This is far too high, nobody has said what an acceptable rate is, but if you think about it, if you do, even if you've got a 99 percent accurate test, if you're doing a test on thousands of people, millions of people, it's going to result in a significant number of numbers being harmed. It's estimated that passengers for example, which are connoisseurs of air, result in about 15,000 misdiagnoses a year in Canada and that's a tremendously high number, obviously far too high.

TERRY MILEWSKI: Now what kind of, so you're familiar with this, you know that this sort of thing happens all the time, so what kind of protocols are there in place to avoid them, deal with them when they happen?

DR. PHILIP HEBERT: So there's two types of ways in dealing with it. One is to improve the sampling process and the other is to improve the interpretation process and various societies, like the concern with oncology, have addressed this by trying to adopt standards, agreed upon standards that interpretation won't be so much dependent upon the interpreter so ensuring that there is a two step process of interpretation, a validation by a second person looking at the sample, providing guidelines, standards for what would be considered to be a malignant diagnosis. So attempting standardization is really the process in place at the moment.

TERRY MILEWSKI: Now this particular case that we've been talking about today in Newfoundland and Labrador is pretty shocking. Have there been similar cases though in the past?

DR. PHILIP HEBERT: I was just reading of one that had to do with testing which depended upon a particular laboratory testing, a young woman of 22 ended up having a hysterectomy and went through chemotherapy and a tremendously harmful process as a result of one lab test that was, in fact, due to, which was performed faulty 40 times. She was awarded \$32 million in a court in the United States.

TERRY MILEWSKI: Forty times?

DR. PHILIP HEBERT: Forty times, astonishing, because it had to do with her own immune system and she produced an antibody that interacted with this particular test, producing a false result each time and the doctors were treating, chasing a symptom of the laboratory test and treating the patient appropriately and the courts were quite unforgiving of the physicians and the medical system involved.

TERRY MILEWSKI: What should patients then be looking out at, is there anything patients can do to look out, to inform themselves when they're getting these kinds of tests?

DR. PHILIP HEBERT: You know it's interesting and it's, pathology is so separate from what patients are normally concerned with. I mean they don't see the pathologist. The pathologists are behind the scenes. I suppose you'd want to know from your hospital how often do you see this diagnosis, how experienced is your pathologist, what quality assurance programs does your hospital have in place to look at these issues?

TERRY MILEWSKI: The patient is not really equipped to ask all of those things and. . .

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DR. PHILIP HEBERT: Well you're right, but I guess any time you go in the hospital for anything it's always good to have someone else with you. If something doesn't fit with how you feel or it doesn't seem right to you, question it, ask if there's anyone else that can be involved in the process. It is difficult, but I think if you don't come armed with extra help you may be more vulnerable.

TERRY MILEWSKI: So, in a way then, we've all got to kind of just accept that are limits to what we can expect from medical professionals, right?

DR. PHILIP HEBERT: Well I think we have to understand that medical professionals are facing a difficult time as well; they don't always the resources they'd like to have to do the kind of quality assurance on their, in their particular field. So, I think, try to sympathize with the health professionals. We are trying to do the best possible. Nobody wakes up in the morning thinking about who they can harm that day; harm is the last thing we want to do.

TERRY MILEWSKI: Thanks doctor very much. That's fascinating stuff.

DR. PHILIP HEBERT: Thank you.

TERRY MILEWSKI: Dr. Philip Hebert is a bioethicist, physician and chair of the Research Ethics Board at Toronto's Sunnybrook Hospital.