COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

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Labrador-Grenfell Regional Integrated Health Authorities

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DR. KARA LAING, EXAMINATION BY SANDRA CHAYTOR, Q.C. (CONT'D)

THE COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Good morning, Commissioner. Good morning, Dr. Laing.

DR. LAING:

A. Good morning.

CHAYTOR, Q.C.:

Q. If we could have, please, P-2610? Doctor, this is a PowerPoint presentation and I understand you're going to take us through this. I understand you gave a version of this presentation dealing with--or throughout the ER/PR issue. Do you recall when that would have been? When would you have given this presentation?

DR. LAING:

A. This was a presentation that I initially gave in November of 2006 and that was to the medical staff. So it was the pathologists, laboratory personnel, oncologists and surgeons from across the province. We did it as a teleconference and that was in November of

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2006, in preparation for the media briefing, which was to occur that December.

CHAYTOR, Q.C.:

Q. Okay, thank you, and then perhaps you could just continue on then and take us through the presentation.

DR. LAING:

A. Shall I advance the slides then myself?

CHAYTOR, Q.C.:

Q. Sure, you can do that.

DR. LAING:

A. Okay. Well, first of all, I'd like to thank you for letting me do this presentation at this time. I thought that it may be valuable to go through the same information that I would--that I presented then and that I would present to patients in the clinic, really to try and help people understand the rationale for hormone therapy for breast cancer, and I thought it was important that we just highlight the epidemiology of this disease and to talk about the difference between adjuvant therapy and treatment for metastatic breast cancer, and talk about the various ways we now have in the clinic to target the hormone

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receptor and to explain, if you will, how things have changed over the years, in terms of treatment of patients with hormone receptor positive breast cancer. When I gave this presentation initially in November, I had included some discussion of the impact that this had on clinical management, and I thought it was important to leave that as part of this presentation and go through that at the end.

The incidents of breast cancer has continued to increase in this country over the last several years, but we're happy to report that mortality has decreased and the decline in mortality is due to improvement in adjuvant therapies, but also to improvement in screening, and we feel that about 50 percent of the improvement is from each of those. We've had a steady increase in the incidents of breast cancer in this province and in 2007, based on the Canadian Cancer statistics, we saw 370 new cases. This would include invasive cancers of all histologies, as well as in situ cancers, and this number certainly has increased. This is a slide that I often use in breast cancer presentations and I

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update it every year, and you know, back in 2000, the number would have just been breaking 300 at that time. So as you can see, there's certainly been a steady increase.

This is the 2006 statistics, and I think it's interesting because you can see that if you go from west in British Columbia to east, that the incidents of breast cancer is similar and varies by province, but if you look at mortality, then the outcomes are actually better in the rest of this country and worse in the east. Part of that reason may be explained by an older, more established screening and treatment program as we alluded to yesterday in our discussions.

When we talk about the treatment of breast cancer, there's really quite a continuum of care. I include here early breast cancer and advanced breast cancer, but if you think about it, really you can go even to the left of the screen and that's where you would place prevention and screening. But the core of what we do within cancer care programs would be to provide treatment for early stage breast cancer, which includes adjuvant

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treatment, that we'll talk about in a minute. Neo-adjuvant simply refers to treatments that are given prior to definitive surgery and extended adjuvant is a term that we use to talk about treatment beyond five years from initial diagnosis. In advanced or metastatic breast cancer, we talk about lines of therapy, and the first therapy that a patient would receive would be first line, second line, third line and so on.

This is a summary of hazard rates which look at the probability of recurrence at each year after initial diagnosis. This is a summary of several different graphs for various patient population, so premenopausal, post-menopausal, those that had chemo, who didn't, had hormonal therapy, didn't, and what we can see is that there is an early peak in recurrence of breast cancer in the first three years, the first two to three years, but that unlike other malignancies, at the five-year mark, the risk of recurrence of breast cancer does not go away. It's less, but it does not go to zero, and in fact, we often see patients who recur in the five to ten-period, and even,

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I have patients in my practice who have recurred 20 and 30 years later.

For patients with hormone receptor positive disease, it's felt that about 60 percent will recur in the first five years, but up to 40 percent may have a recurrence in the five to ten-year period, and this is the reason for the trials looking at treatment beyond five years of Tamoxifen, and this, of course, was a factor that played into our decision about treating patients who may have been more than five years from their initial diagnosis when their new ER/PR test results were available.

When we look at various factors about breast cancer, we divide them into prognostic factors and predictive factors. The most important prognostic factors in breast cancer are, number one, whether or not there's lymph node involvement. The second is the size of the tumour, the grade, with poorly differentiated tumours having a worse prognosis. And the histology, with some less common histology such as tubular, medullary cancers having a better prognosis.

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Lymphovascular invasion, which means the presence of cancer cells in the tiny blood vessels and lymph vessels surrounding the tumour is also known to be a marker for increased risk of recurrence.

Younger patients with breast cancer have a worse prognosis and ethnicity is felt to play a role as well, and in the U.S. population and U.S. studies, there's certainly evidence that African American women have a worse prognosis with this disease.

Prognostic factors are something that tell you how someone is going to do with their disease, irrespective of what treatment that they receive. These are the things that are important in breast cancer. For example, in lung cancer, weight loss is a very important prognostic factor. If we see a patient who's lost more than ten percent of their weight, then we know that they have a worse prognosis, even if they have the same stage, same diagnosis as another person who hasn't lost weight. A predictive factor, however, is something that tells you how likely somebody is to respond to a certain treatment, and in

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breast cancer, the predictive factors that we use every day in the clinic are estrogen and progesterone receptors, the hormone receptors, and HER2 expression.

CHAYTOR, Q.C.:

Q. And wouldn't ER and PR status also be a prognostic factor?

DR. LAING:

A. It's a very weak prognostic factor. So if you look at what's called a multi-variant analysis or if you put all these things into the equation, the ones that come out most strongly are the ones that I have listed there, and so we really consider ER/PR to be a weak prognostic factor, but more so a predictive factor in this disease.

CHAYTOR, Q.C.:

Q. Okay, thank you.

DR. LAING:

A. So adjuvant therapy are additional treatments that are given after potentially curative surgery. So we talk about this in breast cancer. The same is true in lung cancer, colorectal cancer, and we know that in a certain number of patients that we see with

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breast cancer, that they have a chance of this disease coming back and recurring somewhere outside the breast. The most common places are the lungs, the liver and the bone, and in order for that to happen, then there must be cells at the time of the initial diagnosis that get away from the breast cancer primary that's removed by the surgeon, that get away from the lymph nodes that are removed by the surgeon and are there, and so the goal of this adjuvant therapy is to get rid of those, to kill those cells before they have a chance to spread and grow and cause metastatic disease.

Unfortunately, we don't have any special blood test or x-ray or scan when we see a patient. We can only estimate the probability of them having micrometastatic disease, based on their prognostic factors.

So the goal of these treatments, and how we know that these work is that we see a decrease in recurrences and we see an improvement in overall survival, and that's often a question that the patients ask me in the clinic. "Well, how are you going to know that this is working?" Because we don't do

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scans for this. We don't do special blood tests. And we say "we'll know over time when we see what happens."

CHAYTOR, Q.C.:

Q. And do you keep track of, here in your clinic, recurrence rates and survival rates, overall survival rates? Is there any tracking or any measurement of that, in terms of your patient population?

DR. LAING:

A. The only data that we would have would be what would come from our registry and what we get from the statistics from the Canadian Cancer Society, because we don't have a specific database. It's more difficult for us to track that. And recurrence is not something that's as easily captured by the tumour registry, because recurrence in breast cancer is most often a clinical diagnosis, although we're trying to capture that better.

CHAYTOR, Q.C.:

Q. And that's something you spoke about yesterday, in terms of looking at a database such as what was used in BC when you trained there?

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DR. LAING:

A. Yeah. The fact that lymphatic and vascular invasion is an important prognostic factor came at looking at that information in the BC breast cancer database. They were able to go back and identify patients who had that feature and then they could follow them. You know, they had this follow up over many years and were able to show that to be a negative prognostic factor.

So in terms of the types of adjuvant therapy that we offer patients, radiation therapy is part of the local control of breast cancer, so surgery and radiation. And then in terms of the systemic therapies or the drug therapies, they include chemotherapy, targeted therapy, which now includes the--okay, do you want me to -

CHAYTOR, Q.C.:

Q. I'm sorry, Doctor. Go ahead.

DR. LAING:

A. So targeted therapy, which includes Herceptin or trastuzumab, which we've had for metastatic disease in the clinic since 1999 and since 2006 for adjuvant treatment, and hormonal

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therapy. But really, when you think about it, hormonal therapy is the oldest targeted therapy that we've had in breast cancer treatment, way back to the 19th century when somebody's ovaries were removed and it showed that they responded.

So currently, we use adjuvant hormonal therapy for patients with hormone receptor positive disease. It is currently given to both pre and post menopausal patients, and prior to 1998-1999, it was only therapy offered to post menopausal patients.

CHAYTOR, Q.C.:

Q. And was that true across the country?

DR. LAING:

A. Yes, and it's given after adjuvant chemotherapy. So if we determine that a patient requires both adjuvant chemotherapy and adjuvant hormonal therapy, the hormonal therapy is given afterwards, and that's because of some trials that suggest a better outcome than if you give the two concurrently.

CHAYTOR, Q.C.:

Q. And are there any circumstances in which it would be given prior to the chemotherapy?

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DR. LAING:

A. No. And again, as I mentioned earlier, these treatments have shown in several studies to show a significant improvement in both disease free survival and overall survival.

This is a slide that shows that about 75 percent of all breast cancers are ER and/or PR positive and that the likelihood of having hormone receptor positive disease increases with age.

Currently, in 2008, our breast cancer guidelines used the consensus from the 10th St. Gallen's Conference on the primary therapy of breast cancer. So this was a summary report from that meeting in March of 2007, and they divide endocrine responsiveness, so hormone receptor positivity, if you will, into three groups. The first are those patients who are ER and are PR strongly positive. The second are the ones that are negative, so that's with less than one percent staining. So they recommend that these patients not receive any endocrine therapy. And then there's this group now that we call the endocrine response uncertain group. So this

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one to ten percent. Because many of the clinical trials that were done used ten percent as a cut-off, it's not really certain as to how much benefit patients with low expression of ER derive from these adjuvant hormonal therapies.

It's interesting, we're doing a-- participating in a large international phase three trial that's looking at a medication called bevacizumab or avastin in breast cancer, and it's looking at patients who are estrogen progesterone receptor negative and HER2 negative, and that's now what we call triple negative breast cancer. In that trial, patients who have ER/PR between one and ten percent are eligible for the trial. So they can go on study, and interestingly, if the investigator chooses to, they may offer the patients with one to ten percent staining a hormone as part of their adjuvant therapy. So it just speaks to the fact that this is still an area of uncertainty worldwide in breast cancer.

CHAYTOR, Q.C.:

Q. Doctor, just a question before you leave this

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slide. You've indicated that the endocrine response uncertain, between over one percent and ten percent, so between one and ten percent.

DR. LAING:

A. That's right.

CHAYTOR, Q.C.:

Q. For ER, but PR negative. What about the patients who would fall in that range but would be PR positive also within that range?

DR. LAING:

A. So still most of the times that you see low expression of the estrogen receptor, you do not see expression of the progesterone receptor. There's a move to further classify breast cancer into groups that include luminal A and luminal B. Luminal A's are the ones that are very strongly estrogen and progesterone receptor positive. Luminal B's are the ones that have lower expression and certainly those that don't express the progesterone receptor as well, and it's felt that perhaps if you have estrogen receptor expression, but not progesterone receptor expression, that you're less likely to respond

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to hormones and there's a signal that this may be a group that may benefit more from the aromatase inhibitors, although most of this work has been done retrospectively. So it's not common for us any more to see patients who have low expression of estrogen and are progesterone receptor strongly positive. Most often now, when we get our results, if we have very low expression of estrogen, there is no or very low expression of progesterone and they would fall into this group as well. So between one and ten for both receptors.

CHAYTOR, Q.C.:

Q. And how does that compare to what you were seeing in the past, in terms of the results that were coming to you?

DR. LAING:

A. When we did the review and when we did the tumour panel, we noticed that there was a fair number of patients who were estrogen receptor negative, but progesterone receptor positive, and that was something that, you know, again, when we were seeing this individually, it wasn't--you know, it wasn't something that really stood out to us, but when we actually

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sat down and put together everybody from the tumour panel and looked at those numbers, we certainly had a higher than expected number of patients who were ER negative PR positive. On their retesting from Mount Sinai, some of those patients ended up being ER positive, PR completely negative. So it was almost as if the two had been reversed. And some ended up coming back to be positive for both.

If you look at large clinical trials and they summarize the patient characteristics, for example, if you look at the trial that had upfront aromatase inhibitors versus Tamoxifen, and they show you the breakdown of patients, what you'll notice is about 70 percent, 60 to 70 percent, will be ER and PR positive. About 25 percent will be ER positive PR negative, and still in those large trials, there's about a three to five percent reporting of patients who are ER negative PR positive.

Some pathologists would argue that you shouldn't have expression of your progesterone receptor unless your estrogen receptor is expressed in those cells. But you know, that's something that people are still looking

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at.
CHAYTOR, Q.C.:
Q. And in your own practice now, and I hear what you're saying, that you're not seeing that any more, the trend that you're able to detect when you looked at them on review.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. What if you did? What if today you were to get a result which said ER negative and PR positive? What would you do?
DR. LAING:
A. We've had just one instance that I can recall where we had a patient who was ER negative and PR was five percent positive, and it was a result that came from Mount Sinai. So we asked for it to be reviewed and the same result was given.
CHAYTOR, Q.C.:
Q. Okay, and so I take it your practice then today would be if you were to get that, you would request a repeat of the test today?
DR. LAING:
A. In some situations, yes. The other thing that

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we've done is the patients who fall into this grey zone, if you will, and we're not seeing very many of those, but we certainly are seeing them, we present those patients at our tumour board round to have a discussion as to whether or not we should offer them endocrine therapy, and we make that decision based on, you know, what we think their benefit would be and how likely we think that their cancer is going to recur.

The last two I've had with very low expression of estrogen receptor and progesterone receptor negative have had locally advanced breast cancer. So they've presented and required upfront chemotherapy, and I did place those patients on hormonal therapy because I felt that their risk of recurrence was so high, because they had inflammatory breast cancer, which has a more than 80 percent risk of recurrence. Unfortunately, despite both of those patients being treated with Tamoxifen, they were young pre-menopausal patients, both to date have had a chest wall recurrence in a very short period of time, only in a matter of a few months

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after finishing their chemotherapy. So, you know, our experience to date in the clinic has been that these very low expressers are not, you know, many of them don't seem to be deriving benefit from the hormones. If you think about it and if you consider, you know, that you have--sometimes when I think about percentages, I think about a hundred of something, so if I think about patients, I think about if I had a hundred patients. When I try explaining this to patients, I say, you know, if there was 100 breast cancer cells left in your body and on or two of them seem to be dependent on estrogen for their growth, then I can give you a hormone to try and deal with those ones, but the other 98, 99 percent are not going to pay attention at all to the treatment that I've given you, which is why I think that you also need chemotherapy.
CHAYTOR, Q.C.:
Q. Okay. And, Doctor, before we leave it, you indicated about the results from Mount Sinai with ER negative and PR positive and so you would request retests. But the other option, you could bring it to the tumour board panel

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and have--or your tumour board rounds, sorry.
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. And have it discussed in that forum. I take it that's something new that's come out of this, that's recent practice?
DR. LAING:
A. Yes. The reason to bring it to tumour board is to have a group discussion about whether or not we should offer that person hormonal therapy or not. If someone had a very good prognosis tumour that, you know, had a very small risk of recurrence, then we may decide that the potential toxicities from the hormone would not be worth sort of saying to the patient in front of you, I think we should give it a try. When the risk of recurrence is very high, it's easier to make a case to offer treatments with more toxicities because, of course, you're always looking at your risk/benefit ratio for that patient.
CHAYTOR, Q.C.:
Q. Yes. And, Doctor, when you sat down with the results in front of you from the tumour board

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and had the benefit of seeing a large number of patients, you were able then to see this trend as a lot of ER negatives and PR positives -

DR. LAING:

A. Yes, positives, yeah.

CHAYTOR, Q.C.:

Q. I take it that would have been of assistance to you in picking up on an unusual trend or a trend that wouldn't be in keeping with the literature if that kind of tracking had been kept back through the years?

DR. LAING:

A. Yes, yes. And that was--through the process of the tumour panel we would often pick up a chart and say, you know, this is someone and we'd look at their--we'd start with their pathology and then when we'd open the chart, we'd say, oh, look, you know, this patient has been treated with Tamoxifen or another aromatase inhibitor or some sort of hormonal therapy and we'd look and we'd say it was because they may have been ER negative but their PR was very strongly positive.

CHAYTOR, Q.C.:

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Q. Yes, okay.

DR. LAING:

A. And I guess we'll talk about it as time goes on because that's part of the numbers that we saw at the end of the day, there was quite a significant number of those patients.

CHAYTOR, Q.C.:

Q. Who didn't require a change in treatment because -

DR. LAING:

A. Because they had already been on hormones.

CHAYTOR, Q.C.:

Q. - they were treated on the basis on their PR positivity?

DR. LAING:

A. Yes, yes.

CHAYTOR, Q.C.:

Q. That's right, okay. And are those, are those statistics now being kept by anyone in terms of if someone is ER negative, PR positive, is that being kept or is that what you hope to develop in terms of -

DR. LAING:

A. That's what we hope to be able to put into our -

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CHAYTOR, Q.C.:

Q. A database?

DR. LAING:

A. - new database. And the work on the preliminary discussions and that about that have started already with Eastern Health.

CHAYTOR, Q.C.:

Q. Yes, okay. Thank you. Sorry to interrupt.

DR. LAING:

A. No, no, I think that's -

CHAYTOR, Q.C.:

Q. Is that -

DR. LAING:

A. That's exactly what I want -

CHAYTOR, Q.C.:

Q. - more helpful from the last question -

DR. LAING:

A. Yes, yes.

CHAYTOR, Q.C.:

Q. - as we're going, okay.

DR. LAING:

A. So there's various ways that you can target the estrogen receptor. One is that you can block the production of what binds the receptors, so you can take away estrogen. One

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is that you can block the interaction between the estrogen and its receptor. And the third way is that you can do something to the receptor itself, so you can turn it off or what we call down regulate it, so not have it there and expressed within the cells.

This is a cartoon of what the estrogen receptor looks like. And over the years I've had several different pictures and I find this one to be one that helps patients and other people understand. So this is a breast cancer cell. Do we have an arrow? Yes. So estrogen and progesterone receptors are actually steroidal receptors, so they actually sit inside the cell, so they sit in the nucleus of the cell. And this small green box here depicts the estrogen receptor. Estrogen or estradiol are these yellow puzzle pieces, almost, they look like, that come and bind to that receptor.

What a drug like Tamoxifen does, which belongs to a class of medicines known as a selective, estrogen receptor modulator is that it binds to the estrogen receptor shown here at pink, so that the estrogen cannot bind. So

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you have the receptor, Tamoxifen gets in there instead and so you can't cause the downstream or you can't cause the effects of the binding. They're called selective estrogen receptor modulators because they cause different action in different tissues, so they have a negative or an antagonistic effect in breast cancer, in breast tissue and breast cancer cells, but they have a positive effect or an agonistic effect or they work just like estrogen in things like the bone.

Up above on the top of the cartoon it talks about how the aromatase inhibitors work. So in pre-menopausal patients the ovaries are functioning and the majority of estrogen actually comes, as one would expect, from the ovaries. In a postmenopausal patient there is still estrogen made and that estrogen comes from conversion of male-like hormones into estrogen, and one of those is this hormone up here called androstenedione. It's made by the adrenal glands. Some testosterone made, as well. And the enzyme called aromatase turns those into estrogen, so that's where a postmenopausal woman still gets the last

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little bit of estrogen that they have around. The aromatase inhibitors block that. So when I explain it to patients, I say it takes away that last little bit of estrogen in your body, which means that you have the receptors there, but you don't have anything to bind to it. And it also explains some of the side effects that we see from the aromatase inhibitors. For pre-menopausal patients the main treatment that we use and still is the main treatment that we use is Tamoxifen. Because the aromatase inhibitors won't work because the ovaries are still making lots of estrogen.

There are studies going on now that look at what we call ovarian ablation, so that means turning off or stopping the ovaries from making estrogen. That often happens in our older pre-menopausal patients as a result of chemotherapy. However, in some patients this can be done surgically by removal of the ovaries. Many years ago and not so much now and not ever in my practice radiation to the ovaries was a technique that was used. And there are medications similar to medications that we use to treat prostate cancer which

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turn off the ovaries, called luteinizing hormone releasing hormone agonists. And, of course, many of these are done now in clinical trial settings to look at ovarian ablation and we actually are participating in a clinical trial that's looking at ovarian ablation plus Tamoxifen versus Tamoxifen alone versus ovarian ablation and aromatase inhibitor for pre-menopausal patients.

For a very, very long time Tamoxifen was the gold standard and still remains a very important drug in the treatment of hormone receptor positive breast cancer. It was found to have an optimal duration of five years, and this was because trials showed that five years was better than two years but that ten years was actually inferior. And as I said, it's still the main endocrine therapy for our pre-menopausal patients.

In breast cancer we're very fortunate to have something called the Oxford Overview. And what it is is it's a summary of the world's literature in breast cancer which is done as a meta-analysis so all the data from various individual trials are taken and put

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together in a meta-analysis so that you can have more strength, if you will, in looking at effects. This has been--and this is usually updated every five years. This is from 1998, but if you look at these numbers in the most recent update in 2005, they're very similar.

So what it shows is two things. It shows how adjuvant Tamoxifen works in reducing the risk of breast cancer recurrence in the first column and then how it helps to reduce the risk of dying from breast cancer in the second column. And it looks at it by age group, less than 50, 50 to 59, 60 to 69 and greater than 70. And as you can see, these are relative risk reductions. And what a relative risk reduction is looks at the magnitude of the benefit but doesn't look at the absolute benefit to an individual patient. So, for example, if I have a patient that I'm seeing in the clinic who has a 30 percent risk of recurrence based on their prognosis, then Tamoxifen would decrease that by about 40 percent. So instead of their risk being 30, it would come down to about 17 or 18 percent. And the same as you think about a risk of

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death being 30 percent, you would decrease that by a third, so it would take it to 20 percent. So the absolute benefit to the patient is dependent on what their prognosis is. If someone has a 95 percent chance of being cured from their breast cancer, then the absolute benefit for any of these treatments is extremely low and in some situations less than one percent.

I'll ask you just to look at this number here. So if you look at the relative reduction in the odds of death for someone age 60 to 69, it's 33 percent, because that will be important later when we look at the adjuvant on line example.

CHAYTOR, Q.C.:

Q. Doctor, if I could, could we just look at that slide again?

DR. LAING:

A. Certainly. Previous, okay.

CHAYTOR, Q.C.:

Q. Previous, yeah. Thank you. This is the efficacy of five years of adjuvant -

DR. LAING:

A. Adjuvant Tamoxifen.

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CHAYTOR, Q.C.:

Q. - Tamoxifen. Immediately, I take it, following diagnosis and other chemo treatment?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Is there any similar study as to the efficacy up to ten years out from diagnosis?

DR. LAING:

A. The initial trials for--I guess I'll answer that in two ways. The trials that looked at five years versus ten years of Tamoxifen, there was a Scottish trial and there was a NSABP, so that's the National Surgical Adjuvant Breast and Bowel Program, so that's a cooperative group that does clinical trials in the United States had a B-14 trial, both of which showed no advantage to treating patients in a five to ten years, so showed no advantage of ten years of Tamoxifen over five years of Tamoxifen. And in fact, in one of the trials there was the suggestion that there may be a worse prognosis.

CHAYTOR, Q.C.:

Q. Okay. I think my question was more geared

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towards the delay in initiating treatment.

DR. LAING:

A. Oh, okay, I understand what mean now.

CHAYTOR, Q.C.:

Q. So instead if it being immediately following your diagnosis.

DR. LAING:

A. The only--so, of course, when we were faced with our situation of what are we going to do now with these patients, we did find a publication and that looked at late initiation of Tamoxifen. And that was a trial that was done in a time period where Tamoxifen wasn't routinely offered to pre-menopausal patients and then, you know, in the late 1990s it was evidence that it was beneficial. So they took patients who are at least two years from their initial diagnosis who had not received hormonal therapy and they randomized those patients to receive Tamoxifen or not and then they followed them over time. And what they found was that even with the late initiation of therapy that there was a benefit, that there was a benefit in terms of disease-free survival and there was a benefit in terms of

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overall survival, but that the benefit in terms of overall survival was--and disease-free survival were most significant in the patients who had node positive disease, which makes sense because they would have the higher risk of recurrence. And that was the paper that we found. Back in the fall of 2005 when we were first starting this, I had spoken to Dr. Kathy Pritchard, who's a medical oncologist at Sunnybrook Hospital, who's a colleague and a friend of mine and asked her if she had any idea of had there been any experience in the literature and she was the one who forwarded me this article. But you're very correct, that in the overview these are people who were given up-front treatment.

CHAYTOR, Q.C.:

Q. Okay. And the benefit that article speaks of for those with the late introduction of the therapy, while it is a benefit, is it--is there any difference in terms of the percentages from what you would have seen had they received the treatment in the beginning?

DR. LAING:

A. They were similar in magnitude of reductions,

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yeah.
CHAYTOR, Q.C.:
Q. Okay. Thank you.
DR. LAING:
A. I'll get--there's another point that I'll make, but I'll make it as I get to that, to that -
CHAYTOR, Q.C.:
Q. Okay, sure.
DR. LAING:
A. To the relevant section. So I think one of the things that's important to realize about Tamoxifen as a treatment is that it does have some side effects. I usually tell my patients that it has some serious side effects and those include endometrial cancer, and the risk is two in 1000 patients who are treated with Tamoxifen. The risk is more if you're older. There's also a risk of thromboembolic disease, which includes blood clots in the legs, do deep vein thrombosis, and also includes potential for these to travel to the lungs, what we call pulmonary embolism which is very serious and sometimes fatal, and it also includes a risk of stroke. That risk also

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increases with age. And if you look at someone who's greater than the age of 70, then that risk in that age group of severe thromboembolic disease related to Tamoxifen approaches five percent. Vasomotor symptoms, so the hot flashes are probably the most commonly reported and most problematic side effect to the patients themselves and occurs in about 30 percent of patients. Some of them are able to tolerate these quite well and they settle down over time, but for other patients they are very severe, interfere significantly with their quality of life and we may try various medications to lessen those, but I still have patients in my practice who are not able to continue on Tamoxifen because of side effects. We know that it can cause premature cataract formation. It can cause aches and pains in the legs. Most patients complain of muscle cramps, particularly at night time. It's been shown to cause weight gain, which is a concern for some patients, particularly because many of these patients will have finished adjuvant chemotherapy at a time when they've already had some weight gain related

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to the steroids and to their chemotherapy and are not as active and, you know, have concerns about their body image because they've lost their hair and may have had a mastectomy, so weight gain can be of concern to these patients. It can cause mood alteration, and we've seen significant depression. And it can cause, very rarely, some increases in the liver enzymes and lowering of the blood count, so we monitor for that.

There are some good side effects, if you will, or some benefits of Tamoxifen. It has a positive effect on bone and lipids. It has been shown to reduce the risk of breast cancer in the opposite breast in patients with a breast cancer diagnosis. And there are two large trials showing a benefit to Tamoxifen in breast cancer prevention. And because we've known about and have studies Tamoxifen for over 30 years, we know that it has something called a "carry-over effect". If you look at the slides from the overview, what happens is you see a separation of the curves, so that the people who get Tamoxifen are doing better. And that doesn't stop at five years, it

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doesn't stop at ten years, that continues to be separated. So we think that there's an ongoing benefit even beyond the duration of the Tamoxifen. And we're not certain that that is going to be the same for the aromatase inhibitors because they've only been included in the last overview.

So then on to the other types of medications that are key for hormonal therapy of breast cancer. So these are the aromatase inhibitors. When I was a fellow, we had an aromatase inhibitor called aminoglutethimide, which was a first generation aromatase inhibitor and it was used to treat metastatic breast cancer but not in the adjuvant setting. It blocked estrogen production, but it also blocked production of several of other important hormones in the body, so that it was very problematic to give to patients. Then these third generation aromatase inhibitors came out and were initially tested and shown to be superior to Tamoxifen in treatment metastatic breast cancer, and that was in the mid to late 1990s.

The thing to remember about these

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medications is, as I said, they are only effective if the patients is postmenopausal. That can be natural or it can be as a result of ovarian ablation, as we've talked about. There are three of these drugs. Two are called non-steroidal inhibitors and those are the drugs Letrozole and Anastrozole, and there's one that's a steroidal inactivator and that's a drug called Exemestane and they vary slightly in how they work.

So once these drugs had been shown to be very active in metastatic breast cancer, the next natural progression was to test them in the adjuvant setting, and this has been done in three different ways. First of all has been to give these drugs instead of Tamoxifen as the up front treatment, so as you said, right at the time of diagnosis after their chemotherapy if they're going to need it. These patients were randomized to get Tamoxifen or to get these medications. So far the largest of these trials, the ATAC trials, has shown an improvement in disease-free survival but not overall survival yet for the aromatase inhibitors.

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The second strategy is to start with Tamoxifen and then to switch patients after two to three years to an aromatase inhibitor. The rationale for that is extensive, but the two important points of that are if you remember back to the curve I showed you, that there's a peak of recurrence at two to three years. So that was the rational for looking at a switch earlier than five years, because investigators felt, well, if that's when the peak is, should we try and get a potential drug that overcomes resistance to Tamoxifen in sooner in the adjuvant setting than later. The second is that one of the mechanisms that was thought to be responsible for Tamoxifen not working after five to ten years is because it can be estrogen-like or anti-estrogen, depending on what tissue it's in, and it's thought that if you chronically inhibit the receptor in breast cancer cells, over time those cells may actually start to see Tamoxifen as estrogen, and there's some basic science work done to support that. So the rationale for that sequence meant that if your Tamoxifen starts to act to estrogen, you take

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that away, and you also take away the estrogen. So there's a rationale for the sequence of aromatase inhibitor after Tamoxifen. Those are called the switch trials and there are a few of those. Then when these drugs first came out, of course, there was a population of patients who had finished their five years of Tamoxifen, and we knew that giving them Tamoxifen for a longer duration wasn't going to help, but we also knew that the risk of cancer recurrence was still there, and that was the rationale for the NCIC MA17 trial which was the study that looked at Letrozole, one of the aromatase inhibitors after five years of Tamoxifen.

The important thing to remember about this situation is that patients had to make it to the five years without having a recurrence. So, of course, you would have had people that had recurrence in that five years who then wouldn't have been eligible for this study. That also--this is a point I had wanted to make. That also was helpful to us in deciding what to do with some of the patients that we reviewed that were in the five to ten year

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period, so we did have some evidence that treating in the five to ten year period was beneficial. This study was so positive, the MA17 trial, that it was stopped early at the first interim analysis. So you had a situation where you had patients who had five years of Tamoxifen. They were then randomized to get the active medicine or to get a placebo. We didn't know, as the investigators--this was a trial that we participated in, it was a Canadian led study. We didn't know if those patients were taking the active drug or if they were taking a placebo. When the trial showed such a benefit to the treatment in the five to ten year period with the active drug, the Letrozole, the study was stopped early and the patients were unblinded. Half of the patients on the trial would have been getting the placebo, and then it was up to the patient, with some discussion with their physician, to decide at that point if they wanted to go on that study. So then we had patients who had Tamoxifen for five years, who had nothing, no adjuvant treatment for two to three years, who elected

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to go on Letrozole at that point. They have analyzed those patients and those patients who decided to go on late Letrozole also got a benefit. So that was helpful to us --

CHAYTOR, Q.C.:

Q. So even with the gap in treatment?

DR. LAING:

A. Because of the gap, yes, yes. It wasn't until 2004 that the American Society of Clinical Oncology recommended aromatase inhibitors as part of adjuvant hormonal therapy for post menopausal patients. They have not updated that guideline since. That still remains there. However, they point out, and this is the case, that there's none of those three drugs, nor any of those three strategies that are known to be superior to each other because they've not been compared head to head, and that, of course, you need to consider the potential side effects and the risk of relapse for the patient.

Aromatase inhibitors have side effects as well. They're somewhat different than the Tamoxifen side effects. Because they take away that last little bit of estrogen, there is a

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potential for elevated blood lipids. So we monitor that. There is also an increased risk of problems with bone health. So thinning of the bones, osteopenia, osteoporosis, and fractures. So again patients are monitored and they are given supplementation with calcium and vitamin D. Probably the most problematic side effect of these drugs that we see in the clinic is that they cause severe muscle and joint symptoms. It appears to be a class effect. In other words, it appears if you get it from one of these medications, you're likely to get it from all of them, although we do switch and try other of those, but for some patients, that's the reason that they can't tolerate them and they would come off, and then if they didn't have a contraindication to Tamoxifen, then they would go on Tamoxifen. Exemestane is known to cause diarrhea, and, of course, just like Tamoxifen, they can cause significant hot flashes. Again because they take away that last little bit of estrogen, patients tend to complain more of things like vaginal dryness and decreased sex drive or libido and that can

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be a concern for some patients as well. So before we leave the aromatase inhibitors, it's important to realize that we're sort of with them where we were 25 years ago with Tamoxifen, you know, what's the best drug, should we start everybody on aromatase inhibitor right up front, should we give Tamoxifen for a couple of years and then these aromatase inhibitors, what's really going to the long term effect on their bones. I don't think we know that yet. It took us a number of years to understand the long term side effects of Tamoxifen. Of course, there's all this literature now looking at how these predictive factors can play a role. As I mentioned earlier, one of the trials, the big one, 98 trial of Letrozole versus Tamoxifen, which suggested that if you were ER positive and PR negative, you derived a better benefit from aromatase inhibitors, but the other large trial didn't show the same thing. So this really needs to be something that's looked at prospectively before we sort of hang our hat in the clinic on saying that because you're ER positive, PR negative, you should have

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aromatase inhibitor, and also HER2 probably plays a role. There's certainly a lot of interaction between the HER2 receptor and the estrogen receptor that people are trying to understand better.

I think it's important to understand as well that when we see somebody in the clinic, the decision to offer them hormonal therapy depends more than just on the results of the estrogen/progesterone receptors. The most important first thing is what's the prognosis. Someone has an extremely good prognosis, we may decide that they don't require any extra treatments. The next, of course, is the estrogen and progesterone receptor status. Menopausal status helps us to decide what drugs, and, of course, what other health problems they may have. If I have a 70 year old lady who has severe hypertension, ischemic heart disease, a diabetic, and who has had a stroke, then she's not going to get Tamoxifen. If I have someone who is small framed, doesn't exercise, is a smoker and has already had a pathological fracture in their spine, then I'm not going to be as keen on giving that person

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an aromatase inhibitor.

Patient preference is something that comes into the discussion. I have some patients who come in and had a friend or a neighbour or a sister who took Tamoxifen and they sit down and say there's no way I'm taking that medication, I saw what--and there are other people who I talk about the aromatase inhibitor, but their sister who had breast cancer had Tamoxifen and they're more comfortable to start with that medication first. So that certainly plays a role.

Then, of course, drug coverage. Tamoxifen is a generic medication, it's been around for 30 or more years and it costs about $20.00 a month. The aromatase inhibitors are relatively new and they cost about $180.00 a month. So for many of our patients, we have to discuss with them what their drug coverage is.

CHAYTOR, Q.C.:

Q. Doctor, the patient preference issue, I take it that's true on whatever therapies that you offer to your patients?

DR. LAING:

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A. Absolutely.

CHAYTOR, Q.C.:

Q. That there's a dialogue with the patient and input from them, and are you finding more and more that patients are well informed and educated on those things before they ever even come to you to speak about this issue?

DR. LAING:

A. Yes. You know, that's true for chemotherapy. There are patients who we recommend chemotherapy to who just decide that they don't want to take it. What we really try and do, you know, as the clinician who's involved in their care, is make sure that whatever decision that they make is an informed decision. So we try and give them as much information. If I see someone who says there's no way I'm doing such and such a thing, there's usually a story behind it, so I usually say why is it that you don't want to have chemotherapy, and it may be that years ago they had experience with a family member, and if you try and talk to them and take it through and reassure them that we have better medications for nausea--some people are

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terrified of needles to the point that they can't even imagine having a needle, and so we usually try and work through that. Patients certainly are very informed. I think breast cancer patients, as a group, tend to be very well informed, and I think it's because there's a lot of resources out there for them. When a patient in this province is diagnosed with breast cancer, before they ever come to the cancer clinic, they get something called the Purple Lupin Kit, which is a kit that contains a lot of very helpful information about all aspects of breast cancer, their diagnosis, their surgery, lymphedema. So many people already know, they've heard about chemo, they've heard about Tamoxifen, they've heard about the aromatase inhibitors. The Cancer Society provides a lot of helpful information, very general information, what is chemotherapy, what is radiation, and those sorts of things. So, yes, I'd agree with you that patients are very well informed.

CHAYTOR, Q.C.:

Q. And I take it you encourage that?

DR. LAING:

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A. Yes.

CHAYTOR, Q.C.:

Q. And do your part to help and assist them in what they should be reading and the types of literature to concentrate on?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And you encourage them to be involved in those decisions about their care?

DR. LAING:

A. Absolutely. So for many of our patients--so if I think about--this is how I think about it. I think about a third of our patients have private drug insurance in this province, a third of them have coverage through the Newfoundland and Labrador Drug Prescription Program, and a third of patients have no drug coverage. When the aromatase inhibitors first came out for treatment of metastatic disease, it took us quite some time to have this drug funded through the drug prescription program, to have it listed as a special access drug. In September of 2006, I was asked to go and present to the Atlantic Common Drug Review

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Committee, and I did that, and subsequent to that they agreed to fund the aromatase inhibitors for first sign treatment of post-menopausal patients with metastatic or locally advanced breast cancer, and that's because there was trials that showed a clear advantage to the aromatase inhibitors over Tamoxifen. They decided that they would list aromatase inhibitors for adjuvant treatment, but only if the patient has a definite contraindication to Tamoxifen, and what they used for that is thromboembolic disease or endometrial cancer, or if we placed somebody on Tamoxifen and they have very severe side effects and can't tolerate it. So that does limit us in some respect because if somebody has NLPDP coverage, then we have to go and make a case for why we want them to get the aromatase inhibitor up front, and it may be that they haven't had a stroke, but we think that this five percent risk of thromboembolic disease with Tamoxifen is too high. They fund Letrozole for the extended adjuvant therapy, which is quite good, and--so we certainly have better coverage as of 2007 than we did prior,

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but we don't have the same coverage--every other province in Canada lets the medical oncologist who's treating the patient decide which hormone therapy to use and doesn't put stipulations on this definite or severe toxicity from Tamoxifen. So we continue to work to try and get them to change their mind.

CHAYTOR, Q.C.:

Q. And do you know what's the rationale for that here in Newfoundland and Labrador?

DR. LAING:

A. They're waiting, they say, for some of these further updates of the trials that are looking at the aromatase inhibitors and the upfront in the switch strategies, and in December there's going to be a trial come out that's hopefully going to provide us with some more evidence to bring back to them again for review.

CHAYTOR, Q.C.:

Q. Doctor, the people who you deal with on that issue and the people that you have to bring the evidence back to, do you feel that you are better informed on the issue or are they?

DR. LAING:

A. The issue of aromatase inhibitors --

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CHAYTOR, Q.C.:

Q. Are they--for example, are they treating oncologists?

DR. LAING:

A. No, no, and so the reason why I had asked to go to the Atlantic Common Drug Review meeting that time was that there was no oncologist on that committee, and yet they were dealing with the issue of aromatase inhibitors. As you know or may know, there's a common drug review --there's a common drug review for this country, and it deals with new drugs. At that time, there was a decision within Atlantic Canada to have an Atlantic Common Drug Review and they were dealing with new indications for drugs that already had approval, and, of course, the aromatase inhibitors fell into that classification. They listed them for metastatic disease and the other three Atlantic provinces, it was up to the oncologist to decide how to treat the patient. Here they said that they felt that the patient had to have a contraindication to Tamoxifen. So after that September, 2006, meeting we managed to convince them to list that

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restriction on that, the added adjuvant therapy, but they haven't lifted the restriction yet on adjuvant therapy.

Currently the process has changed in terms of drug review in this country, and now there is a joint oncology drug review that is operating on an interim basis of which we are a participating province, but this issue is done, you know, the rest of the world is funding --

CHAYTOR, Q.C.:

Q. Moved on?

DR. LAING:

A. Right. So there's never going to be any more evidence, but we need to go back and again when we get the update data at the San Antonio Breast Cancer Conference, we'll prepare another file and forward it to them and meet with them again to see if we can lift that restriction.

CHAYTOR, Q.C.:

Q. And that's coming up shortly.

DR. LAING:

A. I do want to stress, though, that we are creative, we do get these drugs funded, and we

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actually have a lot of compassion access programs with the pharmaceutical companies. So if somebody--if we feel that somebody really needs this medication, we do not let them go without it.

CHAYTOR, Q.C.:

Q. And the "we", that's the oncologists treating the patient?

DR. LAING:

A. And our clinical pharmacist who works side by side with us.

CHAYTOR, Q.C.:

Q. Makes sure that happens?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Thank you, Doctor.

DR. LAING:

A. So this next slide is taken from Adjuvant Online. Adjuvant Online is a computer program that was designed a few years ago now by Dr. Peter Ravdin, which is a medical oncologist from the United States, and he was trying to come up with a tool to help physicians assist their patients in decision making in the

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clinic. It reminds me of when I was a fellow, we only had one way to treat hormone receptor positive breast cancer, it was Tamoxifen. We only gave it to post-menopausal patients, and there was two types of chemotherapy to use, Type A and Type B. One of the oncologists in Hamilton made a decision for it, and it was a great aid for patients to try and decide, you know, this is the potential side effects of this treatment and this is the potential side effect of that treatment.

Since that time, there are several, several various combinations of chemotherapy, and as you can see, lots of hormonal therapy for breast cancer. So Dr. Ravdin's goal was to try and take this and put it into a system that could first of all give a prognosis, and second of all, help patients visualize and see what the potential benefit to treatments may be. On the top side here to the left, you put in patient information. This can all be changed, okay, so I've just used an example of somebody who is 63, which would be about the median age for breast cancer, minor health problems, you can give them major health

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problems depending on what sort of comorbidity they have, you can put in their estrogen status, you can put in the grade of the tumour, the size of the tumour, and whether or not they have lymph nodes, and you can calculate their prognosis in terms of mortality or you can look at relapse. So this is all the prognostic information that we talked about. What it tells you over here on the side is what that patient's expected prognosis is with no additional therapy. This is how I like to think about if I had 100 patients like this, and this is how--there's a printout that you can actually give to the patients and this is how it comes out looking for them. So this person, even before we decide to give them any adjuvant treatment, has about an 81 percent change of cure. So they have a good prognosis. This particular patient is 63 years old, nine patients like this would die of their breast cancer, and ten of them would die of something else. The older the patient gets and the more problems that you put in under comorbidities, then the larger the blue box gets and the more likely

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they are to die of another cause. Then what it does, it allows you then to go down below to adjuvant therapy effectiveness and it allows you to look at various different treatments that you may offer that patient. So in terms of hormonal therapy, I've picked Tamoxifen. You could pick Tamoxifen followed by an aromatase inhibitor, you can pick an upfront aromatase inhibitor. You can pick ovarian ablation. So I've just left Tamoxifen there. You can pick various different chemotherapies that you may decide to offer this patient, not saying that I would necessarily offer this patient chemotherapy, but we would have that discussion. What the bottom numbers give you is the relative risk reductions, and see here where it's "hormonal therapy", it's 32 percent, which is almost exactly derived from the overview that we looked at earlier. So then what it does, it says, okay, if we treat this patient with hormonal therapy, then they have an absolute benefit of 2.6 percent, or the other way to look at it is if we took 100 people like this and treated them, then two to three would be

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alive because of the hormonal therapy. Two would be alive because of chemotherapy and four more would be alive because of both. That's very important, and I think it's important for two reasons. One is because it tells us that these hormonal therapies are effective at increasing survival in these patients, but it also tells us that even with these treatments there are still those patients who do not benefit. So if you take that group, nine were going to die, three don't, there's still six that despite getting hormonal therapy, and then the next line, despite getting chemotherapy, and then the last line, despite if I gave these ladies both things, that it doesn't prevent recurrences in all people. We wish that it did, we wish that that or all of our adjuvant therapies did, but they don't.

The next patient is going to be almost the same, but I've changed one factor.

CHAYTOR, Q.C.:

Q. Doctor, I just wanted to ask you one thing.

DR. LAING:

A. Yes.

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CHAYTOR, Q.C.:

Q. Is this program available to all physicians, all oncologist --

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Or all, I should say, physicians who would be treating cancer patients?

DR. LAING:

A. Yes. It's available online.

CHAYTOR, Q.C.:

Q. And when did it become available?

DR. LAING:

A. I would say probably about two or three years ago, yes.

CHAYTOR, Q.C.:

Q. So it's sometime since or around the 2005 mark? It wasn't available, I take it --

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Between 1997 and 2005?

DR. LAING:

A. No, no. It's available online, it's available for breast cancer, but you can also--there's

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a program on the same site for colon cancer, for lung cancer. When you go in under this, it suggests that it be used by health care professionals that are involved in cancer care, and that patients should talk to their physicians about using it to make sure that they, I guess, understand what to put in and, you know, the relative risk reductions and the benefits and things. For some of my patients, I do this in the clinic with them. I'll go online, I'll do this, I'll take them out and I'll sit down and show it to them. Not all patients want this degree of information, but certainly some of them do. I find it's really helpful in trying to decide about giving chemotherapy to older patients who have hormone receptor positive disease, and you can see, you know, for some of those patients that the benefit to chemotherapy is quite small, and the benefit to hormonal therapy is actually larger.

CHAYTOR, Q.C.:

Q. Doctor, where does this factor into your decision making in terms of your patient?

DR. LAING:

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A. For a lot of patients, I--you know, this is stuff that I kind of do in my head, if you will. The people that I use it most often for are the people where I know that the benefit is going to be very small, and I think sometimes when we think about chemotherapy, not so much hormonal therapy, but when we think about chemotherapy, we may overestimate the benefit that we think that we're providing to patients by chemotherapy. So if I have a patient in the clinic who's in their late 60s or 70s who has a hormone positive breast cancer, who maybe has one lymph node involved or tumour that's more than two centimetres, or something that puts them into the high risk category, I'll often go and put the numbers in here and sort of see, and I might sort of have in my mind that, oh, they're going to get an absolute benefit of five or seven percent from chemotherapy, and you put it in here and it comes back as one, so--you know, because they derive such benefit from hormonal therapy. So it's when you're--you know, for these borderline cases, I find it really helpful.

CHAYTOR, Q.C.:

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Q. You would do it as a check?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. You make your own determination with respect to the patient before you, but then you could use this as a check?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And you also use it as an educational tool for your patients?
DR. LAING:
A. Yes, yeah, it's really--we use it a lot in the clinic when we're teaching the residents that are working with us because you can, you know, very easily say, well, look what would happen if this patient had nodes involved or look what would happen if this person was hormone receptor negative, you know, this would be why we did something different with another patient as opposed to this one. So it's a very good educational tool, and for some patients, you know, a good tool as well.
CHAYTOR, Q.C.:

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Q. When did you start using it?
DR. LAING:
A. Oh, I've used it for the last couple of years.
CHAYTOR, Q.C.:
Q. Whenever it became available?
DR. LAING:
A. Not right away, but probably for at least the last two years.
CHAYTOR, Q.C.:
Q. And was there a program prior to Dr. Ravdin's, a similar program?
DR. LAING:
A. No.
THE COMMISSIONER:
Q. Excuse me, Dr. Laing, I notice that in respect of ER status --
DR. LAING:
A. Yes.
THE COMMISSIONER:
Q. It says positive. I presume you put in positive or negative.
DR. LAING:
A. You can put in positive, negative, or unknown.
THE COMMISSIONER:
Q. Okay, and in your determination of the advice

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that you might give your client, would you consider the degree of positivity?
DR. LAING:
A. In--I consider that for the patients who have low expression, so the one to ten percent. For the patients who are more than 10 percent positive, then, no, I would consider that to be positive is positive. This whole idea of being both estrogen and progesterone receptor positive and very strongly positive is starting to come out there, and so in some instances I'll look at someone and their results come back and they're greater than 95 percent positive for both, they have a well differentiated ductal tumour, and they're in their late 60s or 70s, and I'll say, great, good, you know, this means I can use a hormone as part of their treatment. But to use that to look at someone who might be ER positive and PR negative, and for me to say I'm definitely going to give that person aromatase inhibitor because of that, we're not there yet. So the level of expression, once it's into greater than 10 percent, is not as important a factor in determining it as some

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other things about the patient.
THE COMMISSIONER:
Q. Doctor, how would you know the rate of positivity?
DR. LAING:
A. It's given to us now in the reports.
THE COMMISSIONER:
Q. And has that been true historically?
DR. LAING:
A. No, it has not been true.
THE COMMISSIONER:
Q. And how long have you been getting it in the reports?
DR. LAING:
A. When we first started changing our thinking about the cutoffs, which was in 2001 and then into 2002, if the number was not present in the pathology report, I would contact the pathologists who signed out and say could you tell me what the number was, was it zero, as in nothing, or was there some staining. Some of the reports would come like that, but some of the reports would just say positive or negative. When we started to get reports in 2005 from Mount Sinai, then we would always

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get reports that actually had the percent staining on the main sheet, and then there would be a summary at the end, and ever since that time when we've gone back to getting the reports from our own lab, they would certainly contain the percent staining for both.

THE COMMISSIONER:

Q. And why is it that if this was valuable information in 2001 or 2002, the oncology department wouldn't talk to the pathology department and say this is a useful piece of information, please put that on your reports?

DR. LAING:

A. I'm not sure. I know that in my own practice, if it wasn't there, as I said, I would contact the pathologist and ask for that information. The discussions that I would have had with those pathologists, as a medical oncologist, you know, I would say to them, you know, could you tell us that because we sometimes will decide to treat somebody, you know, we'd like to know the number and then make the decision. At that time, I wasn't aware or wasn't part of any discussions that may or may not have gone on between the then heads in oncology and

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pathology, but I don't think that there were those types of discussions, but I think that at that time they may have been valuable.

THE COMMISSIONER:

Q. Thank you.

CHAYTOR, Q.C.:

Q. And when you became the Director of Medical Oncology and then into your role of Clinical Chief, as the Director of Medical Oncology, did you embark upon that discussion on behalf of your fellow oncologists?

DR. LAING:

A. No, because I think, you know, once we got-- once I became director in 2002, we were doing our tumour board rounds, we were having some discussions then. There was a committee struck, and I can't recall the name of it, but I think you know, sort of a liaison committee between --

CHAYTOR, Q.C.:

Q. Surgical Pathology Review Committee?

DR. LAING:

A. Right, right. I was not a member of that. Dr. Gardiner was then the Medical Director of the Cancer Clinic, of the NCTRF at that point, and

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he asked Dr. Siddiqui to be a member of that committee. Looking back on it now, I don't think that was a committee that met very frequently or really followed through. In our new breast disease site group, that certainly is a place where we have had opportunity to discuss issues that are relevant to both pathologists and oncologists. That's where we had the discussions about ductal carcinoma in situ and ER/PR testing and that, that's where we have discussions about lymphedema management, but that's a venue where you have pathologists and oncologists and surgical medical radiation oncologist involved in the care of breast cancer patients where you would be able to have those discussions. Maybe, you know, back then had something like that existed, maybe that would have been a forum that maybe somebody would have said, oh, you know, I notice that this is not happening, but at that time, no, it wasn't something that we did.

CHAYTOR, Q.C.:

Q. And do you recall it actually coming up at the tumour board rounds that the oncologists

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raised this with pathologists in that context to say that we need to see this on the reports?

DR. LAING:

A. No, I don't recall that.

CHAYTOR, Q.C.:

Q. You don't recall it coming up?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And I do have one other question arising from the questions of the Commissioner on this issue of positivity.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Is there a difference in how a patient will respond depending on the degree of positivity in the metastatic setting?

DR. LAING:

A. Yes, there is, and--would it be okay if I spoke to that because it's coming up.

CHAYTOR, Q.C.:

Q. Sure, yes.

DR. LAING:

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A. Because that's really where we have--that's where the data comes from because in the adjuvant setting, all you can sort of say is does the cancer recur or not, but in the metastatic setting, you can actually look at response rates.

CHAYTOR, Q.C.:

Q. So in that situation, it would be even more important to have the percentage given to you?

DR. LAING:

A. You know, I remember back to when we were having the discussions about retesting, and, you know, should we retest just the estrogen receptor, should we test just the progesterone receptor, or should we do both, and I think that, you know, one of the things that this whole process has really taught us is that there's so many things that we may not recognize as being so important today that are going to be important five years from now, and I think that there will come a time where if we can be sure that we're getting accurate measurements of the estrogen and progesterone receptor, that, yes, you know, if someone's ER/PR is strongly positive, that's going to

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maybe be the most important factor in deciding about the therapy, that maybe if someone is ER positive/PR negative, that that's going to determine how we should treat people, which is why we felt that we needed to retest both and we needed to have as accurate information as we could on that patient's chart because over time that may be very important, and we may be able to really know that these are reliable predictive factors to determine the type of hormonal therapy that we offer a patient.

CHAYTOR, Q.C.:

Q. Doctor, just before we leave this, and I know you have a similar screen to show us, but under ER status where the program says either positive or negative or unknown --

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Do you know how does Dr. Ravdin define positive?

DR. LAING:

A. It's--I don't believe that it's defined on this. There's no--it doesn't say greater than or less than or anything. It just says

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positive.

CHAYTOR, Q.C.:

Q. Whether it's one percent or ten percent --

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. You don't know.

DR. LAING:

A. No. It's interesting because, you know, I have looked back through various different things, if you will. For example, I've looked back at some protocols from clinical trials just to sort of say, I wonder, you know, how they define positivity. Some of them very clearly stated it was 10 percent, and others said it was institutional, so it was whatever that referring lab, if you will, used to determine positivity, and, of course, that varies from lab to lab, as you know.

CHAYTOR, Q.C.:

Q. Okay, thank you.

DR. LAING:

A. So the only difference that I made in the next screen was that I changed the prognosis of the patient, and I said that she had four to nine

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lymph nodes positive. Everything else stays the same. So it's hormone receptor positive, grade one, same size tumour, but you can see that just by virtue of having lymph nodes involved that this person now has a much higher risk of having breast cancer recurrence, and as opposed to 80 people being alive without any further treatment, it's now changed to 60, and that 30 percent or 30 people would die of breast cancer and 10 would die of other causes. Because your prognosis is worse when you have lymph nodes involved, then we know that your risk is higher, and you can see that your absolute benefit instead of being 2.6 percent with hormonal therapy is now 8 percent. So this just shows that the higher your risk, then the more benefit that you're going to derive from your treatments, but again if you look at this, and I think about this as 100 patients with breast cancer, 30 of them are going to die of breast cancer; if they receive adjuvant Tamoxifen, eight of those people will not, but it does not--you know, there's still 20 people there who would have death as a result of breast cancer.

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In terms of chemotherapy, this is a post-menopausal patient, so you can see that the benefit to mortality in terms of chemotherapy is not as great. So this is where you start to see that the biggest benefit to this person is going to be hormonal therapy. There's still some benefit derived from chemotherapy, and if you combine the two, the thing that you need to notice is that it's not additive, that it doesn't--you know, it's not 14.4 percent that there is--that hormonal therapy and chemotherapy combined, there is some overlap in terms of the benefit. So maybe just in the last couple of minutes, if I could finish this up, we could switch gears and talk about metastatic disease.

CHAYTOR, Q.C.:

Q. Sure.

DR. LAING:

A. And I think, you know, when someone comes in to see you in the clinic, the very first thing that you have in your mindset is what is the goals of therapy here; is this an adjuvant situation or am I treating this person with metastatic disease. The goals of treatment

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are certainly different. When we're treating people with metastatic breast cancer, this is an incurable disease. It remains that, unfortunately, but it's still a disease for which people can live for a number of years. The first thing that you want to do is that you want to make people feel better, so you want to palliate or improve their symptoms. So if they have shortness of breath and pain in their bones because of their metastatic disease, you want to make that better. When you give treatment in the metastatic setting, you want to minimize the toxicity. You don't want to--you know, if someone is getting a short course of adjuvant chemotherapy, you'll put them through the ringers because you know at the end of the day you're going to make them live longer. It's not the same when you're treating metastatic disease.

Through these two things, what you want to do is maintain or improve quality of life for your patients, and you want them to live longer, you know, you want them to be these people with metastatic disease that are around for a while. In order to do that, you need to

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be thinking about long term disease control, and we've heard cancer referred to as a chronic disease. So if you're looking at people with metastatic disease, then the next thing you're going to say is am I going to use hormonal therapy to treat this patient, or am I going to use chemotherapy. Obviously, you need to know that they're hormone receptor positive, but you also have to look at other things; where is the cancer, is it life threatening, this is someone who's short of breath who's on oxygen and sitting in a wheelchair where I need something that's going to work quickly, or do they have very minimal disease in the lungs or liver, or certainly we know that hormonal therapy works best for people with bone disease, soft tissue, chest wall recurrences, and lymph node disease, and it's very clear that the longer the interval between your initial diagnosis and when your cancer recurs, that your prognosis is better and that your chance of responding to an hormonal therapy is better. Two years is kind of the cutoff that we tend to use in our minds, and have they responded to hormone

Page 80

therapy previously. So is this someone who has been on adjuvant Tamoxifen for five years and has now recurring, or is this someone who I treated with Tamoxifen and they've gotten, you know, a good response for a couple of years, that are more likely to go on--I think I mentioned to you a case earlier of someone who had been on Tamoxifen for a very short period of time and relapsed. That's not someone who I'm going to be thinking now about giving a hormone to. I may retry them down the road, but if they have disease again that I need to get under control quickly, I'm likely to go to a chemotherapy option.

The aromatase inhibitors, as I indicated, have the best upfront response. If someone--and now we see there's people who have been treated with Letrozole or Anastrozole in the adjuvant setting are unfortunately still coming with breast cancer recurrences. So if they've had that, we'll often give them Tamoxifen. If they have had one class of the aromatase inhibitors, we'll give them the other. There's a medication called Faslodex, which is a down regulator of the estrogen

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receptor, and there's a medication called Megace, which we still use. This gets to the whole idea of response rate. In the adjuvant setting, the only way that you know that someone is responding is whether or not their cancer recurs. In the metastatic setting, however, you can see what's happening, you can do CAT scans and measure how big the liver lesion is, is it getting smaller, you can go by symptoms. If you look at all patients who come with metastatic breast cancer who are hormone receptor positive, only 60 percent of them are going to respond to hormonal therapy in the metastatic setting. It's not 100 percent, it's only 60 percent. Again, if you've had a long disease-free interval, if you're both ER/PR positive, then you're more likely to respond.

If you look at there are some older studies done that actually looked at whether or not people were ER and PR positive, ER positive, PR negative, ER negative, PR positive and negative for both and looked at what the likelihood of those patients were for responding to hormonal therapy. So if you're

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positive for both, you got about a 50 to 60 percent chance of responding. If you're ER positive, PR negative, then your response rates fall down around 40 to 50. If you're ER negative, PR positive, it's sort of a 20 to 30 percent chance. And if you're ER/PR negative, then you have, you know, a very low chance of responding. And it's interesting because in some studies it's reported to be, you know, five to ten percent, and that's probably patients who were false negatives.

There's also this whole issue about changing the estrogen receptor status between a primary disease and metastatic disease. Most often when patients are diagnosed with metastatic breast cancer, it's a clinical diagnosis. They come in with the usual spread and pattern of metastatic disease, and so we don't always biopsy it. There are some instances, however, where biopsying is not invasive, too invasive to the patient, for example, if someone has a lymph node recurrence or a chest wall disease. And, in fact, in some instances we end up biospying those areas because we're not sure if a small

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node under the arm is simply reactive or if something along the scar is post surgical or if, in fact, represents recurrent disease. In those settings we do ask for the hormone receptor status to be repeated on the tissue because it will be sent to pathology and they'll look at it and say, yes, this is recurrent breast cancer.

There have been some publications in the literature where people have gone back and looked at their institutional experience in this setting. The most recent one that I've seen presented was last year at the Canadian Association of Medical Oncology meeting where one of the residents in Toronto went back and looked at paired samples. So if had a sample from the metastatic disease, plus they looked at the original pathology and to see how often the ER/PR status--they also looked at HER2, but I'll focus on ER/PR, how often it changed from, so it went from being positive on the initial tumour to being negative on the metastatic disease, and that happens in about 20 to 25 percent of the cases. And the rational or the reason for that is is that as

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breast cancer becomes metastatic, what you've done is you've taken the worst of the cells. You know, so if someone's been on adjuvant Tamoxifen all the ER positive clones, you're hoping that you've eradicated those and then the metastatic disease is going to be populated with most aggressive cells. Cancers are always changing, they're always going new mutations and growing and dividing and becoming more aggressive, so this is the reason why we see this change as people develop metastatic disease.

The other thing to remember, and this is, you know, this is difficult, but when we're treating patients metastatic disease, it's an incurable situation. And we will start them with hormones and we will keep them on hormones for as long as we can, but eventually all of those people are going to have hormone resistant disease, it's the natural progression of this disease, and at that point that's when we will consider stepping in with chemotherapy or if some time during the course of treating them for their metastatic disease, they develop significant lung or liver lesions

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or bulk of disease that we really need a quick response. Because a response to hormonal therapy can take up to three months, whereas a response to chemotherapy, particularly if it's a rapid growing tumour, can be much quicker, because of course, chemo kills cells that are growing and dividing quickly, that's how it works.

CHAYTOR, Q.C.:

Q. So, Doctor, before we leave that, so over time the cancer will evolve?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. I'll use the word "evolve" it's probably not-- it's probably too positive of a word, but it'll evolve so the person will go from being hormone dependent to hormone independent or -

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. - the disease will be hormone resistant as you've said here. Can it ever happen the other way around, can you go from actually being negative to positive?

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DR. LAING:

A. No. If you look at a normal breast cell of a normal breast tissue, then it's estrogen receptor positive. As it goes on and develops into cancer, as it becomes more aggressive, then it loses that positivity. If you look at these reviews and if you look at the patients who went from being negative to positive, you usually see one or two cases and usually what it is is either your initial result was a false negative or your second result is a false positive. So, no, the cells don't go back and gain -

CHAYTOR, Q.C.:

Q. There's something wrong with your test if that happens?

DR. LAING:

A. The only thing that sometimes weighs in is this whole idea of, you know, when you take a biopsy and when you do the testing and the pathologists certainly speak to this better than I can, but, you know, you're looking for the most representative sample of your tumour to do the testing on.

CHAYTOR, Q.C.:

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Q. Um-hm.

DR. LAING:

A. There's always a possibility that you may pick a clone of cells that is estrogen receptor positive and you may sample a lymph node and it might be estrogen receptor negative cells in it, so there's always that possibility. Each cancer cell is different from each other. I explain it to my patients by saying that, you know, cancers grow and divide very quickly. By the time you get to a one centimetre lump of cancer, you've had about a billion divisions. And think about your own family members, you know, these cells from cancer cells are called their daughter cells. You know, if I think of myself and my four sisters, we're all very different. So, and they continue to be different, so, you know, you can start with one cell in the lab and after a few divisions, you have a cell that you're looking back at a cancer that is very different than the first one. So the heterogeneity of your cancer cell populations is what makes metastatic disease still a disease we can't cure. When we get excited

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because the CAT scan looks better and things are shrinking, it means that the cells that are sensitive to that chemotherapy die off. The ones that are left behind are the ones that are resistant and then they are the ones who grow up again and then repopulate the tumour. If we could come up with a way that we could kill all of the cells, you know, no matter what made them grow or--then we would get rid of that disease. And we can do that in some malignancies. Leukaemia is a wonderful example of--lymphomas, testicular cancer, there's lots of cancers that are metastatic that are curable by chemotherapy, but unfortunately breast cancer is yet -

CHAYTOR, Q.C.:

Q. Not there yet?

DR. LAING:

A. - is not one of them. Not there yet.

CHAYTOR, Q.C.:

Q. Okay. So, Doctor, on that question about going from negative to positive, as an oncologist receiving such a report where your primary tumour, your original was negative and then, as you say, you would do another test at

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the time of the metastatic disease and you get the ER test or ER/PR test then and it's indicating that it's positive at that point, I take it that would cause you to call into question -

DR. LAING:

A. The original test.

CHAYTOR, Q.C.:

Q. The original test?

DR. LAING:

A. Yeah. Unless you explained it by some sort of clonal thing, but it's, you know, my first indication would be I wonder if maybe the initial test wasn't correct.

CHAYTOR, Q.C.:

Q. And in reviewing the cases through the panel in the aftermath of the retesting did you, in fact, were there patients who had been originally tested ER negative and the--on the tests on their primary tumour and then their metastatic tests showed ER positive?

DR. LAING:

A. I can recall one such case. It wasn't a patient of mine, but it was a patient who had had a chest wall recurrence shortly after

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their initial diagnosis and the repeat, the repeat test was positive and that patient had been started on one of the aromatase inhibitors. But this was all during--when we presented this patient at the tumour panel, this was after we were already sort of along the process. Prior to that I did have a patient who had a differing result from their initial biopsy and their mastectomy specimen.

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. And I did ask for a repeat on the mastectomy specimen.

CHAYTOR, Q.C.:

Q. And I'd like to get into that with you -

DR. LAING:

A. So, yeah, we can talk about that -

CHAYTOR, Q.C.:

Q. Yeah, because I'd like to talk to you about that case in some detail.

DR. LAING:

A. Sure, yeah, and we can do that.

CHAYTOR, Q.C.:

Q. So in the review, though, in terms of going

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from the primary to metastatic, because I think that other case we're going to talk about is actually the same tumour?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. But this situation which I was just asking about is a situation where primary had been one---had been, one result had been positive and then the metastatic had gone negative. So there was one such case that you found in the review?

DR. LAING:

A. Right, but it was all during the middle of this. When I think back, I cannot come up with a similar case. I wonder, though, as I sit here and think about it, may it have been because if someone was initially said to be ER/PR negative, we may not have--it may not have been repeated on the metastatic disease. Because really, the reason to check it again when you're faced with a recurrence is to reassure yourself that you're giving--by giving them a hormone for chest wall disease, that you're going to treat. Do you know what

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I mean? So if someone was ER positive to begin with, they have something that's easily accessible to biopsy, such as a lymph node or a chest wall disease, you ask for it to be repeated to make sure that it's still positive. I wonder if maybe there was instances, and this is just me thinking, that if someone was negative all along, that you may not have asked for it to be redone because you're not thinking about using hormonal therapy.

CHAYTOR, Q.C.:

Q. But you do recall one case where -

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. - there were the conflicting the report?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And had you been the treating oncologist in that case, you would have questioned the original test?

DR. LAING:

A. It's hard to say because that's when we were

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already in the middle of this. But I would think, yes, you know, if someone was negative to begin with and you got a test that was positive, that you would question. I certainly did that, you know, in the instance that we'll talk about, albeit slightly different.

CHAYTOR, Q.C.:

Q. And is there any policy in place now that would require a retest in such a situation?

DR. LAING:

A. If someone has--if, so -

CHAYTOR, Q.C.:

Q. If your metastatic is not consistent with -

DR. LAING:

A. Right. So if we were to send--if we were to take a biopsy today of someone with metastatic disease, the pathologist would automatically do the retesting, yeah.

CHAYTOR, Q.C.:

Q. No, I'm -

DR. LAING:

A. They would retest somebody.

CHAYTOR, Q.C.:

Q. Yes, and I'm--is there a policy for the

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oncology service that if you were to get a result which would be inconsistent with the original test, that it would be required that a retest be ordered or -

DR. LAING:

A. Yes, absolutely, absolutely.

CHAYTOR, Q.C.:

Q. And is that a written policy now?

DR. LAING:

A. I don't think it's written down, but it certainly would be something that we would do.

CHAYTOR, Q.C.:

Q. Okay. Thank you. I'm sorry, continue on?

DR. LAING:

A. I think I'm almost done, actually.

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. Okay. So then this brought us to the concluding slides in the presentation back in November of 2006. So I was there to try and explain how this had played out in terms of the care of the patient and that, you know, through this review the things that, you know, confounded where we were, were the changes in

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the threshold for positivity, the changes in the patients who were offered hormonal therapy and getting to the pre-menopausal patients. It's interesting because I finished my training in Vancouver in 1998 and we didn't routinely give Tamoxifen to pre-menopausal patients. In fact, we put them on a study called MA 12, which was one of the NCIC trials that's actually coming out with it its ten-year follow-up. It's going to be published very soon. And what that trial showed was that for the patients who were randomized to Tamoxifen after chemotherapy, so they all got chemotherapy, they're pre-menopausal patients, they all got chemotherapy and then they were randomized to Tamoxifen or not. But actually 30 percent of patients came off Tamoxifen because of toxicities or patient choice. So I don't know the final results now, but I know that it's coming out soon, that they're not actually that robust, but part of the reason that it's felt for that is because of the non-compliance of patients, and then, of course, in the change in the agents that we had available. We looked at cases from 1998,

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1999, 2000, 2001 where if they couldn't tolerate Tamoxifen, there wasn't another option. It wasn't really until 2004 that the aromatase inhibitors were something that we had available to us in the clinic.

CHAYTOR, Q.C.:

Q. Doctor, the change in accepted threshold for ER positivity at greater than 30 percent, the greater than 10 percent, I think, as well, discussed and we've seen a lot of the literature on that, but where does the greater than 30 percent come from?

DR. LAING:

A. That was, there's some literature supporting that, as well. And when we would get our pathology reports, there was a reference to a journal article that actually looked at a correlation between the old Ligand binding assay and what level of positivity, and that's what many of the labs in Newfoundland used as the basis for choosing the 30 percent cutoff.

CHAYTOR, Q.C.:

Q. And when did the ten percent, the studies recommending the accepted threshold be ten percent, when were those studies published?

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DR. LAING:
A. Some of the references that I found subsequently were from around 2001, 2002, yeah.
CHAYTOR, Q.C.:
Q. Okay. And are there some before that?
DR. LAING:
A. Not that I know of, no.
THE COMMISSIONER:
Q. I'm sorry, I don't think I followed the question. You were asking when it was--when the ten percent?
CHAYTOR, Q.C.:
Q. When the literature indicated ten percent or -
THE COMMISSIONER:
Q. Well, the discussion was about the literature, not about when it was actually implemented?
CHAYTOR, Q.C.:
Q. Yes, not when it was actually implemented in St. John's.
THE COMMISSIONER:
Q. All right.
CHAYTOR, Q.C.:
Q. When the literature discussed that. And I'm wondering whether or not you're aware of any

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studies which would have indicated ten percent or back perhaps lower, prior to 2001, 2002?
DR. LAING:
A. There were, in terms of studies, then, you know, as I said, some of--when I went back and looked at some of the actual trials that looked at treating with hormonal therapy, some would say positive greater than a certain amount, some would say just institutionally positive. The NIH came out with a consensus conference in 2000 that talks about hormonal therapy and they indicate any level of positivity but they don't use a cutoff. They don't say does that mean greater than ten percent or does that mean, you know, what that means by any level of positivity. At the same time they talk about pre-menopausal patients and that's, you know, similar to when--that would have been around the same time that that recommendation was coming out to offer hormonal therapy to pre-menopausal patients.
The other thing that we haven't touched upon that's interesting is that the Europeans for years never did estrogen and progesterone receptor testing. They gave pre-menopausal

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patients chemotherapy and postmenopausal patients Tamoxifen and didn't look routinely at the estrogen and progesterone receptor staining. And the ATAC trial that I told you about, which was Arimidex versus Tamoxifen was run both in North America and in Europe. And in the European trial almost 50 percent of the patients are estrogen receptor unknown, because it wasn't something that was routinely done. And of course, this was during the change over and people trying to establish, you know, what would be an appropriate threshold in relation to the Ligand binding assay. You know, as a resident, as a fellow, and as a junior oncologist, this wasn't something that, you know, that we were reading about or, you know, looking at ourselves in the literature. So if there were things before that, I'm not aware of it.
CHAYTOR, Q.C.:
Q. Wasn't anything that was taught specifically to you during your training?
DR. LAING:
A. No.
CHAYTOR, Q.C.:

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Q. Okay. And the 2000 study, the National Institute, did that say one percent?
DR. LAING:
A. No, it doesn't say. If you read that, it wasn't a study -
CHAYTOR, Q.C.:
Q. Any degree of positivity?
DR. LAING:
A. - it's a consensus--it's a consensus statement.
CHAYTOR, Q.C.:
Q. Yes, yes.
DR. LAING:
A. And I know I did review it sometime in the last week or so in preparation and it just sort of says that any degree of positivity, but it doesn't sort of come out and say--you know, because as I said, there's different ways people do it. Some labs would report threshold, some labs would report a number, some would look at its intensity and give a score and--but, you know, our lab used 30 percent initially and then, you know, then as time went on as we as the oncologists started to change our thinking, we didn't have any

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formal process, as I said, it was really just by dialogue directly with individual pathologists.

CHAYTOR, Q.C.:

Q. And the wording, and we don't have that study readily in front of us, but any degree of positivity could mean something other than one percent?

DR. LAING:

A. Sure.

CHAYTOR, Q.C.:

Q. In your interpretation?

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. Yes, okay. All right, I'm sorry, Doctor.

DR. LAING:

A. And then, of course, we discussed the impact that this had on the patients. And certainly there were people who should have received adjuvant or metastatic treatment with hormonal therapy that did not. We touched very briefly on the issue of, you know, were there some people who you may not have offered chemotherapy to and most of those discussions

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we had with patients on an individual basis. But just to say that in many instances patients get both chemotherapy and hormonal therapy. That the flip of what we want to happen with adjuvant therapy, of course, meant that there were patients who, because of not getting hormonal therapy were at increased risk of relapse and increase risk of death from breast cancer. That we appreciated the stress that this caused to all of the patients, even in people who were hormone receptor negative to being with and stayed hormone receptor negative; that we felt that we really needed to say that this was something that we were dealing with with all patients, and not just people whose results changed, and I would argue maybe not even just breast cancer patients, because it certainly did have an impact on all of the people that we were seeing in the clinic, and of course, the very difficult issue with uncertainty about their care.

And then I think we'll talk about this later, about the tumour panel and how we did that and why and the recommendations that we

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made. So I think maybe we'll leave that for when we come to that discussion, if that's okay with you?

CHAYTOR, Q.C.:

Q. Sure.

DR. LAING:

A. And then really just to say that, you know, the story's not over, in terms of hormonal therapy, be it adjuvant or metastatic, that you know, as time goes on, we really need to better know how to use these predictive factors, and when you say that, then the next thing that you have to say is that if you're going to use them, then you need to be assured that the results that you're getting from the pathologists are as accurate as they can be. Because if you're going to start to get into looking at degree of expression, HER2 and ER/PR linking together, all these sorts of things, then you know, then you need to be sure that not only is it is there staining there, but if we're going to start using thresholds then that information needs to be as accurate as possible. That there's all sorts of--I could sit here for an hour and

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tell you about all the trials that are going on looking at various combinations and permeatations of hormonal therapy.

My suspicion is that we're going to start to leave patients on hormonal therapy for a much longer period of time. That, you know, now we're doing the ten-year trials and maybe we'll be doing the 15-year trials and on and on we'll go. And I think the main thrust of that is that we do still see these late recurrences and if we can find treatments to give to people to prevent cancer recurrence that are not detrimental to their other health, such as their bone health and that sort of thing, that you know, keeps their cancer away until they--as I always say to my patients, until you get to live to be old and cranky and die of something else, then that's certainly worthwhile. And that, you know, we try and provide as much ongoing support and education for our patients. I think the breast cancer retreat in this province is a prime example of excellent work being done there, and that you know, we do this because we want to continue to have that mortality

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line go down. We're not happy with where it is today. We're happy that it's coming down, but we would like to eventually get to a point where, through prevention and screening and effective adjuvant treatments, that we wouldn't have breast cancer be a cause of death for patients. And I believe that that's the end.

CHAYTOR, Q.C.:

Q. Okay. Thank you, Doctor.

THE COMMISSIONER:

Q. Ms. Chaytor, would you like to take the morning break before you continue? Because we're about a couple of minutes away from that.

CHAYTOR, Q.C.:

Q. Okay, sure. Thank you.

THE COMMISSIONER:

Q. We'll take 15 minutes.

(BREAK)

THE COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. Commissioner, I have three new exhibits that I would ask, please,

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to have entered. It's C-0243, C-0244 and C-0245.

THE COMMISSIONER:

Q. 243, 44 and 45?

CHAYTOR, Q.C.:

Q. Yes.

THE COMMISSIONER:

Q. Entered.

EXHIBITS ENTERED AND MARKED C-0243, C-0244, C-0245

CHAYTOR, Q.C.:

Q. Thank you. Doctor, I just want to clarify a couple of things from the presentation. You mentioned that there are 350 new breast cancer patients each year or approximately. I think it's up to 370 now the presentation said.

DR. LAING:

A. That's right.

CHAYTOR, Q.C.:

Q. And those included in situ as well as invasive?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. In situ disease as well as invasive.

DR. LAING:

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A. Yes.

CHAYTOR, Q.C.:

Q. And that would be ductal, I would take it, DCIS, as well as lobular in situ?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And are DCIS cases and lobular in situ cases currently tested for ER/PR?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. They're not, and about how many, what number of the new breast cancer patients would fit into that category?

DR. LAING:

A. I'd actually have to go look at the numbers, but I would think that lobular carcinoma in situ would be an uncommon presenting for us to see at the Cancer Centre. So I would say out of that 370, maybe ten at the most. Ductal would probably be about 50 or 60. I don't believe that I looked at the actual breakdown for 2007, but in other years, it would be a similar number. The incidents of ductal

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carcinoma in situ is actually going up because of mammographic screening, because these are the ones that are picked up easily on mammograms, because of the calcification.

CHAYTOR, Q.C.:

Q. Okay, and so ER/PR tests then are done on all other breast cancer patients?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. There are no other categories that are excluded?

DR. LAING:

A. No, there isn't.

CHAYTOR, Q.C.:

Q. Okay. So there'd be, according to that, there'd be about approximately 300 tests?

DR. LAING:

A. To 320, I'd say.

CHAYTOR, Q.C.:

Q. ER/PR tests?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. That would be done if it were happening here

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in St. John's?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Yes, okay. The importance or significance of the ER/PR test in determining the treatment that a patient will receive, and you've taken us through some detail in terms of hormone treatment, does the result also determine or affect the type of chemotherapy that the patient may receive, whether or not the patient would, in fact, receive chemotherapy, duration of chemotherapy and the timing of the chemotherapy?
DR. LAING:
A. No, it doesn't determine what type of chemotherapy that someone would receive, nor the duration. In terms of timing of all the systemic therapies that we use, chemotherapy comes first. Hormonal therapy and Herceptin come second and radiation comes third. The reason for doing systemic therapy, chemotherapy, specifically prior to radiation, is that if it's done in the opposite sequence, there's a higher risk of systemic failure. So

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if you give the radiation first and give the chemotherapy second, there's some very old trials that show an increased risk of systemic failure, which is incurable, and so and the reason to not give chemotherapy and hormonal therapy together is that there is a trial from some time ago, from the CALGB. Dr. Kathy Albain was a principle investigator on that trial, where patients received an anthracycline-based chemotherapy regiment, plus Tamoxifen at the same time, and they actually had a worse outcome than if they got the chemo first and then the hormone second. And it is thought that because chemotherapy works by killing cells that are growing and dividing and it takes longer for hormonal therapy, as I mentioned in metastatic disease, to have an effect. So what you often see when you first treat people with hormonal therapy is you get a stases of the cells, so that they're not dead, but they're just not growing and dividing, which means then you put chemotherapy on top of that and the cells are quiescent. They're in their resting phase, so they're not--they're protected, if you will,

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from the affects of the chemo. So that's why that sequence.
But in terms of determining if someone needs to have chemotherapy and what type chemotherapy, it doesn't matter. The estrogen receptor doesn't play into that role. Where it comes important is for some patients who may have early stage disease who you're looking and saying if they're hormone receptor positive, I'd likely just give them hormonal therapy. But if they're negative, I'm going to give them a short course of chemotherapy. But in many instances, when you see patients, even if they're hormone receptor positive, it's the prognosis that's the most important thing. So you might say, look, this person might be very strongly ER/PR positive, but they've got a large tumour. They've got lots of lymph nodes involved. They've got lymphatic and vascular invasion, so I'm going to give that patient chemotherapy and then the hormonal therapy comes after.
CHAYTOR, Q.C.:
Q. Okay, and do you know, in the review of this case, on patients who originally were ER

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negative and on retesting were positive, were there cases when you reviewed the matters that perhaps, had you known, or had the treating oncologist known they were ER positive, would have been set on a course of hormone therapy as opposed to the chemotherapy they received?
DR. LAING:
A. Yes, that was a more difficult issue to address, and the reason was two-fold. One was because, as I said, in many instances, patients require both, and the other is that, you know, that decision is based on a balanced discussion with the patient, and then the third reason was is that for many of these patients, we were--the people who were doing the tumour panel were not the original oncologists, and so, and sometimes when you went back and looked at the notes, it was difficult to recall how much, if any, conversation was had around, you know, giving them chemotherapy versus a hormone.
I know that when I sat down with my own patients and disclosed the change in results, that on an individual basis, because I had been there for the initial discussion, that

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there were some patients who we did discuss, you know, and they said to me, quite out and out, "Dr. Laing, if you had known this, would you have still offered me chemotherapy?" and for many of those patients, I said "yes, I still would have" and for some of those patients, I said "no, perhaps I would not have given you chemotherapy for your stage one, node negative, one and a half centimetre tumour had I know that it was ER/PR positive." Yeah.

CHAYTOR, Q.C.:

Q. Okay. So there were some of those cases. So what the review indicated, and the impact of all of this on the patients, it's not only that there were patients who missed out on the opportunity to have hormonal therapy earlier, there are also some patients who perhaps had treatment that otherwise would not have been indicated had the treating oncologist known the correct ER status in the first place?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Yes, okay. Doctor, the point too that you

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made about at the tumour board and obviously you would have your own patients, you would have your independent recollections other than what's written in the chart and I'm sure that varies over time and with the volume of patients that you have, but you would have at least some recollection of discussions beyond that. Was there any consideration given along the way for any of those oncologists who were still with you, and I appreciate that there has been a turnover as well, but inviting them to attend tumour board or the physician review panel while their patients were being considered?

DR. LAING:

A. No, we didn't think about that at the time. The physicians who participated in the tumour panel were myself, Dr. McCarthy, Dr. Zulifqar, Dr. Ahmad on a few occasions, and some of the patients, as you know, were cared for initially by those oncologists. There were an awful lot of patients though, particularly in the '97, '98, '99 and even in early 2000, who were not--that their oncologist simply wasn't around any more and wasn't available. So the-

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-when the letter was written to that attending oncologist, if they were still somebody who was practising and working with us, then you know, on some occasions they would come up and say, you know, "I got your letter from tumour panel. I know you talked about such and such a patient, and you know, what did you say? I get this recommendation. I'm going to see her next week," or whatever, you know, and we would review the discussion with them on a more in-depth basis. But you know, at the time, there were very few of us around who were able to do that work and really trying to get everybody together was--you know, trying to come up with a time and trying to ensure-- we wanted, at each tumour panel, for there to be at least two medical oncologists there, so that there could be a balanced discussion back and forth.

CHAYTOR, Q.C.:

Q. Yes, and I'll talk to you about that too, yes, because there are times obviously that you weren't able to achieve that as well. Doctor, so in terms of consulting with the treating oncologist, if he or she were still within

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Eastern Health, there were times when you did have discussions with them about what was recommended in the letter. Prior to the recommendation going forward, were there ever any times when the panel tried to consult with the oncologist, the treating oncologist?

DR. LAING:

A. No, not that I can recall. We would have had the notes there and the notes from most of the--from the oncologists that were still there, would often be detailed enough that we could know that those discussions had happened. It was some of the older notes that, you know, there were--that the actual discussion about what was talked with the patient were not as detailed.

CHAYTOR, Q.C.:

Q. And I take it then, those oncologists were no longer within Eastern Health and you couldn't consult or there was no attempt made to try and consult with them?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Okay. And I'll ask you some more questions

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about that whole process. I'd like to get into some detail on that in a little while, but in terms of ER/PR, are there certain types of cancer that are known--breast cancers, that are known to be more likely considered hormone receptor positive?

DR. LAING:

A. Yes. So lobular cancers are more likely to be hormone receptor positive. Well differentiated cancers are more likely to be hormone receptor positive.

CHAYTOR, Q.C.:

Q. And how long have you known that?

DR. LAING:

A. About lobular cancers being more likely to be?

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. Since my training.

CHAYTOR, Q.C.:

Q. Okay, and what about the other types, the -

DR. LAING:

A. Ductal?

CHAYTOR, Q.C.:

Q. Yes, the--no, not ductal, the well

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differentiated. I'm sorry, what did you--what was your second type that you gave?

DR. LAING:

A. Oh no, so if you look at grades of tumour and association with ER positivity, poorly differentiated tumours are more likely to be ER negative and well differentiated tumours are more likely to be ER positive.

CHAYTOR, Q.C.:

Q. Yes, okay. So and when would you have known that?

DR. LAING:

A. Since my training as well.

CHAYTOR, Q.C.:

Q. Okay, and in terms of more likely, what was your understanding--up until say 2005, what was your understanding as to how likely lobular cancers would be ER positive or hormone receptor positive?

DR. LAING:

A. Right, so we were always taught somewhere around 85 to 90 percent of lobular tumours would be hormone receptor positive.

CHAYTOR, Q.C.:

Q. 85 to 90 percent?

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DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and again, Doctor, in doing the tumour board or physician panel review, I think that's what I'll call it, physician panel, so we don't confuse tumour board.

DR. LAING:

A. Okay, yes, so we don't confuse it with our usual ones.

CHAYTOR, Q.C.:

Q. Yes, and I believe that, in fact, is what it was called for the purpose of your minutes. It was physician review panel.

DR. LAING:

A. We called it the panel, yeah.

CHAYTOR, Q.C.:

Q. All right, the panel. So in doing the physician or the review panel, were there a number of lobular cancers which had been originally tested as ER negative?

DR. LAING:

A. In the very beginning, when--you know, and I'm sure that we'll discuss that with the index case.

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CHAYTOR, Q.C.:

Q. With the index case, yes.

DR. LAING:

A. That was, you know, this is how this all started. The very few set of patients that we asked to be retested, you know, in that, in the spring and early summer of 2005, many of those patients were lobular. At the end of the day, once the whole panel was finished and we had reviewed patients, I've never actually seen the statistics come out of that to know how many of those were lobular, but it was less as time went on, you know. When we started to get the retest results back, many of the patients who had a change in results were in fact ductal, and that probably has to do with the fact that 70 percent of breast cancers are ductal to begin with.

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. So you know, when I think back through the lobular patients of mine who had a change, it wasn't very many of them, and I think you and I are going to talk about those as we go,

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yeah.
CHAYTOR, Q.C.:
Q. Yes, and there were others as well, in terms of other oncologists had lobular patients who were originally negative as well?
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. So again, in terms of pooling the knowledge and keeping track of that, and whether or not that may have alerted the oncologists to anything earlier, do you think that might have been a worthwhile endeavour?
DR. LAING:
A. You know, when I think of all the people that we reviewed at the end of the day on the panel, that information has gone into the Centre for Health Information database that Eastern Health had constructed.
CHAYTOR, Q.C.:
Q. The type of tumour?
DR. LAING:
A. We asked for that to go in, because I think that would be worthwhile to look at.
CHAYTOR, Q.C.:

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Q. Um-hm.
DR. LAING:
A. But I'm not sure that that has been done. What I can tell you though is that as time went on, the fact that this was something that we were seeing only in the lobular cancers was not--you know, I can tell you that as part of the whole review, that wasn't something that stuck out at the end, that these patients changed because they were all lobular tumours, that was not the case.
CHAYTOR, Q.C.:
Q. No, not at all.
DR. LAING:
A. Not at all.
CHAYTOR, Q.C.:
Q. But whether or not there were 85 to 90 percent of them were positive, that's something--whether or not you were fitting within that range are you able to say whether or not it appeared to be more than 85 to 90 percent?
DR. LAING:
A. No, because I think there's two things there. One is that of the patients that were reviewed, not as many of them were lobular as

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were ductal, and without a database to go back to and say let's look at, say, the last ten years before 2005 and see how many of the lobular cancers that were reported were positive, then I can't really say.
CHAYTOR, Q.C.:
Q. Right.
DR. LAING:
A. In the early days when--you know, after the index case came, I had two patients in my practice who I identified who were lobular, who were said to be ER/PR negative and I had those retested, and both of those had a change in their results.
CHAYTOR, Q.C.:
Q. Okay, and Doctor, I guess my point being that on a go-forward basis, the importance of tracking that type of information and how it may have been helpful in the past -
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. - to have had had that type of information into a database?
DR. LAING:

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A. Yeah, I think with a database, you would be able to look at trends and you know, you would be able to look at what was your overall ER positivity rate, knowing that it should fall somewhere around 75 percent, looking at what your overall positivity rate is. You know, I think Dr. Banerjee made a reference to their lab in BC, it was 92 percent, you know. So I guess with their database, they were able to keep track of that. We didn't have that ability. In retrospect, when I looked back at the cases that I had of patients who were lobular, who were said to be ER/PR negative, there wasn't anything at the time that I looked at that sort of made their case jump out and say "wait now. You know, these should be patients who are positive," knowing that, you know, not everybody is. That if it's 90 percent, out of every, you know, 100 lobulars that you're going to see ten of them should be negative. I would imagine that the majority of lobulars that we were seeing were in fact positive and there was no sort of alarm bells raised.
You know, and I think we'll talk about

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this as time goes on, but certainly this is something that I've thought about. The index case presented with metastatic disease, very aggressive cancer, very young patient. The person who I identified next who just happened to be coming for follow up who had lobular disease had a poorly differentiated tumour, and the other patient had metastatic disease and had a very aggressive tumour, and in fact, the pathology was signed out as undifferentiated. So it was a very aggressive looking cancer. So you know, these patients had very advanced disease at presentation, were said to have poorly differentiated tumours, had an aggressive course. So there wasn't anything about the ER negativity associated with the lobular histology that really raised any concern with me.

CHAYTOR, Q.C.:

Q. Okay. Doctor, and the issue that we discussed during your presentation as to the correlation between ER positivity and PR positivity, was that also something that you would have learned during your training?

DR. LAING:

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A. No, I think that's something that's been recognized more of late. You know, we were certainly taught that there was four different combinations that you could have, positive/positive, positive/negative, negative/positive, negative/negative. The whole teaching around response rates, you know, went right back to my residency training and that information really hasn't been updated in any way in the literature because, you know, those were studies that were done back even in the 80s.

When this whole idea of, you know, the expression of estrogen being related to the expression of progesterone is very new, like in the last couple of years, as people are really looking at level of expression and what that means, particularly for, you know, type of adjuvant therapy that's required, and you know, the feeling in the oncology community is that this is something that really needs to be identified on a prospective basis. So people need to be gathering that information at the time of putting patients on clinical trials, and then following it forward, as opposed to

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taking a clinical trial that's already been done and then retrospectively going back and looking at ER/PR expression and response to therapy.

Whenever you use a predictive factor retrospectively, we consider that to be hypothesis generating. So this wasn't the main point of this study. So the studies may not be powered. They might not have enough patients in each of those categories to really make a conclusive statement, and so we consider those--and there's all sorts of things that you'll see done, so sort of post trial analysis that may look at things like, not just hormone receptors. They might look at HER2 expression. They may look at nodal involvement, and really to get some sort of an idea. But when it's done in a retrospective fashion like that, we tend to think about it as being hypothesis generating and really before it's practice changing, it needs to be shown prospectively to be a persistent and robust result.

CHAYTOR, Q.C.:

Q. So the idea of--and some of the literature

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that we've seen talking about ER positive if you're PR positive, 95 or 96 percent or 98 percent, very high percentage then, would also be ER positive if you're PR positive, you know.

DR. LAING:

A. Yes, I see what you mean.

CHAYTOR, Q.C.:

Q. It would be less than four or five percent that would, in fact, be ER negative. That idea, when did you learn about that?

DR. LAING:

A. Later on, as well.

CHAYTOR, Q.C.:

Q. And what do you mean by later on?

DR. LAING:

A. You know, when I think back to when I was, you know, a resident and even, you know, a newly attending oncologist, there wasn't as much discussion about, you know, level of expression and what it all meant. It's only been since we've started to do the adjuvant trials, looking at the aromatase inhibitors and really trying to understand better predictive markers in oncology. So you know,

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what's known about the estrogen receptor in 2008 and even 2005, is a lot more than was known back in 2000. So -

CHAYTOR, Q.C.:

Q. So you didn't know that in -

DR. LAING:

A. You know, it wasn't something that I can tell you that -

CHAYTOR, Q.C.:

Q. So in 2002, you weren't aware of that?

DR. LAING:

A. It wasn't something that I was aware of. We mostly -

CHAYTOR, Q.C.:

Q. In 2002?

DR. LAING:

A. - we mostly went by, you know, what the results were from the lab. Was it positive or negative? And that's how we based our decision in the clinic.

CHAYTOR, Q.C.:

Q. And seeing anything in terms of PR positivity and ER negatives, the idea of that being, you know, a rare occasion -

DR. LAING:

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A. I'm sorry, ER negative PR positives?

CHAYTOR, Q.C.:

Q. ER negative PR positive, yes, sorry.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. ER negative PR positive, and seeing that as being something that should be infrequent, probably only four or five percent of the time, did--you weren't aware of that, say in 2001, 2002, 2003?

DR. LAING:

A. I certainly would have had patients that were ER negative PR positive. I just don't think that I was seeing enough patients or seeing enough of that for it to register as a trend. Certainly we knew that it existed. It was well described and it's only been recently that, you know, that the actual percentage of that that should exist is about five percent.

CHAYTOR, Q.C.:

Q. And what do you mean by recently?

DR. LAING:

A. So if you look at the adjuvant trials for adjuvant--the new trials for the aromatase

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inhibitors, and if you look at the patient characteristics and sort of see that, you know, the majority are ER/PR, then there's ER positive, PR negative, and a smaller percentage are ER negative PR positive, I mean that's been in the last four or five years. There are some--I mean, you have to realize that, you know, because of this process, I've probably read and learned more about the estrogen receptor and that than I probably would have otherwise.

CHAYTOR, Q.C.:

Q. And that's what I'm trying to understand.

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. Like what would your knowledge level be in, you know, the time period that the Commissioner is looking at here?

DR. LAING:

A. You know, in that time period, you know, this was a new test. The cut off was not well defined. You know, I have, through the course of reviewing materials for this, have found references in 2001 and 2002 from Dr. Allred

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that looked at ten percent as a cut off. I can--you know, I can remember that, you know, I trained and we got a number. I came back here, we got a percentage. The pathology reports often referred to the 30 percent. We accepted that. It was really in the San Antonio Breast Cancer Conference in 2000, during a--at that meeting, one of the things that we found quite valuable was that there's a panel where you can go and present cases, and so oncologists from around the world can get up and on that panel, there are, you know, experts in radiation, medical oncology, pathology. In fact, they even have, for many years, a patient on that panel. And I remember at that conference that Dr. Kent Osbourne who's from San Antonio, from the Cancer Centre there, who's a medical oncologist, saying that people really--you know, that the cut off wasn't well defined, but people were starting to recognize that the cut off maybe should be as low as ten percent, and that was the first time, you know, when I think back, that I can ever sort of remember hearing that, and then so that's when, sort of

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when I came back, I worked in the early part of 2001. I was off then for six months, and then coming back, and really start of--when we didn't have that information, we didn't actually have the percentage in front of us, that we would sort of start to talk to the pathologist. But that was the first time that I had ever, you know, heard a reference to ten percent as being as a cut off.

CHAYTOR, Q.C.:

Q. So that, in terms of the change then in the cut off here, that would have been later into 2001, after you're back from your maternity leave?

DR. LAING:

A. Right, yeah.

CHAYTOR, Q.C.:

Q. And you started having that conversation with the pathologists?

DR. LAING:

A. Right, but this was an opinion from an expert in the field. This wasn't really based on anything that I could find in terms of a publication, but this was based on their experience, and again, bring back to the point

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that it's based on the experience of seeing how metastatic patients do, because you know, they might have someone in the clinic who perhaps had cut off--you know, if they were using a higher cut off and said well, there really isn't anything else, and I remember him saying we've treated some patients who only have around ten percent staining, and we've seen some good responses. So they were rethinking at that time, in late 2000, what their cut off should be in their institution.

CHAYTOR, Q.C.:

Q. So Doctor, in terms of that though then, sometime then later in 2001, the decision was made to change in Newfoundland what would be considered positive result to the ten percent? Is that right?

DR. LAING:

A. I think it would be fair to say that a decision was made by the individual oncologist, because again, there wasn't any formal statement. We weren't in the process of having the time or the resources to write guidelines or really to do things in that way.

CHAYTOR, Q.C.:

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Q. Okay.

DR. LAING:

A. And I know that when I came back in late 2001, at that time, you know, we were joined on staff by some physicians who had trained in Ontario and who had been trained in the later years than I had, and I remember some discussions with them that they were starting to--you know, that they had been starting to use ten percent as the cut off, in terms of treatment. I think that there's--you know, there's a difference sometimes in what is reported in the pathology lab and what--you know, what clinicians are using in the clinic, and that's not just true for ER/PR. You know, when we sat down and talked with our colleagues in Ontario, you know, leading into this and the tumour panel and all that sort of stuff in 2005, you know, you have one hospital in Ontario who reports, and that was Mount Sinai, of course we were starting to get the reports. They were--you know, they started to be the things that we were seeing every day, in terms of our day-to-day practice, and they reported as positive as being greater than one

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percent, and I recall having some conversations at meetings and stuff with my colleagues and saying "well, what are you guys treating? Are you treating one percent?" and many of them said "no, no. The pathologists report that, but you know, we mostly treat still at ten percent."

At the same time that Mount Sinai was doing that, Sunnybrook Hospital, down the street, would report as, you know, negative as being less than five, and five to ten to be minimumly positive. So there's all sorts of different cut offs that were used in different labs, and you know, and in the tumour panel, there were some patients that we reviewed who might have had an ER test result come back at five percent. But they were an older patient who were not fit for chemotherapy. So you may have made a decision based just simply on that to have offered that patient Tamoxifen. There were people who were ER/PR negative -

CHAYTOR, Q.C.:

Q. Were there anybody--I'm sorry, did the tumour panel recommend Tamoxifen for anyone under ten percent?

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DR. LAING:
A. When--and the reason for all that I just talked about, in terms of going looking at it, was that we--because we were getting these very, very few Mount Sinai reports at that level, that we needed to make a decision. So for the most part, no. The tumour panel didn't recommend treatment on results that were between one and ten percent. There were very few of those that came back that low, and most of the ones that we saw that there was a change in, you know, they were strongly positive for PR or for ER and/or PR.
THE COMMISSIONER:
Q. I think I've gotten more confused than less with that last little bit of the conversation. Early this morning, I got an impression as to how things worked, and now I don't think I had it right. So can we just go back and -
DR. LAING:
A. Certainly.
THE COMMISSIONER:
Q. - see whether or not what I've understood is correct. In answer to Ms. Chaytor's question, and I don't really think you answered her

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question. You answered perhaps some other one, but that's beside the point. You talked about the recognition of a cut off as being as low as ten coming out of the San Antonio conference. You came home, you were off on leave, you came back, and then you made the remark that essentially, that was a--whether to go to ten percent was a decision for individual oncologists.
DR. LAING:
A. I think what I meant at that point was that there wasn't any other formal mechanism. This morning we had discussed whether or not there had been a consensus amongst the local physicians that there would be a new cut off used or that there had been any meetings between oncology and pathology in those days to say, you know, starting now, this is how we're going to report things, and this is how things are going to go ahead. That didn't happen at that time, no. But what had happened, I guess, is that, you know, individual people had somehow changed their thinking. New staff had come in who were, you know, who had been trained, just finished

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their residencies in 2001, who thought about ten percent as a cut off.
THE COMMISSIONER:
Q. Okay. So can we say that whether by osmosis, whether by informal discussion or at some point, and you can't--can we really even identify when in 2001 ten percent became the cut off?
DR. LAING:
A. I think it's very difficult to put an exact time on when that changed, and I've thought about that, and you know, there are times in medicine where things change just as you described it, sort of gradually over time. You know, patterns of practice change. You know, how we look at things changes over time, and sometimes -
THE COMMISSIONER:
Q. So couldn't, for example, the change have run into 2002, for example?
DR. LAING:
A. I think it did.
THE COMMISSIONER:
Q. Could there have been oncologists well into 2002 who might have been using 30 as opposed

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to ten?
DR. LAING:
A. I think there was, and I think that that was evident when we did the review, and when we did the tumour panel, and there were instances where when we reviewed the initial pathology reports, that there were still references made to the article that used 30 percent as a cut off, and I recall, in the tumour panel process, looking at some pathology reports from external labs that would say "estrogen receptor negative, progesterone receptor negative" and then below that, there was a comment made that, you know, there may have been 25 percent staining, but as to this particular article, we would consider this negative. So I think that there were instances where people looked at the result and said "okay, it's negative" and that's how the patients were treated. So it's been difficult to define an exact moment where things shifted from one to the other. And on top -
THE COMMISSIONER:
Q. So two questions come to my mind in respect of

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that information. One is, is it not then entirely possible that in the retest process, there were people who were determined to be in or out of the retest on a basis that did not apply to them originally?

DR. LAING:

A. That is a very good question, and that is something that we have had discussions about in the last several months, and in my own practice of people that are still following me, there was one patient who was identified by that mechanism, because in somewhere after 2001, they had a result that was 20 something percent, and it was--they were not retested.

CHAYTOR, Q.C.:

Q. And we've heard certainly from one of your patients here that would have fallen -

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. - she was 23 percent.

DR. LAING:

A. So we have had some discussions in the last few months about really making sure that there weren't those patients who had been missed. I

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think that if I think about the patients that are still being followed in the Cancer Centre, I can tell you that everyone of my patients, and I'm--you know, the other oncologists can speak for themselves, but I'm sure you'd probably get a similar answer, that we have picked up and gone back through and read through the pathology reports to ensure that there wasn't someone who perhaps fell through the cracks. Could there be someone who wasn't identified by that mechanism? Could there be someone who's not followed any more? Yes. And certainly, the last place that we left this discussion with Eastern Health was to actually start to compile all of the breast cancer patients in that time period, from 1997 onward, to put them into a database and to ensure that there were not patients that were missed, and if they were identified, to have them retested. And I guess it came back to the same premise as our original reason to redo the testing was that, you know, if we could find one person that results may change. I'm not certain as to where that activity is now. Mr. Miller from--who's in charge of

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research and that at Eastern Health was working on getting that information with Mr. Gulliver, from the lab, to ensure that we would have a complete data set that said, you know, what the person's initial--what their ER/PR was to make sure that there are people that there may have been flag come. And of course, that would involve a review of their cancer patient chart.

CHAYTOR, Q.C.:

Q. And, Doctor, we'll follow up then that with Mr. Gulliver when he gets here next week. But originally there was a decision made back in 2005 when the decision was made to do the retest, the decision was made to use a cutoff, January 1st, 2001. Anything after that date, patients were identified based on a ten percent cutoff.

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. Were you part of that decision?

DR. LAING:

A. I did not make that final decision.

CHAYTOR, Q.C.:

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Q. Were you consulted on that decision?

DR. LAING:

A. What I--the conversations that I recall having with Dr. Williams and Dr. Cook were really to sort of outline when--what we were using in the clinic at that time and I spoke to that from my own practice as an oncologist, that it was after that San Antonio meeting that we started to consider ten percent.

CHAYTOR, Q.C.:

Q. So they would have been told that we started to consider ten percent after the San Antonio meeting in 2000?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. But not that everybody had adopted the practice as of January 1st, 2001 of using ten percent cutoff?

DR. LAING:

A. It would be difficult for me to say that everybody did that without, you know, having known what each individual oncologist was doing at that time.

CHAYTOR, Q.C.:

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Q. And did you alert that--did you alert Dr. Cook to that?
DR. LAING:
A. I'm not certain. I cannot recall that conversation to the degree to know whether or not he had spoken with Dr. McCarthy about the same issue or--to be quite honest with you, I don't think at that time that we realized that there may have been some delay in other people adopting that as their practice, if you will.
CHAYTOR, Q.C.:
Q. But you, yourself, had patients that you hadn't adopted that as the practice. We've seen--at least one of them has been here, so.
DR. LAING:
A. That actually is, it wasn't that I hadn't adopted that practice, it was there was other factors that weighed into whether or not that patient took the Tamoxifen.
CHAYTOR, Q.C.:
Q. Okay. And perhaps then we'll discuss her case a little later then and you -
DR. LAING:
A. Sure.
CHAYTOR, Q.C.:

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Q. - and you can explain that to us. But you, when did you come back from your maternity leave in 2001?
DR. LAING:
A. October.
CHAYTOR, Q.C.:
Q. October. And so it was sometime after you came back from your maternity leave that the change was made. So it would have been--in terms of practice. So it would have been late in 2001. So did you express any concern to Dr. Cook about using a January 1, 2001 cutoff as the time period as opposed to no cutoff, for that matter, going with 30 percent throughout?
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. Or going late into 2002?
DR. LAING:
A. Yeah. I wasn't part of that final decision. And as I said, I just, you know, communicated what my practice was. And so, you know, in fact, when I did look specifically at the case that we've briefly alluded to, if you read -

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CHAYTOR, Q.C.:
Q. Yes. No, I'll come back--I don't mean to cut you off, Doctor, but I'll come back to that particular case.
DR. LAING:
A. Okay.
CHAYTOR, Q.C.:
Q. Because I'm not necessarily concentrating on you individually in your individual practice. I'm asking about your discussions with Dr. Cook around coming up with this cutoff.
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. And you as director of medical oncology at the time, whether or not you inquired of your other oncologists as to, well, what was their practice and is this a safe thing to be going with, a January 1st, 2001 cutoff knowing that you didn't come back from your maternity leave until late into 2001 and that the discussion around changing the cutoff happened then?
DR. LAING:
A. Right. No, I didn't have any further discussions other than what I've outlined to

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you with Dr. Cook. And, you know, perhaps, you know, in retrospect we should have had a cutoff of less than 30 percent for the entire time period. But, you know, that was a decision that was made once they decided which slides to pull and send after, you know, some consultation with me, but that final decision wasn't one that I made.
CHAYTOR, Q.C.:
Q. And in the fall of 2001 when the conversations or discussions took place about changing the cutoff for treatment purposes, what discussions would have been had with the pathologists at that point in time?
DR. LAING:
A. Again, at that time the discussions that we would have had with the pathologists would have been individual discussions between individual medical oncologists and pathologists. I can only speak from my own practice. I wasn't director at that time. But just, you know--and most of the patients that I would have seen, you know, would have been from the same group of pathologists and most of the reports that I would have had

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would have had all the necessary information. If there was ever a pathology report that I felt that I didn't have all the adequate information I needed, be it, you know, the percent staining of ER/PR other than just negative, be it the number of lymph node samples, then I would consult the pathologist formally, usually with either a phone call or a formal consultation letter and ask to have that information clarified.

CHAYTOR, Q.C.:

Q. So was there anything brought up, for example, at the tumour board rounds at that point in time? I know you had told us yesterday there was a period of time, 2001, when there wasn't tumour board rounds?

DR. LAING:

A. Right. So they probably started up again in 2002.

CHAYTOR, Q.C.:

Q. Okay.

DR. LAING:

A. I can't recall any specific discussions, as I mentioned yesterday, about the issue of thresholds or reporting at that time, no.

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CHAYTOR, Q.C.:

Q. And nothing in writing, no memorandum between the cancer care program oncologists and pathologists to say we are now using a ten percent cutoff?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And how was it communicated amongst the oncologists?

DR. LAING:

A. So -

CHAYTOR, Q.C.:

Q. That we're now moving to a ten percent or that I've been to this conference, it's indicated that ten percent would be a more prudent marker, how was that communicated to the other oncologists?

DR. LAING:

A. Again, the only person that I can recall having specific conversations related to that to would have been Dr. McCarthy. And you know, it would have been as we went into 2002. At that point I had been back from maternity leave and she had already commenced her

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practice there. And you know, at that point we were starting to evolve to be the medical oncologists who got asked to see a lot of the breast cancer patients. And so through some discussions with her, you know, we talked about cutoffs and thresholds. That's not an uncommon thing to happen. We do lots of clinics where they are together and we run things by each other and--but again, there certainly wasn't any formal process in place at that time where I think this information could have been shared and nor do I recall thinking in those days that, you know, maybe we should have any sort of a formal change or, you know, announcement or those sorts of things.

CHAYTOR, Q.C.:

Q. But there's no--there's only a handful of you, really, as medical oncologists at that point in time?

DR. LAING:

A. There's -

CHAYTOR, Q.C.:

Q. Five--there's seven of you now and there was less?

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DR. LAING:

A. There was less and there were different people and there were people coming and going and, you know, people that did breast cancer and--I mean, still at that time -

CHAYTOR, Q.C.:

Q. Well perhaps more important then if that's your situation that you would have something reduced to writing that everybody could follow?

DR. LAING:

A. You know, if you sort of sit here and look back at that, you know, I can--yes, you know, I cannot disagree with you. But I think that you need to sort of think about how things were at that time. There was still a large turnover in 2000 and 2001. You know, I had been on maternity leave. One of my colleagues left just as I got back. One of them left shortly after that. We had new oncologists. You know, we were just basically keeping our head above the water to get the patients seen and cared for on a day-to-day basis. There was a lot of concerns about workload, volume and you know. Yes, should we have been

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sitting down looking at guidelines and all that at that time, yes, in the ideal world, but I can tell you in those days we were just, you know, we were -

CHAYTOR, Q.C.:

Q. Well, Doctor, even without coming up with a formal guideline practice, you know, just a memorandum or an e-mail or any communication whatsoever with the medical oncologists, did anything like that happen to say this is now recommended to be the guideline?

DR. LAING:

A. Not that -

CHAYTOR, Q.C.:

Q. As the cutoff?

DR. LAING:

A. That didn't happen and I can't recall that, not at all.

THE COMMISSIONER:

Q. Do I take it--going go back to the second of my questions. And that is you indicated that for yourself the information that you would require was primarily on the report that you would get from the pathologist?

DR. LAING:

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A. That's correct.

THE COMMISSIONER:

Q. And if it wasn't, you would look for it?

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. Do I take it from that that generally speaking at that time it was your view that pathologists were reporting the percentages?

DR. LAING:

A. If I think back to that time, and of course, now having reviewed some of the reports through the process, but when we would get a pathology report and when we would sit in the clinic and see the patient, all of the important prognostic factors we would need to be there. And so it was not uncommon for us to have to talk to pathologists if there was some other piece of information that we thought might have been important that wasn't there. But I don't recall having to do it on a regular basis in terms of getting the percent staining for ER/PR. For a lot of the times it was there and sometimes it was--you know, there were reports that would say ER

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negative and then underneath it would say PR faint positivity in less than ten percent of the cells, which would still be considered a negative result from the clinical point of view at that time. So, you know, I wouldn't ask for that to be--you know, because the ER said negative, it was inferred that that was zero because the PR would have a qualifying comment. I can recall, you know -

THE COMMISSIONER:

Q. So whenever it said negative, you were assuming it was zero?

DR. LAING:

A. Not always. It would depend on how it was put into the context of the report. And because if there was a qualifying statement after something, then it would be--you know, they would say it was negative, but they might give a qualifying statement as to that, yes, we're calling it negative, but in fact, there might have been a little bit of staining in some of the cells, that sort of respect. But often they would say ER negative, five, you know, five to ten percent faint staining or zero percent staining or, you know. So for the

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majority of the time the information that was needed was there. If it wasn't there, then we would ask for it. And the reason why we started to ask for it was in some of these instances where we thought, well, it says that they're negative, do they mean that there might be--you know, are they saying that because there's 25 percent staining, well, I really need to know. And so when I would call the pathologist, I would say, got your report, you have negative there, was that no staining or was there a little bit of staining there and, you know, they would go back and look at the slides and issue an addendum to the report. No different than if, you know, they said that there was they may not have commented on whether or not there was a lymphatic and vascular invasion. And you know, those days there was some synoptic reporting, so there was some sort of consolidation of the important information into a synoptic template, but in some instances there wasn't. So I might have been very concerned to know if there was lymphatic and vascular invasion particularly if the

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patient had a medial tumour and if that wasn't there, I'd send a consult to the pathologist. Even though I called them, we would always follow-up with a written consult note because we'd want to identify the specimen number, so that, you know, that we were sure that they were looking at the right case and the right patient. So you know, when I think back to those days, the majority of time, you know, the information there, if it wasn't, then we spoke to the pathologists.

THE COMMISSIONER:

Q. So if the report came back simply negative or simply positive, you would call?

DR. LAING:

A. If it was--yes, if it just said ER negative, PR negative, and nothing else, then I would call and say, you know, what do you mean by negative, is there some staining there or not.

THE COMMISSIONER:

Q. All right. And if it said ER negative and then PR positive in less than something or another, because it said positive in less than ten percent, then you would make assumptions about what ER negative meant?

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DR. LAING:

A. Yeah. But they would actually--most often what they would say would be ER negative and then they would actually say PR negative, not PR positive, but they'd say PR negative, and then in a bracket would be a comment about things like faint staining seen in less than five percent or ten percent or some percentage -

THE COMMISSIONER:

Q. So if I go back through the reports in the time frame that we're talking about, I should expect to find, for the most part, not just positive and negative, but some kind of comment which would indicate to you what the pathologist saw as being negative or positive?

DR. LAING:

A. And the ones that I really, you know, would question were the ones that they still used the reference to the 30 percent cutoff. And the thing to remember, too, is is that, you know, this was what I was--my thinking during those days and my practice. Now I can think about pathology reports that we read as part of the tumour panel that had differing ways

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of, you know, writing things and expressing things and qualitative things after it. And certainly there were still reports that we saw from the 2002 time period, as we've discussed already, where they may have said that. The--you know, if I got a pathology report that said ER is ten to 15 percent positive and PR is negative and they still gave that reference, then that was fine because I still had the number so then I could base how I wanted to treat that patient in the clinic based on the number that was there. So the most important thing was to have the number so that we could--to make that decision based on that. But again, I need to stress that that's one of the factors. There are lots of people who are ER/PR strongly positive who we decided not to give hormonal therapy to. Maybe it was because their prognosis was so good, maybe there was a contraindication -

THE COMMISSIONER:

Q. That wasn't the point, Dr Laing. The point of the question is a communications one.

DR. LAING:

A. Yeah.

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THE COMMISSIONER:

Q. And frankly, the impression I'm getting from you and the one I got from the pathologists who have given evidence so far is different. I'm not seeing your versions of the communication the same. So what they thought they were telling you might be different than what you thought you were getting is my problem.

DR. LAING:

A. Okay.

THE COMMISSIONER:

Q. But that's my problem. So carry on.

DR. LAING:

A. Is there something else that I can -

THE COMMISSIONER:

Q. No. I think you've told me what you -

DR. LAING:

A. Okay, all right, okay, fair enough.

THE COMMISSIONER:

Q. - believe the situation to be.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. And, Doctor, I just want to clarify a couple

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of points, too, regarding the decision that was made in 2005 on retesting.

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. To use that ten percent as the cutoff as of January 1.

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. What you're telling the Commissioner is that Dr. Cook consulted you on it?

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. You told him about your own practice?

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. And you may or may not have told him in terms of when you came back from leave and when you think in 2001 those discussions took place in terms of changing the practice?

DR. LAING:

A. Um-hm.

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CHAYTOR, Q.C.:

Q. You did not consult the other oncologists in terms of what their practice may have been or relay any information to Dr. Cook about the other oncologists practice. Ultimately you did not make the final decision?

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. Were you aware of the final decision that was made?

DR. LAING:

A. Yes, subsequently I was aware of the final decision, which brings me back to the comment that I had started to make earlier regarding the patient who was--and the 20 something percent.

CHAYTOR, Q.C.:

Q. Did the final decision cause you any concern, Doctor, the decision to use the ten percent as of January 1st, 2001?

DR. LAING:

A. Not at that time, no. And when, you know, when we finally sat down and, as I said, recently, and had discussions about whether or

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not we should revisit that area, you know, I guess the difficulty is is trying to determine, one, do I think that those patients exist and the answer would be certainly it is possible. And do I think there are people that may not have been identified through review of their clinicians afterwards. I think that that is possible. I think that number is probably extremely small. It would be interesting to see at the end of the day if we do find anybody who falls into that category, but -

CHAYTOR, Q.C.:

Q. And the whole thing being if there's one patient -

DR. LAING:

A. And that was -

CHAYTOR, Q.C.:

Q. - I take it that's -

DR. LAING:

A. That was the discussion, you know, that was the decision -

CHAYTOR, Q.C.:

Q. So even if it is extremely small number?

DR. LAING:

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A. Yeah.

THE COMMISSIONER:

Q. I take it that is an ongoing project?

DR. LAING:

A. That is an ongoing project, that's correct.

CHAYTOR, Q.C.:

Q. And when was this initiated?

DR. LAING:

A. I'm just trying to recall. It was we had some--I'll tell, it was in about April.

CHAYTOR, Q.C.:

Q. April -

DR. LAING:

A. Just this past year.

CHAYTOR, Q.C.:

Q. 2008?

DR. LAING:

A. Yeah. And the reason why I remember that is that we did have some discussions about, you know, doing that and going back, because this is going to--this is sort of part of what I think, you know, can be done as part of the database. In fact, when we went to those meetings, I said, you know, this is a great opportunity for us to really put all this

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information into a database because I think-- and I think you need more than just the pathology information in there. I think you need to have the outcomes, and that's going to involve going to the clinic charts to determine that. But I also--at that time we did have some discussions with Dr. Maureen Trudeau who Eastern Health contacted to have an opinion from her as to, you know, whether or not, what she thought about this potential that could there have been some people missed in the retest during this what I would probably call the grey period. And there was actually a conference call that we had with her shortly after our NCIC meetings which were in April. And then Mr. Miller, who is in charge of research and that, it's been given the task to--or had been working with the Newfoundland and Labrador Centre for Health Information really to put together this database. But there's an incredible amount of information that I think is going to even make this picture clearer. I mean, your questions regarding how many of these people ended up being lobular, when I think of that as time

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went on, it was less, less and less. And even seeing, you know, how many people decided to take late adjuvant therapy, how are these people doing. I think there's a lot of information that can be derived from this experience that is going to be helpful to more than just us here in Newfoundland and Labrador.

CHAYTOR, Q.C.:

Q. Doctor, why was Maureen Trudeau, as a breast oncologist in Toronto, why would she be consulted on the issue as to whether or not patients may have been missed?

DR. LAING:

A. I have no idea. I only found out they consulted her when we were at a meeting together.

CHAYTOR, Q.C.:

Q. Okay, you didn't sit in on that conference call?

DR. LAING:

A. I did, but I didn't know that Eastern Health had asked her to weigh in.

CHAYTOR, Q.C.:

Q. And how--what did Dr. Trudeau have to say, how

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did she bring anything relevant to bear on that discussion?

DR. LAING:

A. The discussion really revolved around could there have been patients who were in that period of time between going from 10 to 30 percent was the first part of the discussion, and then the second part of the discussion comes back to --

CHAYTOR, Q.C.:

Q. Let me stop you at the first part. How could Maureen Trudeau assist in that first part of the discussion, whether or not patients had been missed in the 10 to 30 percent? She wouldn't know --

DR. LAING:

A. No, no, there's a second part to it.

CHAYTOR, Q.C.:

Q. Okay, sorry.

DR. LAING:

A. That's okay.

CHAYTOR, Q.C.:

Q. Go ahead.

DR. LAING:

A. And then the second question really comes back

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to a lot of the discussions we had this morning would be would the percent of positivity change, you know, so would you have someone who is sitting in a clinic who, for example, was just border--just made positivity, 10 percent, 24 percent, 30 percent, you know, would that factor into the patient's decision, would it factor into the oncologist's decision to then turn around and say, oh, look, you're 95 percent positive for both, would you have a different--either, you know, would the medical oncologist be more or less likely to offer hormonal therapy in that instance, and secondly, would the patient be more willing to accept to it, albeit we think that there's a benefit. You know, the response rate data comes from metastatic disease, but there's--you know, there may be, as I say, some emerging data that suggests that the level of positivity may impact on the likelihood of benefit in the adjuvant setting. So I think that's why they had asked Dr. Trudeau to weigh in on the discussion, just as a medical oncologist from a--just another opinion from an outside medical oncologist was

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how I had interpreted that to be. It was interesting because in the discussions with Dr. Trudeau one of the things that came out was, well, just go to your database and pull them out, and we had to say again we do not have a database. It is incredibly difficult for us to identify these patients, you know, to be able to say, well, can we go back now and find all the patients from 2002 who had receptors at this particular level and who were offered treatment. You're going to have to review--pull all the pathology, pull all the clinical charts.

CHAYTOR, Q.C.:

Q. So I just want to understand then. I guess I can see now then why the consult or the role that Dr. Trudeau would have played in it.

DR. LAING:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Before the decision was to be made as to whether or not the effort would be expended to go through the pathology reports to identify those potential patients that are missed --

DR. LAING:

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A. Yes.

CHAYTOR, Q.C.:

Q. Before that decision was made, it was decided to consult Dr. Trudeau to see whether or not it would be beneficial to those patients having been identified to then offer them hormonal therapy? Is that an accurate summary of what happened here?

DR. LAING:

A. Yeah, yeah.

CHAYTOR, Q.C.:

Q. Okay, and what was Dr. Trudeau's opinion? The search is under way, so do I take it that --

DR. LAING:

A. So at the end of the conference call there was actually a consensus amongst all those involved that--you know, that it would be worthwhile to do. One of the things that--you know, when we had had these discussions as a group within Eastern Health, you know, one of the things was how--just really putting our heads together to think of how are we going to find these patients, number one; number two, do we think that there's anybody else who's out there that could potentially fall in this

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category, and my answer to that now would be, "I think so, because there's all sorts of people that we're still discovering", you know, that there's still patients that are being identified that, you know, for whatever reason, were not found in the initial retest, not because it was 2002, or not because they were 23 percent, but just that, you know, we still have people coming forward.

CHAYTOR, Q.C.:

Q. There are other ways that people were missed as well.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And that's been explored here and will continue to be explored.

THE COMMISSIONER:

Q. I'm just making sure I understand the current search, is that just for those patients who might have been between the 10 and 30 and might have been missed because of the cutoff, or are there other patients?

DR. LAING:

A. No, I think it's just the former. However,

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one of the things--one of the reasons to sort of get all this finally put into a database was really to sort of see that if, you know, we may find people that were outside those parameters. So the decision at the end of the day was to take all of the breast cancer patients and put them all in a database.

CHAYTOR, Q.C.:

Q. But, Doctor, if you're going to go through that effort and review--have all the charts reviewed and pulled, wouldn't you identify everyone as opposed to just the 10 and the 30 percent, so it may have been in that gap?

DR. LAING:

A. So those are the people that you kind of have your eyes and ears open to find, but if you're really at the end of the day going to have a comprehensive understanding of this whole thing, then everybody needs to be put in there.

CHAYTOR, Q.C.:

Q. What's the search criteria right now, though? Have people been asked to review their files just looking for this 10 to 30 percent potential gap?

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DR. LAING:
A. I'm not sure where they are with who they're putting in, but --
THE COMMISSIONER:
Q. And who's doing it?
DR. LAING:
A. Mr. Wayne Miller is the lead on it, working with the Centre for Health Information, who have the information that we have thus far on the patients who have been retested in a database.
CHAYTOR, Q.C.:
Q. And have the clinician been asked to review your chart--review your charts?
DR. LAING:
A. No, not --
CHAYTOR, Q.C.:
Q. You're not doing any review --
DR. LAING:
A. Not yet. Actually, I'd have to find out from them where the process is.
CHAYTOR, Q.C.:
Q. But it is contemplated that each oncologist would review their charts?
DR. LAING:

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A. No, usually when you have a chart review, and we've done chart reviews in the Cancer Centre for other reasons, they can be done by--they don't have to be done by a physician, but they have to be done by somebody who has an understanding of what they're looking for. We've hired summer students and things to do chart reviews to look for--you know, for example, when we wanted to identify patients who might benefit from extended adjuvant therapy, we pulled all of the breast cancer charts and we hired a pharmacy student and educated him and he went through all the charts and identified people. So I think, you know, at the end of the day, if there was something that wasn't clear, then, yes, the physician would be the one who would eventually go and look in the chart. The discussion of the database, you know, goes beyond just those people because--you know, I think one of the things to look at is what the recommendations were for the panel, you know, what patients decided to do, where people are. You know, there's a lot of--when we looked at the database initially when we had the first

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meetings with the Centre for Health Information after they had taken all the patients who had gone for retesting, there was elements in the database that we, as clinicians, felt were important to include. In fact, when they first put together the database, they just had the estrogen receptor results in it, they didn't have the progesterone receptor results, and, you know, I think that there's some valuable information regarding the patients that--you know, that I would include. I think a basic breast cancer database should have stage at diagnosis, nodal involvement, pre or post menopausal, all these sorts of things, if we're going to at the end of the day take the lessons learned here and try and apply them or at least share them with other people. So, I guess, the point is that this database should be all inclusive, should be retrospective in that we really need to get in what's gone on in the past, but also needs to be prospective, and I think at that time we would have a very, very valuable resource that we could use. Even to do simple things like outcome, once that information is in there,

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you know, there are things not related to ER/PR that we could look at. That's the benefit of a database. You can look at trends, you can do outcomes, research, you can do all sorts of things that if you're left every time--and this happens to us all the time in the clinic, wait times. You know, when we went to the National Initiative for Wait Times two years ago and we had to do wait times between when people were seen and when they started chemotherapy, we had to pull the charts. You know, nowhere in any of our computer systems did we even capture something as simple as that.
CHAYTOR, Q.C.:
Q. Doctor, the conference call with Dr. Trudeau, you recall that it happened in April. Do you recall when in April?
DR. LAING:
A. No, I'm saying April because our national cancer meetings are the end of April and it was shortly after that, like maybe the next week. So it would have been the very end of April or the very beginning of May.
CHAYTOR, Q.C.:

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Q. Okay.
DR. LAING:
A. But I could find the exact date.
CHAYTOR, Q.C.:
Q. Okay, thank you, and who besides yourself was on that call?
DR. LAING:
A. Mrs. Pilgrim would have been on the call, and Mr. Miller, and Dr. Trudeau, and I. Those are the ones I can remember for sure. I know at some of the discussions we had, Mr. Gulliver was there, and they also asked for some opinions from some of the epidemiologists at the hospitals. I recall Dr. Brendan Barrett being at one of the meetings prior to the conference call, but I can't remember exactly if he was on that particular conference call.
CHAYTOR, Q.C.:
Q. And was there anyone from pathology?
DR. LAING:
A. I'm not sure if there was a pathologist or not. There certainly would have been at the meetings that we had had in Eastern Health. I know Dr. Denic was there, but I can't recall if on the conference call--I was in my office,

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so that's why it's harder for me to remember who was around the table.
CHAYTOR, Q.C.:
Q. Yes, you can't picture the people around the table.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Fair enough. The other point I wanted to clarify from the line of questioning I was asking you is to go back to that issue about the ER and PR positivity and the correlation between the two.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And I just want to be clear because I know you said to me--you've said as of late, you've become aware of it and recently. So I just want to be clear that in asking you, were you aware that it was rare for a tumour to be ER negative, PR positive, you're aware of that now. When did you become aware of that?
DR. LAING:
A. So in--I would say that in my training, we

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were taught that that was not common. I wouldn't have put it as low as 5 percent, but I can't remember a number. You know, maybe somewhere around 10/15 percent.
CHAYTOR, Q.C.:
Q. So it was just as rare as having a lobular --
DR. LAING:
A. Not as rare as that.
CHAYTOR, Q.C.:
Q. Not quite as rare as that?
DR. LAING:
A. Not as rare as that for sure.
CHAYTOR, Q.C.:
Q. I thought it was 85 to 90 percent --
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. From what you've said.
DR. LAING:
A. Yeah, the time that I became most aware of it was through the tumour panel. Again looking back at that time, can I recall through my practice in the first few years --
CHAYTOR, Q.C.:
Q. That's the Review Panel, right, we're talking

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about?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. "The" panel.
DR. LAING:
A. "The" panel.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. When I look back to my practice, you know, from 1999 on, can I say that it ever entered my mind, "Um, you know, we seem to have a lot of tumours here that are ER negative/PR positive", no, it didn't. When I first noticed it was when we did the panel.
CHAYTOR, Q.C.:
Q. Yes, but the knowledge that that is a fairly rare thing --
DR. LAING:
A. Sure, the knowledge was there.
CHAYTOR, Q.C.:
Q. You knew since your training days?
DR. LAING:
A. Right, but there wasn't--I wasn't picking up

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that I was seeing those consistently in the clinic to the point where it raised any sort of concern.

CHAYTOR, Q.C.:

Q. And nobody was tracking that?

DR. LAING:

A. Nobody was tracking it. Again it comes back to the fact that you have a whole bunch of different people involved, and, you know, there wasn't any--I cannot recall at that time. When I do recall it was as part of the panel because what would happen is that the decision was made to retest based on ER only, and that, you know, we would get these charts and we would open them up and we would look at what it was initially and what it was on repeat, and then we would look and we would see, oh, look, good, the first one was ER negative, PR 60 percent positive, we'd read down through the notes, they were started on appropriate adjuvant hormonal therapy, good, you know, and we'd say, no change in treatment, review of the chart shows the patient was on Tamoxifen and on we would go. And, you know, over time, we would see so many

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of these --

CHAYTOR, Q.C.:

Q. Again and again that you started to --

DR. LAING:

A. Again and again in the panel, and we called them the saved by the PR's and, you know, it was interesting to look--and as I said earlier, some of those patients, it almost seemed that they flipped, so that they were ER negative/PR positive and became PR positive/ER negative, and for some of them, they went from negative positive to positive for both.

CHAYTOR, Q.C.:

Q. Uh-hm.

DR. LAING:

A. And when we had the final numbers, there were 130 some odd of those people. We'll talk about that I know, but just--you know, that's when it struck home in those early days of the panel and we all--I can remember us all looking around and saying, my goodness, now that we sit down and look at this, we had more of these than we should have, but as time was going on, I didn't recognize it, and I don't remember any discussions or even --

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CHAYTOR, Q.C.:

Q. None of your colleagues brought it to your attention in the years prior either?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Nobody queried that as being something passing strange?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. That was never brought up?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Is there any correlation between gender and hormone receptivity?

DR. LAING:

A. Oh, in terms of male breast cancer patients?

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. Again, you know, if you look at men with breast cancer, they're uncommon, but they're still about one percent of all the breast

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cancers that we see. It's generally thought that again the majority of men with breast cancer end up having hormone receptor positive disease. There is very little data, close to none, on actually how they respond to hormonal therapy aside from anecdotal information and--because if you look at all of the breast cancer trials, they're done in women. There are actually no breast cancer trials that--large breast cancer trials done that include men. If you look, though, at the experience in the clinic, they do respond to hormonal therapy and they can respond to Tamoxifen, and they can also interestingly respond to aromatase inhibitors because there is some estrogen made even in males.

CHAYTOR, Q.C.:

Q. And so the thinking--generally the knowledge was that they tend to be hormone receptor positive. Would that have been known in--we had Mr. White testify here, and he was diagnosed in 1999. Would that have been known in 1999?

DR. LAING:

A. I mean, I knew it as a resident, so I would

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have to say from my point of view, yes, but again it wasn't an all or none phenomena.

CHAYTOR, Q.C.:

Q. An absolute.

DR. LAING:

A. It wasn't an absolute, it was just--I mean, when I look back to my training, I would have certainly--I've seen male breast cancer patients and I've cared for some in my own practice, and, you know, the thing that I remember being taught was that men who present with breast cancer, they all get a mastectomy, they all get radiation because of this whole idea of having a smaller amount of breast tissue, and that you would otherwise treat them the same way that you would treat a female. So you would look at the same prognostic factors, you would determine whether or not they needed chemotherapy in the same way, and that, you know, if they were hormone receptor positive, which many of them would be, then you would treat them with hormones. More recently, and I mean more recently as in the last few years, there have been some--I've had some conversations with

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people regarding aromatase inhibitors for males with breast cancer, and there is some at least experience in clinics that these patients seem to respond, and I do have a patient of my own who's responding well to an aromatase inhibitor who has metastatic male breast cancer.

CHAYTOR, Q.C.:

Q. And I take it any males that came up in the review then were treated no differently in terms of considerations as to whether or not they would now be offered Tamoxifen or some other treatment?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. They were treated the same as the females?

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. Ms. Chaytor, we're getting near the luncheon break, so wherever you can find a convenient spot.

CHAYTOR, Q.C.:

Q. Thank you. Doctor, along life's way, I guess,

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from the time of your training up until, say, 2005, when all of this starts to unfold, had you ever been aware of any concerns regarding the reliability of ER and PR testing on a global or wider--global or national basis in terms of any limitations with the tests, anything like that ever brought to your attention?

DR. LAING:

A. As part of our training, we would have been told that this is a test that there were certainly false negatives. The--you know, you're looking for something--you're looking to see if these receptors are present, and, you know, my training and my understanding at that time was that, you know, there was a possibility that you could get a result that was negative, but really the receptors were there. I don't remember at that time knowing what that accepted percentage was or those sorts of things, and, of course, subsequently through this process, you know, I now know all about the importance of getting the sample, getting it to the lab, fixation, and all those other issues, but really as an oncologist and

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my oncology training, that wouldn't have been things that had been discussed or taught to us or anything like that.

CHAYTOR, Q.C.:

Q. But you were aware that there is such a thing as there could be false negatives, and would that cause you then to be more vigilant in terms of questioning any results that you would get from an ER/PR test? For example, if the result that you received didn't really meet your expectations or what you would expect for the vast majority of patients in a particular category, whether it's type of disease, PR positivity --

DR. LAING:

A. Sure, yeah. I mean, I think in general in medicine, you know, we know that there's limitations in many of the things that we do. When I look back over the early days of my practice, I can probably think about one or two times when I may have asked for an ER test to be repeated because it was an elderly patient who had a well differentiated tumour and it was more just trying to see, you know, if--because I wasn't--I didn't feel that that

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person could tolerate chemotherapy, I may have asked for, you know, could you please review this to make sure that this is negative, but it was--the two instances that I can think back to where in people that were older, and again, you know, getting back to the general idea that the older you are, the more likely you are to be positive, but--and then, of course, the other instances were the ones that we're going to talk about specifically where we had differing reports on two different patients.

CHAYTOR, Q.C.:

Q. So you never asked to have a test repeated because it was a lobular, invasive lobular, until the --

DR. LAING:

A. That's right, yeah.

CHAYTOR, Q.C.:

Q. Until the index?

DR. LAING:

A. Yes, and again, as I said earlier, when I look back, you know, and again looking back retrospectively is always different, but, you know, when I looked back at these patients

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charts, when I read through my notes, there wasn't anything obviously at the time that made me think, oh, my goodness, this person is lobular, should I question this, and I think it was because of the way that they presented with the poorly differentiated and the advanced disease in that instance.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. This is a good time to break.

THE COMMISSIONER:

Q. All right then, we'll meet at five after two.

(BREAK)

THE COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. Good afternoon, Dr. Laing.

DR. LAING:

A. Good afternoon.

CHAYTOR, Q.C.:

Q. Dr. Laing, we know that Dr. Siddiqui sat on the surgical pathology review committee. I think you mentioned this morning in your evidence that Dr. Gardiner chose him for that

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position. I think Dr. Siddiqui was of the understanding that you, in fact, invited him to participate or sit on that committee?

DR. LAING:

A. I do recall that at that time Dr. Gardiner was the Medical Director of the Newfoundland Cancer Treatment and Research Foundation, so we would have had regular weekly meetings with him. So that would have been Dr. Ganguly who was the Director of Radiation Oncologists, and as well myself as Director of Medical Oncology, and when the issue of having some representation from the NCTRF on that committee came up, Dr. Gardiner had suggested that perhaps it would be somebody other than the directors, that we would ask another one of the oncologists to sit on that committee. Perhaps I had recommended Dr. Siddiqui, I don't recall that, but I think that the actual decision to appoint someone would have come from the medical director.

CHAYTOR, Q.C.:

Q. Okay, and what did you understand Dr. Siddiqui's role would be on the committee?

DR. LAING:

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A. That they wished to have someone who was a clinician who was involved in the cancer clinic itself with the care of patients, I guess to be able to act in an advisory role if there were issues that came up to the connection between pathology and oncology.

CHAYTOR, Q.C.:

Q. And did you expect him to fill any sort of liaison between information from the medical oncologists to the committee and vice versa?

DR. LAING:

A. Usually that would happen at our senior management committees. So those people who were representatives on various committees, that would filter back through Dr. Gardiner for information to our senior management meeting. So I would have expected that that committee would have followed the same structure that we were used to.

CHAYTOR, Q.C.:

Q. So Dr. Siddiqui, in sitting on that committee, his reporting role from that committee would not have been to you, but directly to Dr. Gardiner?

DR. LAING:

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A. Yes.
CHAYTOR, Q.C.:
Q. And why would that be?
DR. LAING:
A. Because Dr. Gardiner was the medical director at that time, and that this was--Dr. Siddiqui wasn't simply representing medical oncologists, but he was an oncologist who was chosen to sit on that committee. There was not a radiation oncologist who was represented on that committee.
CHAYTOR, Q.C.:
Q. And did you ever receive any information or feedback from Dr. Siddiqui with respect to anything that was being discussed or any issues that came before that committee?
DR. LAING:
A. No.
CHAYTOR, Q.C.:
Q. And do you know whether or not anyone else did, whether or not Dr. Gardiner or any other oncologist received such information?
DR. LAING:
A. No, I don't know.
CHAYTOR, Q.C.:

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Q. And if we could have, please, P-1572. This is the first set of minutes of that committee, April 15, 2003, and there's an issue in here about the ER and PR receptors at Item 3.1.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Where Dr. Ejeckam stated that ER and PR receptors are not being performed for the next six weeks due to a technical problem and if a solution can't be found, they're looking to send it the tests outside, and it's being considered to send one or two technologists to Halifax or Toronto for training. Was any of that information at the time in 2003 ever brought to your attention?
DR. LAING:
A. No.
CHAYTOR, Q.C.:
Q. And when, in fact, did you first see this set of minutes or learn the content of the minutes?
DR. LAING:
A. After the whole issue came about regarding the problems with the ER/PR testing.

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CHAYTOR, Q.C.:
Q. And when was that?
DR. LAING:
A. It would have been well into 2005, if not into 2006 before I ever saw this memo.
CHAYTOR, Q.C.:
Q. Okay, and if we could have, please, P-0113, and these, Doctor, are a series of memos that we're familiar with here at the Commission, and they're written by Dr. Ejeckam.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And the first is dated April 4th, 2003, the second is May 2nd, 2003. Both of these are addressed to pathologists.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And copied to others, but not oncologists.
DR. LAING:
A. That's correct.
CHAYTOR, Q.C.:
Q. And June 19, 2003, addressed to Mr. Gulliver and that one is copied to Drs. Robb, Cook,

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Parai, and Mr. Dyer. This series of memos, were they ever brought to your attention at the time?
DR. LAING:
A. No, they were not.
CHAYTOR, Q.C.:
Q. And when did you first see those memos?
DR. LAING:
A. In fact, it was well into this whole process before I ever received these memos--were shown them. In fact, in the early days that we were in discussions with the pathologists, this had not come up. It wasn't until these--later on perhaps in 2006 before I was aware that these memos existed. In other words, in the early days of the discussions regarding the ER/PR testing and the meetings that we had with the pathologists, nobody had said, oh, yes, you know, remember back in 2003 when this happened and that happened. It wasn't until later on into this process that I realized that such memos existed.
CHAYTOR, Q.C.:
Q. Okay, and so not only did you not realize the memos existed, but what about the content of

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the memos, for example, the April 4th memo where it refers to stains including, "The ER/PR stains have remained unreliable, erratic, and, therefore, unhelpful for diagnostic purposes", what about the message that's being portrayed there, did that come to your attention at the time?

DR. LAING:

A. Absolutely not, and I had no idea that this was something that was of concern to the pathologists. That had never been brought to my attention.

CHAYTOR, Q.C.:

Q. Okay, and again the fact that this issue had happened in 2003, I understand you to say that you didn't see the memo until perhaps into 2006, well into the retesting process.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. But the fact that there had been a suspension of ER/PR testing in 2003, or that some problems had been detected in 2003, when did you first learn that?

DR. LAING:

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A. When I first saw the memos. In fact, I'm not certain if this was the memo or if it was one of them that the Premier had, and had made reference to, and that, I believe, was well into 2006.

CHAYTOR, Q.C.:

Q. That was in 2007, in fact.

DR. LAING:

A. In fact, it might have been around May of 2007.

CHAYTOR, Q.C.:

Q. You're talking about the Premier publicly having the memo?

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. I'm sorry, are you saying you didn't know about it until then?

DR. LAING:

A. I did not ever see a copy of--I'm not sure which of these memos were--I think it was this one because I do recall that when I first actually read that first statement that said that they were "unreliable, erratic, and, therefore, unhelpful", you know, that really

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struck home with me, that this was not something that I had seen. When we had some discussions through the process of the review, the pathologist did mention to us, and I believe that was well into when we were, you know, meeting with the tumour panel and panelling patients that there was a period of time that there had been some difficulty. First of all, it was around 2002, but these were not things that I had seen, and the other issue--because again, you know, I sort of thought about this. I do not recall a time period during this time that we had a delay in receiving back test results. When we would see patients in the clinic, it is sometimes, but not usual and not often that we would not have the ER/PR results back yet whilst we were seeing those patients, and I do not recall at any time period that there was a prolonged delay in receiving this information back. So if a referral was sent to the Cancer Centre, the new patient referral clerks would gather all the information and there's a checklist. So for a new breast cancer referral, one of the items on the checklist is the ER/PR

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results, and so sometimes going to the clinic to see a new patient, I may not have had those results back because of some delay in getting those, but never during this time in 2002 or 2003 do I remember there being a long delay in any patients, or that there were a lot of patients delayed. So I guess what I'm trying to say is I didn't see these memos, nor did I notice at that time any change in practice that would have made me question, well, why are we not getting these back, you know, is there a problem, what's the delay.

THE COMMISSIONER:

Q. Excuse me, Dr. Laing, I just want to make sure that I have your evidence clear.

DR. LAING:

A. Okay.

THE COMMISSIONER:

Q. Is your reference to the pathologist having mentioned this shutdown period during panelling your first information regarding Dr. Ejeckam's action?

DR. LAING:

A. Yes, it is.

THE COMMISSIONER:

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Q. And presumably you would not have actually seen the memos at that time, you just heard about it?
DR. LAING:
A. Heard about them.
THE COMMISSIONER:
Q. And can you be more precise about when you actually first saw the memos or any one of them?
DR. LAING:
A. I would have first seen this one when the Premier made it public knowledge.
THE COMMISSIONER:
Q. So 2007?
DR. LAING:
A. So that would have been in the spring of 2007, and though it was--I remember reading it and the impact that it had, seeing that there, and not having known it at the time, but also not having seen it through the process of these discussions. I guess there hadn't been an opportunity for someone to say, here, these are the minutes or the memos from Dr. Ejeckam.
THE COMMISSIONER:
Q. And there are, in fact, three memos.

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DR. LAING:
A. Okay.
THE COMMISSIONER:
Q. Did you see the three of them or only one of them?
CHAYTOR, Q.C.:
Q. This is the first, this is the second, it's at page two.
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. And this one talks about May 2, 2003, "I'm glad to inform you that we have rectified the difficulties".
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And then sets out a number of--some information for the pathologists.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Issues of fixation, pointing out types of tumours that would be expected to be ER positive. Then the third memo is the one

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written to Terry Gulliver, and that's June 19th, 2003.
DR. LAING:
A. This is the one that I saw--this is the one that the Premier had, the third one. Subsequently I've seen all three of them, but this I recall, Commissioner, was the first one, the one that was from Dr. Ejeckam to Dr. Gulliver. That was the first time that I had seen this in writing, and subsequent to that, I would have seen all three of those memos.
CHAYTOR, Q.C.:
Q. And what did you do upon learning that this memo existed, the June 19, 2003--you're saying you learned about that when the Premier used it publicly?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. So what did you do?
DR. LAING:
A. What did I do?
CHAYTOR, Q.C.:
Q. Yes, what did you do upon learning that this memo existed? Did you make inquiries of

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anyone, did you ask what is this, where can I get a copy?
DR. LAING:
A. Yes. So then I would have--we were provided then with a copy of this to read, as well as the other ones pertaining to it, and I believe perhaps that it was either--by this time, it was either Dr. Howell or perhaps Dr. Denic who had provided us with a copy of it. I simply felt it was something that I recognized that I hadn't seen or known about during that time period, but I felt that perhaps it would have been something that through this whole process and the review that we would have been seeing and had looked at as the oncologists prior to seeing this come out the way that it did.
CHAYTOR, Q.C.:
Q. So sometime in April of 2007, or thereafter, you were provided copies. Who gave you the copies?
DR. LAING:
A. As I said, I believe it was either Dr. Howell or Dr. Denic, but I can't recall.
CHAYTOR, Q.C.:
Q. And did you ask them why wasn't this brought

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to our attention beforehand as the oncologist looking into this matter? I take it you felt it would have been helpful for you to have known about this?

DR. LAING:

A. I think it would have been helpful--well, I guess there's two points when it would have been helpful. It would have been helpful, obviously, to know back at the time in 2003, and I also felt that if there had have been, you know, such a discussion that--you know, I suspect that the pathologists were looking at this when they were thinking about sort of things from their side with the retesting, and perhaps didn't--because it was a lab issue and things, didn't feel that they, you know, needed to bring it forth to our attention and to show it to us. I guess it wasn't until I saw it and sort of read how it was laid out, that it really made it clear that this was something that we should have known in 2003. I don't believe that the pathologists or Dr. Cook or Dr. Williams, and subsequently Dr. Howell or Dr. Denic didn't show it to us on purpose, I just think that it was something

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that they were dealing with on the laboratory side. It was just that, you know, once it was out there and it was something that, you know, the people said, well, didn't you see that or didn't you know it, and I say, no, but then obviously we sat down and we looked at it, and we did address some of the limitations that we know with the test and some of the possible things, but, of course, these were also factors that we had heard about through the peer review process, if you will. So, I mean, by that time, this was things that I would have heard about through different venues, but I think it was just that I felt that at some point in the beginning of this process, it would have been helpful for us to have sat down and looked at this.

CHAYTOR, Q.C.:

Q. And what explanation was given to you as to why it hadn't been provided to you beforehand?

DR. LAING:

A. I think it was just that it was something that was, you know, part of the laboratory, part of the pathology department, and it was more of a --not a thought that it would be something

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that we might want to see and read.

CHAYTOR, Q.C.:

Q. So was that the explanation as to why it wasn't given to you in 2003?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. That's the explanation as to why it wasn't given to you in 2005?

DR. LAING:

A. Right, when we were--when we were sitting around and having--working together with these people in a panel process. I'm not sure why it wasn't given in 2003. I was not part of those discussions.

CHAYTOR, Q.C.:

Q. And --

DR. LAING:

A. I actually wasn't there at this particular point. I was on leave again.

CHAYTOR, Q.C.:

Q. In June of 2003?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

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Q. And when were you gone in 2003, what time period?

DR. LAING:

A. From June 17th, the early arrival of my second child, until January of 2004.

CHAYTOR, Q.C.:

Q. Until January '04?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. So you were there in April when the shutdown occurred?

DR. LAING:

A. Oh, certainly. I was there in April, and perhaps that's why --

CHAYTOR, Q.C.:

Q. And you were there in May when it started up again?

DR. LAING:

A. Yes, so I actually--I left right when I had the baby.

CHAYTOR, Q.C.:

Q. So the only time you wouldn't--you were gone then was the third memo.

DR. LAING:

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A. Yes, but I didn't see either of them at that time.
CHAYTOR, Q.C.:
Q. And I take it from what you're saying, as Director of Medical Oncology at the time, and as an oncologist practising within the same institution, this should have been brought to your attention?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and had it been, Doctor--for example, if we look at the first memo and it's worded to say that ER and PR have remained unreliable, erratic, and, therefore, unhelpful for diagnostic purposes, had this been brought to your attention, what would you have done in 2003?
DR. LAING:
A. I would have contacted Dr. Ejeckam and would have wanted to know for what period of time had this been an issue in the lab, was this something that had been happening for this last month, was this something that had been going on perhaps for a longer period of time,

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and then, you know, would have had to say, well, what are we going to about this now, we've had some test results come out that we've acted upon, treated patients in the clinic based upon those results, and would have wanted to go back and look at those again.
CHAYTOR, Q.C.:
Q. So what was initiated in May of 2005 --
DR. LAING:
A. Would have done back then.
CHAYTOR, Q.C.:
Q. Would have been done back then had it been brought to your attention?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. The second memo, May 2nd, 2003 --
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And this refers to results of the immunostains may be affected by, and there's different issues regarding fixation mentioned.
DR. LAING:

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A. Yes.
CHAYTOR, Q.C.:
Q. And it also refers to this consensus statement under paragraph five, reporting or ER/PR, and several formulae are in the literature for positive results, ER plus greater or equal to 5 percent nuclear staining, ER plus 10 percent of tumour staining, ER positive, 1 percent shown to benefit from endocrine treatment and the reference to the consensus statement.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And that's in 2000, National Institute of Health, and we spoke about that earlier.
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. That's the consensus statement that we spoke about.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and this is where it says, "Being any positive nuclear ER immunostaining is

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considered to be a positive result".
DR. LAING:
Q. Do you know if that was taken directly from the consensus statement?
CHAYTOR, Q.C.:
Q. We haven't compared the quote, but it is consistent with what you were saying in terms of any positive nuclear ER immunostaining, so I just wanted to bring that to your attention that this is the statement that you were referring to.
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. Have you compared it, do you know the answer?
DR. LAING:
A. It doesn't say exactly that, it's similar, but it does not say exactly that.
CHAYTOR, Q.C.:
Q. Okay, but your point earlier was that the one percent --
DR. LAING:
A. It just says hormone receptor.
CHAYTOR, Q.C.:
Q. It appears wasn't referred to.

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DR. LAING:
A. Right, it doesn't--it actually--it doesn't use any cutoffs in the consensus statement. It says that--it starts out by saying that, "Irregardless of age, menopausal status, a patient should be considered", and then it says, "While there's some evidence that the greater the staining, the greater the benefit", something around that--it says any staining or any positive results, it doesn't use thresholds or cutoff, "may be considered for hormonal therapy".
CHAYTOR, Q.C.:
Q. Okay. I'm just looking at a portion of it here now and it says, "While the likelihood of benefit correlates with the amount of hormone receptor protein, tumour cell patients with any extent of hormone receptor in their tumour cells may still benefit from the hormonal therapy".
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. So does that sound consistent with your recollection of the paper?

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DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. Doctor, regardless of not having seen the memos until into 2007, and not knowing the specific content of the memos, were you otherwise aware in this time period, 2002, 2003, any of that time period prior to 2005, were you aware of any problems in the lab or concerns with ER/PR staining?
DR. LAING:
A. No, I was not.
CHAYTOR, Q.C.:
Q. If we could look, please, at P-0075. This is a briefing note.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. You've seen this, I take it, have you, Doctor?
DR. LAING:
A. I have, yes.
CHAYTOR, Q.C.:
Q. And when did you first see this briefing note?
DR. LAING:
A. This was--this would have been the briefing note that went prior to our meeting with Minister Ottenheimer, I believe, in 2005.
CHAYTOR, Q.C.:
Q. Yes.
DR. LAING:
A. So--I'm not sure if I saw it before that meeting or after the meeting, but, you know, I'd be very aware of the content --
CHAYTOR, Q.C.:
Q. You'd be aware of--so sometime around July, August, of 2005?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. You were aware of this. Doctor, on page three of that exhibit, that briefing note, it's written, "Eastern Health, Vice President of Quality Diagnostic and Medical Services, Dr. Robert Williams, has also asked that an investigation be conducted into the five week stoppage of immunoperoxidase staining for ER/PR receptors in 2003 by Dr. Ejeckam". So, Doctor, would you not have been aware from this memo then in July or August, 2005, that there had been an issue in 2003?

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DR. LAING:
A. The--when we first started to meet with the pathologists as part of the panel and have some discussions, my understanding was that the problem was in--that there may have been a problem that went back to 2002. You'll recall that as we went through the process with the index case, there would have been some--you know, we had picked some patients in the clinic and they had retested and then there was a small sample taken from 2002. So it was my understanding that the period of concern according to the pathologists had been in 2002. I'm not sure if the note from Dr. Ejeckam is based on concerns that he had at that exact time, in the spring of 2003, or if they stem back to issues in 2002.
CHAYTOR, Q.C.:
Q. Okay. My question, though, was whether or not, by having read this memo in 2005, July, August, 2005, you would have been aware that there was reference to an issue arising in 2003 which was identified by Dr. Ejeckam?
DR. LAING:
A. To me that, when I read that, I just thought,

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okay, this is what the pathologists have been talking to us about about the problem in 2002.

CHAYTOR, Q.C.:

Q. So you thought that should be 2002, not 2003. And so then you would have been aware that there had been a five-week stoppage of staining for ER/PR receptors and you were thinking it happened in 2002?

DR. LAING:

A. My recollection was that the problem, when I first talked to Dr. Cook after the index case, they had been concerned about the period of time from 2002, which is why they picked patients from that time period as to the retesting. So I wasn't certain if this meant that Dr. Ejeckam was concerned about what had happened in 2002 and decided that he was going to halt testing until he sorted things out. So how long back, as I mentioned to you, that would have been my first question to them was how long has this been a concern, has this been something going on in the lab for the last three months or the last, you know, couple of years, when did this exactly happen. And to be quite honest with you, when I would

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read something like this, most of what I would be focusing on would be the chronology of events related to the index patient and, you know, what Dr. McCarthy and I had done surrounding that.

CHAYTOR, Q.C.:

Q. So regardless if it's 2002 or 2003, upon reading this memo in July or August, 2005, you would have become aware?

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. If you weren't before, you would have become aware that there was some issue -

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. - raised by Dr. Ejeckam which caused a shutdown or a stoppage of the staining for a period of time?

DR. LAING:

A. For a brief period of time.

CHAYTOR, Q.C.:

Q. Okay. So you were aware of that then in July or August of 2005?

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DR. LAING:

A. If I picked it up on that by reading that memo, certainly. But as I said, my first recollections of a concern were from my conversations with Dr. Cook regarding the 2002 time period.

CHAYTOR, Q.C.:

Q. Okay. And what did Dr. Cook tell you about the 2002 time period, why were they concerned about that time period?

DR. LAING:

A. That when they--well, let me just stop and think. During 2002 when they went back and looked at the percent of positivity, I'm not sure if that was one of the years, because Dr. Cook and Dr. Williams had some summary numbers of the percent of overall tumours that were ER/PR by year and I know that in one of-- sometime during that time there were instead of being around 75 percent, which is what's suggested in the literature, that there was a lower number. But I don't, you know, I don't recall him telling me specifically that there was a problem with fixation or that there was a problem with something else. You know, at

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that time my main focus was on, you know, the patients in the clinic and really, you know, the issues related to the pathology lab and all that were being handled directly by Dr. Cook at that time.

CHAYTOR, Q.C.:

Q. So, Doctor, prior to 2005 you said you weren't aware of any issues or concerns regarding the results -

DR. LAING:

A. That's right.

CHAYTOR, Q.C.:

Q. - coming from the lab. Did you ever have reason or cause to have an ER/PR test repeated?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And under what circumstances did you ask to have that done and did you have a changed result?

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. And this is again, of course, prior to what

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happens in 2005.
DR. LAING:
A. Right. So I can recall three instances. Two of them were patients that I had who were elderly patients with breast cancer who had ER/PR tumours and who I was not prepared to offer them chemotherapy because of their comorbidities and things. And so I asked if they would recheck the ER/PR because they came back as negative and the test results were still negative; there was no change. And that's, you know, kind of sitting back and sort of searching through and remembering calling Dr. Chittal at one time to ask him that. The second instance was I had a patient, and I'm not sure what year it was, but I think it was 2002, 2003.
CHAYTOR, Q.C.:
Q. I believe it would be July, 2002.
DR. LAING:
A. Okay, so it was in 2002. Who was referred to me from Dr. Kwan. And this lady had had her initial biopsy which showed that she had a breast cancer done in Clarenville.
CHAYTOR, Q.C.:

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Q. And I just want to caution you that we're not using this particular patient's name.
DR. LAING:
A. Oh, of course.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. Yeah, that's fine. And so then--so she had the biopsy done at an outside hospital.
CHAYTOR, Q.C.:
Q. In Clarenville?
DR. LAING:
A. In Clarenville.
CHAYTOR, Q.C.:
Q. Thank you. Sorry, I threw you off there.
DR. LAING:
A. Okay. And then she elected to come and have her mastectomy done in St. John's. And subsequently she was referred to me for adjuvant therapy. At the time of--so she had a biopsy and then at the time of her mastectomy there was residual disease and so both of those breast cancer specimens had ER/PR testing done. The first sample was done and reported through the lab in Clarenville

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and the second one was done through the lab in St. John's. The result from the Clarenville testing was positive and the result from the lab in St. John's was negative. So because of this I asked if they would repeat the testing on the mastectomy specimen, which they did -
CHAYTOR, Q.C.:
Q. Who did you ask to do that?
DR. LAING:
A. I had asked the pathologist.
CHAYTOR, Q.C.:
Q. So, Doctor, I take it it made--it didn't make any sense to you that the biopsy of the same tumour has positive and the residual of the tumour had a negative?
DR. LAING:
A. Right. So, you know, this was one of these situations we talked about this morning where you kind of said, hum, that's a bit strange, you know, we have these two differing results.
CHAYTOR, Q.C.:
Q. And it caused you to question it and you asked for a repeat?
DR. LAING:
A. Right. So I asked for it to be repeated and

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it came back as still being negative. And we talked about it, we being the pathologist and I.
CHAYTOR, Q.C.:
Q. And who was that pathologist?
DR. LAING:
A. I'm not 100 percent certain. Was it Dr. Chittal? I'm not--perhaps you know, but -
CHAYTOR, Q.C.:
Q. Dr. Chittal is the name on the pathology report.
DR. LAING:
A. Yeah, so that's who it was.
CHAYTOR, Q.C.:
Q. Is that who you would have had your conversation with?
DR. LAING:
A. Yes, it is, yeah.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. So I remember having a discussion then with the patient and explaining to her that we had two different results, that one was from the excisional biopsy, so it wasn't simply a

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needle core, it was actually, you know, a fair piece of tissue, that there was some residual tumour left at the time of the mastectomy, that one was positive and the other one was negative, that we had retested the negative one and it had remained negative, that perhaps there had been a clone of cells along the edge that was different, but in any case, because the biopsy was positive, that I would treat her following the completion of our adjuvant chemotherapy with adjuvant Tamoxifen, which I did do.

CHAYTOR, Q.C.:

Q. Okay. And did you inquire of the pathologist as to how this could be, and, if so, what explanation was given to you as to how there could be two different results?

DR. LAING:

A. Well, when I explained the reason for the retesting, because I had the two different results, the pathologist did repeat the test. And then when I spoke to him subsequently to say, you know, it still came back as negative, then the discussion to that could this just be because of, you know, this was the rim, if you

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will, of the tumour and it might have been some sort of a sampling or a clone of the cells that were ER/PR negative. You know, at the time I didn't--I suspect because the two results came back as being the same that I didn't sort of think that there was a problem with the test that had been done in St. John's at all. And you know, when I explained it to the patient, I said given the fact that we do have one that's positive and that that was the actual, you know, larger piece of the primary tumour, then that's the one that I'm going to base my treatment recommendations on and that's what we did. The other thing that's interesting about this case when we did review it was subsequently this patient was left and we had to transfer her care to another oncologist. That was when I was on my second maternity leave and Dr. McCarthy had assumed this patient's care in my absence. And she wrote a referral letter to the oncologist where this patient was moving, to a different province and had made a comment in the referral letter, interestingly, this lady's, you know, ER/PR status from her biopsy was

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positive but from the bit that was left, that the mastectomy specimen was negative, but we went ahead and treated her with adjuvant Tamoxifen.

CHAYTOR, Q.C.:

Q. Yes. And without Dr. McCarthy obviously not being able to explain why that, in fact, might be, why there might be these conflicting results?

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. And, Doctor, the test on the mastectomy specimen and the retest were both done in St. John's?

DR. LAING:

A. Yes, yes.

CHAYTOR, Q.C.:

Q. And you chose to go with the result from the biopsy?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And were you aware, this would have been according to the record, the pathology record

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for this patient is July 26th, 2002. Does that sound about the right time period?

DR. LAING:

A. Yes. You said that she came to see me as a new patient in July of 2002, so the pathology would have been just prior to that.

CHAYTOR, Q.C.:

Q. Yes, okay. And I think the biopsy specimen was done July 26th, 2002 and the mastectomy was August 1st, 2002, the ER/PR first test.

DR. LAING:

A. So would have I had seen her then in August of 2002?

CHAYTOR, Q.C.:

Q. Sometime around that time period, I believe.

DR. LAING:

A. Okay, yeah.

CHAYTOR, Q.C.:

Q. And my question is when you had this conversation with the pathologist, who you believe would be perhaps Dr. Chittal, was there any conversation as to where the biopsy test, the ER/PR test on the biopsy had actually taken place?

DR. LAING:

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A. None whatsoever. I was under the assumption that the staining had taken place at the hospital in St. John's. The slides would come in from the outside labs, they would have staining done and then they would be sent back for reporting to the pathologist in Clarenville or whatever other region. So in my conversations with Dr. Chittal, the pathologist, I had not been given any idea that the testing was actually done at a different institute, nor did it indicate on the pathology report that this was actually sent out for testing. It wasn't until later on, much later on, through the review process, that we indeed discovered that Clarenville Hospital was sending their specimens to Mount Sinai Hospital for testing.

CHAYTOR, Q.C.:

Q. And had you known in 2002 that the original test had been conducted at Mount Sinai Hospital, the original positive test, would you have asked anything further or made any other inquiries?

DR. LAING:

A. You know, in retrospect knowing that the

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testing was done at a different hospital, I may have, you know, asked that specifically to Dr. Chittal, to say, well, this is the Clarenville specimen and it was done at Mount Sinai, you know, do you think that that might be the reason why the test results are different. I mean, if you get a test result that's from a different province, then it may raise a question. But, you know, at that time I thought that the staining for both specimens was done in St. John's, although the reporting, the actual interpretation of it may have been done by two separate pathologists. And I cannot recall if Dr. Chittal did or did not review, you know, the slide of the biopsy from Clarenville. I don't remember that being part of the conversation at all.

CHAYTOR, Q.C.:

Q. Okay. And, Doctor, do you know was this patient's negative ER test repeated through the -

DR. LAING:

A. Yes, it certainly was.

CHAYTOR, Q.C.:

Q. - review process?

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DR. LAING:

A. Yes, it was.

CHAYTOR, Q.C.:

Q. And what was the outcome of that?

DR. LAING:

A. It was positive.

CHAYTOR, Q.C.:

Q. It was positive?

DR. LAING:

A. Yeah. I don't have the numbers in front of me or know if it was ER/PR, what it was, but I do know that she, this patient did come up in the review panel and, of course, we remembered her case, both Dr. McCarthy and I, because we had both seen her at one time and that's when we were aware that, in fact, the specimen had gone to Mount Sinai for testing.

CHAYTOR, Q.C.:

Q. So she fell into the category of somebody whose test result had changed but she didn't require change in treatment because you had started her on hormonal therapy based on the result of the biopsy test?

DR. LAING:

A. Yes.

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CHAYTOR, Q.C.:

Q. The test on the biopsy sample?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. Doctor, did--through the review process were there any other of those types of cases noted, where the biopsy or a test done on the biopsy specimen, in fact, was different from the results of a test on the mastectomy specimen?

DR. LAING:

A. Not that I can recall between the biopsy and the mastectomy specimen. There may have been another case where there was a difference between the lymph nodes and the primary. And there were some other cases we had had where we had had a biopsy from the primary disease and we had primary disease and we had a biopsy from the chest wall recurrence. We had cases where there was bilateral breast cancer and we had biopsies from the left side and the right side, and they would have -

CHAYTOR, Q.C.:

Q. Which were different?

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DR. LAING:
A. - been exceptions. Which were different tumours and--but there are patients who present with synchronous breast primaries, so they have one on the left side, one on the right side. They're diagnosed at the same time, but the biology tells us that they're two separate cancers.
CHAYTOR, Q.C.:
Q. Okay. And in terms of the lymph node being different than the primary, would that have been something at the time, had you been the treating oncologist, that that have appeared to be unusual to you just like the patient's case that we just discussed?
DR. LAING:
A. Sure, but we often would not have ER/PR testing on lymph nodes. It's usually done on the primary tumour. I'm sort of searching to try and remember the actual logistics around that case. But sometimes patients with breast cancer present with axillary lymph nodes without any palpable or diagnostic imaging revealing an abnormality in the breast and we assume it to be breast cancer until proven

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otherwise. And often those patients will have surgery that is the removal of a lymph node and once it's determined, for example, not to be something like a lymphoma and it appears to be a breast cancer, then they would go on and have the breast removed, so there may have been ER/PR testing done on a lymph node and then subsequently on the breast sample. Most times you'd have a concordance between that, but it would not be common. When a pathology from a breast tumour, you wouldn't check the nodes and check the breast primary separately.
CHAYTOR, Q.C.:
Q. Okay. In those cases where you requested repeats, did you ever have any reluctance from a pathologist to accommodate your request?
DR. LAING:
A. I had some minor reluctance with the case that we just spoke about, and the reason was is because of a completely separate incident with a patient that involved the same pathologist. And this was a gentleman who I had seen when I was on call who presented with a mass in his chest and was thought to be small cell lung cancer. I don't treat lung cancer, it's not

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one of my major sites and it never has been. And but often when I'm on call, I'll get a consult from a colleague to say that, you know, just diagnosed a new small cell and they need to start their chemotherapy treatments right away. This was the instance with this gentleman. So I was looking after the patients in the hospital, treated him with a cycle of chemotherapy and subsequently on pathology review they determined that, in fact, what he had had was a lymphoma. He's done extremely well and is still alive and we transferred his care over to the hematologist. And fortunately, the type of chemo that we gave him for a small cell lung cancer was effective against the lymphoma and he's gone on to do extremely well and--but in any case, the pathologist was the same. And the only reason I say that is that when I first called him and asked him, he said, you know, oh, are you getting all, you know, sort of asking this because of what happened with the other case. And I said, no, certainly not, it's just that, you know, we have one that says one thing and one that says the other. But that was the

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only sort of discussion around it was, you know, why are you asking this to be repeated, you've got the result and, you know, are you just now have a heightened sort of sense of rechecking things because of the previous case. The previous case was, just so that you know, certainly not unexpected. Small cell lung cancer and lymphoma can look very similar under the microscope. They're small round blue cells. And it was only after that the lymphoma panel for markers had come back on this specimen that they decided that it was a lymphoma, so.
CHAYTOR, Q.C.:
Q. And your knowledge of that in terms of what it would look like under the microscope, I take, that the pathologist would have explained that to you?
DR. LAING:
A. My knowledge of that comes from there's about five percent of cancers are what we call cancers of unknown primary, and there's a certain sent of circumstances when you're faced with one of these cancers that you need to sort of stop and think about is this

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something that's potentially curable. And one of them was the instance that I mentioned to you about a patient who presents with an axillary lymph nodes, always think about breast cancer. Someone who presents with lymph nodes in the neck, head and neck, always think about a head and neck primary. And someone who presents with a tumour that's got small round blue cells, always think about a lymphoma. And that's where that comes from.

CHAYTOR, Q.C.:

Q. Okay, thank you. And if we could have, please, C-0226? This is a request form, IHC request form. And then attached at page 2 of the exhibit we have a pathology report which has been redacted. And this particular pathology report there's an addendum No. 2 entered March 26th, 2003.

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And it's written, "I have received a request from Dr. Kara Laing to review this case to clarify lymph node status and ER/PR status. In review this patient's original biopsy,

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which was an axillary node biopsy, does show extra extracapsular extension and lymph node status is therefore" and we have here, I guess this is -

DR. LAING:

A. That means extranodal.

CHAYTOR, Q.C.:

Q. Okay, thank you, Doctor. "Further, estrogen and progesterone receptors have been reviewed in both cases. In both case," and there's two numbers given there. "In the earlier case ER and PR are both weakly positive. In the later case ER and PR are both negative. It is worth noting that the areas of DCIS in" and then the number again, "are positive for estrogen receptors. Overall, given that the metastatic lesion is weakly ER/PR positive, this is interpreted as a tumour having ER/PR receptor positivity. The discrepancy on the later case is possibly on the basis of weak presence of estrogen and progesterone receptors overall in the tumour, with the possible existence of hormone receptor negative clones within the slide tested on the latter case." And it's signature on file by Dr. Ford Elms on March

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28th, 2003. And you'll see the addendum, first addendum had indicated that immunohistochemical staining for estrogen and progesterone receptors is negative and that had been entered on March 4th, 2003. Doctor, do you recall the circumstances of this case and why you would have asked Dr. Laing (sic.) to review the case to clarify the lymph node status and ER/PR status?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Okay.

DR. LAING:

A. If I perhaps had the patient's file, I might be able to, but not just by looking at this.

CHAYTOR, Q.C.:

Q. Okay.

DR. LAING:

A. Perhaps I could speak to why I had asked for the lymph node status to be reviewed.

CHAYTOR, Q.C.:

Q. And I guess, Doctor, the main point being that at this point in time, for whatever reason, there would have been something to cause you

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to ask to have and I don't want -

DR. LAING:

A. Does this sound like something in which there was both lymph nodes and that done at a separate time period?

CHAYTOR, Q.C.:

Q. And I don't know that -

DR. LAING:

A. I'm not sure.

CHAYTOR, Q.C.:

Q. - I'm not sure if that's from just the pathology report.

DR. LAING:

A. No, I'm not sure. No, neither am I just by looking at that.

CHAYTOR, Q.C.:

Q. But for whatever reason something caught your attention and you asked to have both the lymph nodes and the ER/PR status reviewed. And -

DR. LAING:

A. The lymph nodes would have been because if there was extranodal extension, that would have been an indication to consider adjuvant radiation. So if it wasn't clear to me if there was extranodal extension or not, I would

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review that. And if there was extranodal extension, I would arrange for that patient to have an opinion from a radiation oncologist.

CHAYTOR, Q.C.:

Q. And, Doctor, if you hadn't done that and the addendum 1 were to go forward, this patient would have been treated as though he or she were hormone receptor negative, but upon review -

DR. LAING:

A. It just makes me curious because it does say that there's two separate specimens here and it looks like they're both from St. Clare's, they're both St. Clare's specimens, they're both from 2003, and but they're different surgical numbers. So I can only assume that perhaps because I did have those two separate things that, I had asked for it to be, but I just, I'm sorry, I can't tell you any more than that just by looking at that.

CHAYTOR, Q.C.:

Q. And at the end of the day, Dr. Elms has indicated that the second addendum is that the tumour is seen to be ER/PR positive?

DR. LAING:

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A. Yes.

CHAYTOR, Q.C.:

Q. And if we could have--well, actually, Doctor, if I could ask you first then, do you know if anyone else or any other of your colleagues who had occasion to ask to have an ER/PR test repeated prior to 2005?

DR. LAING:

A. Not that I can recall right now off the top of my head, no.

CHAYTOR, Q.C.:

Q. And if one of your colleagues had had a test repeated and had a different result, would you expect to have known about that?

DR. LAING:

A. Not necessarily, no.

CHAYTOR, Q.C.:

Q. Okay. And why not?

DR. LAING:

A. Because they may not have seen to tell me about it.

CHAYTOR, Q.C.:

Q. So if something like this, something like this happens or what happens, we'll get to Peggy Deane's case, would it be required that an

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incident report of any type be filed?

DR. LAING:

A. We do have a process for incident reports at the Cancer Centre. It mostly, in our realm, deals with issues related to treatment, but certainly there are other--you know, pretty much anything that happens that a staff member identifies as, you know, a potential important event can be put forward on an incident report. But, you know, in medicine, there's often times where we get one report. We may, you know, look at something ourselves or we may get another report back on something that it doesn't necessarily always mean that you would fill out an incident report related to that. Perhaps radiology reports would be a good example. Unless there was something about that that, you know, the process of how the different result came was a cause of concern. I'm thinking of perhaps a laboratory test that you got back on a patient that just looked completely like nothing that you ever expected, and if you looked into that and found out it was because the specimen was mislabelled, then certainly that would be

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something that I would expect somebody to bring forward, because that could be something that could happen again, but with these sorts of instances, then, you know, it wouldn't be something that I would necessarily think that people would fill out an incident form about, no.

CHAYTOR, Q.C.:

Q. Okay, and if we could have, please, C-0175? And Doctor, this is a pathology report, again, and we've redacted anything that could--the patient's identifying information.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. And addendum one of this report is, and I believe that to be May 6th, 2003. "Stains have been delayed due to unavailability in the lab," and then it says "when compared to controls, the specimen is negative for HER2/neu, ER and PR."

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And then three days later, there's an addendum

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two, May 9th, 2003. "The ER and PR were repeated due to quality assurance issues. The repeated stains show the following, ER positive in 80 percent of the cells, PR positive in ten percent of the cells. This replaces the previous report," and then in brackets "phoned to Cancer Clinic voice mail on May 9th, 2003" and signed by Dr. Morris-Larkin. Does this ring any bells to you? I'm not suggesting that you were the medical oncologist involved, but -

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. - you don't recall getting a phone message on this particular matter?

DR. LAING:

A. No, I don't.

CHAYTOR, Q.C.:

Q. And you don't recall any of your colleagues bringing it to your attention that this had happened?

DR. LAING:

A. No. No, this isn't--I've not ever seen this before. This is not something that rings any

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bells with me, no.

CHAYTOR, Q.C.:

Q. Okay, and C-0228, please? And this is just the requisition form, and on page two of the exhibit, again we have a pathology report, and if we go to page four, we have an addendum one, which is entered March 17th, 2003, "estrogen and progesterone, ER occasional positive cells, less than one percent. PR 15 percent positivity, no controls available."

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And addendum two, "as requested, repeat. Estrogen and progesterone receptors by immunoperoxidase staining. Estrogen receptors 40 percent positivity. Progesterone receptors 73 positivity" and that's done on May 28th, 2003 and entered as the addendum, and in this particular case, there was a request obviously for a repeat.

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And this would have been--and the only reason

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I bring it to your attention, it's--I'm just wondering if you recall any discussion around, again, in May of 2003, around the same time period, of a request to have an ER/PR repeated?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And having a change in the result?

DR. LAING:

A. None of this is anything that I'm familiar with.

CHAYTOR, Q.C.:

Q. Familiar to you.

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and if I could have then, please, C-0174? And Doctor, this is a case that we know is Dr. Zaidi's case.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. And if I could just bring you to the fourth page of this exhibit. Again, it's a pathology

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report and the first addendum is actually July 31st, 2002, "immunohistochemical staining is negative for metastatic deposits."

DR. LAING:

A. Um-hm, on the sentinel node.

CHAYTOR, Q.C.:

Q. Yes, thank you, and addendum two, then August 29th, 2002, "immunohistochemical staining for progesterone receptors is positive in approximately 15 percent of lesional cells and staining for estrogen receptors is negative," and signed by Dr. Elms on August 29th. And then on June 11th, 2003, "at the request of Dr. Zaidi, immunohistochemical staining for estrogen and progesterone receptors has been repeated. Estrogen receptor show faint positivity in approximately 10 to 15 percent of lesional cells. Progesterone receptors are unequivocally positive in approximately 75 percent of lesional cells." Do you recall-- and I realize that you went on your maternity leave shortly after this, but in June of 2003, do you recall did Dr. Zaidi discuss with you the fact that he'd had an ER/PR test repeated and some changes in the results?

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DR. LAING:
A. No. No, and this was a little bit different than the other one because this was a whole year later.
CHAYTOR, Q.C.:
Q. Yes.
DR. LAING:
A. If I remember the other one, it was just sort of as a quality assurance review. No, I don't have any recollection.
CHAYTOR, Q.C.:
Q. And yes, as you point out, it's almost a year between the two.
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. Which makes it seem a little unusual. You don't recall that being brought to your attention?
DR. LAING:
A. No. You don't know if this patient had metastatic disease develop in that interim, do you?
CHAYTOR, Q.C.:
Q. No, we don't know on what we have here, but we

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could certainly check that.
DR. LAING:
A. I'm wondering if maybe that that was why.
CHAYTOR, Q.C.:
Q. Okay. We could certainly check that. And again, I take it that would have been then unusual to get a chance in the result?
DR. LAING:
A. I could only say that he--there must have been some reason why he would have requested for it to be repeated, but I don't know why that would have been, without looking at the patient's chart or seeing what he may have documented at that time.
CHAYTOR, Q.C.:
Q. And Doctor, what I've taken you through there indicates that there were four cases in 2003, in less than a three-month period, the first being yours in late March of 2003, March 26th, and two in May 2003, and another then on June 11th, 2003 which resulted--were repeats of ER/PR tests which resulted in different results, and this wasn't the subject of discussion amongst oncologists at the time?
DR. LAING:

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A. No.
CHAYTOR, Q.C.:
Q. And this wasn't brought to your attention as director of medical oncology at the time?
DR. LAING:
A. No.
CHAYTOR, Q.C.:
Q. Looking back on it, Doctor, do you think perhaps it should have been?
DR. LAING:
A. It's hard to know because these are--although they're tests in which the results changed, the clinical circumstances surrounding them are slightly different. The first case, you know, without having known that it was sent to an outside lab for testing, makes it different. The other ones seem to be -
CHAYTOR, Q.C.:
Q. No, the first case that I'm referring to is March 26th, 2003, the review of the lymph node and the ER -
DR. LAING:
A. Oh, the one that I -
CHAYTOR, Q.C.:
Q. Yes, the other one was back in '02.

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DR. LAING:
A. Oh, okay. Okay, all right, sorry.
CHAYTOR, Q.C.:
Q. The one with the outside lab was separate again.
DR. LAING:
A. Okay, okay, sorry. I didn't realize you were thinking about--it's difficult for me to say for sure, without kind of knowing what the circumstances were around the retesting, and you know, I guess it comes back to the question too, you know, when do you decide that something is happening frequently enough that it sort of tweaks your attention. Again, I think this speaks to the fact that yes, if there had been some sort of follow up and some sort of database to capture these, that this may have probably first been tweaked the attention of the pathologists that they were having these changes, but you know, in retrospect it's fine for me to say yeah, knowing what I know today, yes, but in 2003, if we had had three or four people who changed, I'd suspect that we would have had some discussions, just like we did with the

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index case in 2005. I can't imagine that I would not have had a discussion at that time with the pathologists, but you know, it's hard to say that looking back, for sure that I definitely would have. Knowing what I know now, yes, but you know, it would be a lot more helpful if I had some more information surrounding the request, why the repeats were requested and those sorts of things.

CHAYTOR, Q.C.:

Q. And regardless though of why they would have been requested, if it results in a change?

DR. LAING:

A. The results changed?

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. This results is different. The one that you showed me just prior to this says it was--was it negative? Yes, it was negative or was it unavailable to test?

CHAYTOR, Q.C.:

Q. The one before that went from being less than one percent ER, 15 percent PR. The repeat resulted in 40 percent ER -

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DR. LAING:

A. Oh, and 73

CHAYTOR, Q.C.:

Q. - and 73 percent PR.

DR. LAING:

A. Yeah, and then the one before that, it says that it wasn't available for testing or -

CHAYTOR, Q.C.:

Q. No, the one before that was negative, and -

DR. LAING:

A. And then came back positive.

CHAYTOR, Q.C.:

Q. - came back positive, yes. So all of those resulted in changed results.

DR. LAING:

A. Yeah, they were--I would agree that they would have been a significant change, yeah.

CHAYTOR, Q.C.:

Q. And it wasn't any discussion though amongst the oncologists, and I take it no incident report filed for any of those that you're aware of?

DR. LAING:

A. Not that I'm aware of, no.

CHAYTOR, Q.C.:

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Q. And as director of medical oncology, if there is to be a incident report filed, would you be made aware of it?

DR. LAING:

A. Yes. So how we looked at the incident reports that were, that many of them would come through to senior administration and we have a provincial pharmacy and therapeutics committee and we would look at incident reports during that time and we look at incident reports--and they would be ones specifically pertaining to treatments, and then we would also look at incident reports as part of senior management.

CHAYTOR, Q.C.:

Q. And I would take it then, Doctor, if incidents reports had been filed on those and brought to your attention, then you would have noticed that we have four of those now within -

DR. LAING:

A. A short period of time.

CHAYTOR, Q.C.:

Q. - short period of time?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

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Q. Doctor, I'd like to turn now then and--before I do though, the two that you requested the repeat for on your elderly patients, and you asked for a repeat, why did you think there might be a chance in result?

DR. LAING:

A. Really the main reason for asking for them to be repeated was that because they were elderly patients and because the incidents is higher in patients as they get older, that was the one reason and the second one was they had well differentiated tumours and, you know, as I said before, I wasn't prepared to offer them chemotherapy, and often when you see elderly patients with breast cancer, it's more common for them to be positive. So because I didn't have another treatment option that I was prepared to give them, then I did ask for that to be repeated, and as I said, the results didn't change.

CHAYTOR, Q.C.:

Q. Did you have any reason to doubt the original results?

DR. LAING:

A. No, I think I was just sort of looking, if you

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will, for, you know, sort of grasping at straws, if you will, for another treatment that I may offer these patients. It's interesting, as part of the tumour review, we looked back to 19--back as far as 1997, and there were a couple of patients that we found who were ER/PR negative who were offered hormonal therapy simply based on their age, without looking at their ER/PR status, and that would have been a practice that would have been common for European physicians to not rely on ER/PR testing, and so one of our more senior oncologists, on a couple of occasions, had prescribed Tamoxifen to hormone receptor negative patients, just simply based on their age and the fact that they had high risk disease for which there wasn't any other option available.

CHAYTOR, Q.C.:

Q. Thank you. I'd like to turn now then, Doctor, and talk about what's been referred to as the index case.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

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Q. Peggy Deane's case.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And from your perspective and involvement, perhaps you could tell the Commissioner how it all began?

DR. LAING:

A. Sure. So Peggy Deane was a patient under my care. She first came to see me in July of 2002, at which time she was diagnosed with breast cancer. She had had--prior to this, had had a breast lump for some time that had been investigated back in 2000, and then noticed that the lump was increasing in size and this led to mammograms and ultrasounds and subsequently to a biopsy. She then had surgery prior to me seeing her, and had had a metastatic work up, and the metastatic work up, unfortunately revealed that she had evidence of liver metastases. There was a lesion in the liver that was evident on her staging CAT scan, and in fact this was biopsied just to make sure that it wasn't something else, although characteristically on

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imaging, it did look like a metastatic deposit and in fact, it was confirmed to be metastatic disease.

So when I saw her for the first time in the clinic, she had stage four disease. She had a tumour that was fairly large. It was three centimetres or so. I can't remember exactly, but somewhere around three or four centimetres, and she did also have lymph node involvement at that time. The report that we received regarding the ER/PR on the primary tumour was what we would consider negative. So one was, I think, zero percent and the other one was certainly less than ten percent.

CHAYTOR, Q.C.:

Q. Less than ten.

DR. LAING:

A. And you know, I recall sitting there with her and her husband and explaining that, you know, we were now faced with metastatic disease and what that meant, that this was an incurable situation, that given the fact that she had less than ten percent staining, in fact I said ER/PR negative disease, that I didn't feel that she would derive benefit from hormonal

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therapy and that I felt that we should treat her metastatic disease with chemotherapy.

She was very young, younger than our usual breast cancer patient, so someone that I would group in my group of young patients. Obviously, you know, an aggressive disease. It's not very often that our patients who present, present with metastatic disease at initial diagnosis. That's very uncommon. In fact, most people that I would see like her would be coming to me for a discussion regarding adjuvant therapy, but knowing that she had, I think, four or five lymph nodes involved and knowing that, you know, she certainly would have been in a high risk category, and she would have had chemotherapy.

So after that discussion, I commenced her on treatment with chemotherapy. She would have initially received anthracycline based chemotherapy, which would be standard, particularly certainly standard then and now. The anthracyclines and the taxanes are our most active medications against metastatic breast cancer. So she had that, and she responded, was off treatment for a few months,

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progressed again, started back on treatment, and on and on we went over the next couple of years, and she received numerous chemotherapy regimens for her metastatic disease.

Initially when she received treatment, she did have response. Now we're talking about metastatic disease, so you know, things are shrinking on CAT scans. But as time went on, the chemotherapies that we were trying were less effective and her disease progressed. She went from having just disease initially in the liver to more significant disease in the liver, eventually to disease in the lungs, including the pleura, and in her bones.

When she progressed after the anthracycline, we made a decision to treat her with taxane based chemotherapy. At that time, there was a trial that came out that suggested a higher response rate, and in fact, a survival advantage with a combination of chemotherapy for metastatic breast cancer, which included two drugs, taxotere, docitaxil and capecytabine, and that, in fact was the second line regimen that we initiated, but she

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had quite severe toxicity, so we had to go back to just giving her single agent taxatere.

That was at the--so when she was started on that treatment, it was 2003, at which point I started my maternity leave, and in fact, Dr. McCarthy resumed her care for me while I was off on my maternity leave, and I did discuss with Dr. McCarthy, somewhere around, you know, when I was off, about the fact that we would just go back to single agent taxatere. So we gave her taxatere by itself and then when she progressed, we went on and gave her capecytabine.

She then, in 2005--so we're now into sort of early 2005, is becoming less well. This is a lady who was unbelievable in how she kept going and she was slowing down and required admission to hospital and was having fluid drained from her abdomen, was really starting--her performance status or her ability to be up and around and able to do the things that she needed and wanted to do was deteriorating.

We talked about whether or not there

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might be some experimental treatments that she may qualify for. We didn't have any clinical trials open at our cancer centre that she would be eligible for. She had already had six or seven lines of chemotherapy, and I felt that her performance status really wasn't good enough that she would be eligible for a phase one, so an early type of clinical trial. She herself said to me, you know, "can I go down to the States? Do you know someone down there that I might be able to go to and see that might have something to offer me?" and we talked and I said, you know, "I don't think you're well enough to make that trip, but, you know, I do know some people in the States and if it's okay with you, I'll send a note and see if they have any other ideas of what we should do at this point."

So I sent an e-mail to Dr. Cliff Hudis, who is a medical oncologist at Memorial Sloan Kettering, and he was a gentleman that I had met on a few previous occasions. So I knew him well enough that I felt comfortable to send an e-mail, that he would respond to that, because we had met on a few occasions.

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CHAYTOR, Q.C.:

Q. I'm sorry, but the--to use Sloan Kettering or Dr. Hudis, was that your idea or was that something that Dr. Deane mentioned to you?

DR. LAING:

A. No, I think it was my idea. I think it was just sort of "who do you know down in the States, you know, who you might be able to talk to?" Probably about a year and a half or so before this, I had been asked to contribute to a slide kit on the treatment of metastatic breast cancer and there were a few oncologists from Canada and Dr. Hudis came from the U.S., and this was a slide kit that was being prepared to be used as an educational tool for medical oncologists, and that was the first time I had met him. So this was at a meeting and so we had spent a fair amount of time together at this, and then, at the meeting, and subsequently, I had heard him speak at another meeting, and I was struck by the fact that he seemed to be a very sensible, sort of straightforward kind of caring guy, in terms of his approach, and in fact, one time, we teased him that he was like a Canadian in his

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approach to, you know, care, because sometimes our American counterparts are seen by us as being sort of more aggressive and that sort of thing. But, so I knew him well enough, so I sent him an e-mail, and because I was doing this as a consultation, I took out Peggy's chart and sort of sat down and sent this as if I would send, you know, a consult.

So I included in it, you know, her initial diagnosis, her pathology, her hormone receptor results, and all that information, the treatment that she had received to date. I explained that I didn't feel that she was well enough to travel, but if he had any ideas of what might help to let me know. So within a day or two, I got an e-mail back from him saying that, you know, picked up on the fact that she was lobular and I had said that she was ER/PR negative, and he said, you know, "very rare indeed" kind of thing, and I explained that, you know, that she had this less than ten percent staining and he said that he'd try a hormonal therapy. That he hadn't seen a negative lobular cancer.

So subsequent to receiving this e-mail, I

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spoke to both the patient and her husband and as well as to Dr. McCarthy. At this point, Peggy had been cared for myself, then Dr. McCarthy and so we kind of both considered ourselves to be, you know, her oncologists, her medical oncologists. And so I called Dr. Ford Elms, because he was the pathologist who had signed out the original ER/PR. I explained the correspondence that I had had with Dr. Hudis and I said, you know, would you retest her tumour.

CHAYTOR, Q.C.:

Q. And Doctor, prior to doing that and making the contact with Dr. Elms, did you discuss the issue with the patient?

DR. LAING:

A. Yes, I did.

CHAYTOR, Q.C.:

Q. So she was aware that she was going to be retested?

DR. LAING:

A. She was aware that this is--right, yeah.

CHAYTOR, Q.C.:

Q. Okay, sorry, go ahead.

DR. LAING:

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A. So I recall that when Dr. Elms went and he got the slides and subsequently we spoke again and he said he was going to do the testing, and he said that the--although it was a lobular cancer, that it may have had some ductal features, which sometimes lobular tumours will have, and that, you know, he would run the test. At this time, they had the Ventana system and that he would get back to us, you know, in the next little while with the test results.

At this point, Peggy was an in-patient in the hospital, and you know, we had explained this, and so she was waiting for the test results, just as we were, and -

CHAYTOR, Q.C.:

Q. And what was her reaction? What was her reaction when you told her that she was going to be retested?

DR. LAING:

A. She was very hopeful. She was hopeful that this was going to come back as being positive and it meant that, you know, we could try hormonal therapy for her.

CHAYTOR, Q.C.:

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Q. It's another form of treatment for her?

DR. LAING:

A. Yeah, so yes.

CHAYTOR, Q.C.:

Q. And what reason did you give her for having the retest done? What was she told as to why she was going to be retested?

DR. LAING:

A. Oh, exactly what Dr. Hudis had said to me, was that, you know, she had lobular pathology and she was aware of the fact that she had lobular pathology. Interestingly, for another reason, because she went at one point and had a PET scan done and there was some discussion about PET scans in lobular breast cancer and things, but the--so I explained that I had spoken with Dr. Hudis, that he felt that we should repeat it, given the fact that it was lobular, and that you know, he felt that that was an indication to retest it at that point to see if it was positive, and if it was, to try her with hormonal therapy.

We were then waiting for the test results to come back, and when they did, she was an in-patient and one of our other medical

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oncologists, Dr. Stewart Rorke, was looking after her, and we had done some hormone levels to see if she was pre or post menopausal and it still indicated that she was pre-menopausal, and so our instructions to Dr. Rorke was if you get a positive test result, start her on the Tamoxifen, and that's what happened.

CHAYTOR, Q.C.:

Q. Okay, and if we could have, please, P-0489? Doctor, this is the e-mail exchange that you had with Dr. Cliff Hudis.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And it begins on April 9th, 2005 at 11:34 in the morning, on a Saturday morning, and you write "Dear Cliff, I'm wondering about a patient of mine, at the request of her and her husband. This 46-year-old lady was diagnosed in July 2002 with infiltrating lobular cancer of left breast," and you probably can interpret what those numbers mean, "with biopsy proven liver mets, ER/PR negative and HER2 non over expresser" and then you indicate

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which treatment that she has received, and you tell him that she had liver, bone, large pleura based mets with pleural infusions and extensive peri -

DR. LAING:

A. Peritoneal disease.

CHAYTOR, Q.C.:

Q. - peritoneal disease," thank you. And you go on to say, "I have told her that I don't think we have any more standard options and that it is unlikely that she will respond to anything, given the resistant nature of her disease. She and her husband asked me to previously contact someone in U.S. re: possible trials. She has been to see Maureen Trudeau previously as well. Her PS is now," and you go on from there. "Prior to this last worsening with the right effusion and increased abdominal disease, she was still quite active. She is a lovely lady with three young children, and does her best to keep going. Her husband is one of our colleagues and is having a difficult time, understandably, and wanted to know about other options. I realize that there are likely not any, but did want to ask,

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for their benefit."

And Dr. Hudis responds on Sunday to you, Sunday evening, the next day, April 10th, "ER and PR negative invasive lobular" with a question mark, "very rare to say the least. If you are sure it is invasive lobular, I would repeat the ER/PR. If it is really ER/PR negative and she is S/P" all of those things, "would you normally try" and he goes on from there, and he tells you he doesn't have a clinical trial option at the time.

DR. LAING:

A. Yeah.

CHAYTOR, Q.C.:

Q. "Good luck." You respond to him the next day, Monday.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Close to one p.m., "ER was negative and PR was weakly positive in less than ten percent, which we consider negative. Can get it rechecked." And then he gets back to you shortly after, a couple of hours later, "I'd try hormonal therapy. I have never seen an

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ER/PR negative invasive lobular." So I take it, Doctor, without even having the retest done, Dr. Hudis was saying try the hormonal therapy?

DR. LAING:

A. Right. I think there's two parts of that. One was that we had had some discussions about whether it was lobular or ductal, but at the end of the day, it didn't change. It was still a lobular cancer, and -

CHAYTOR, Q.C.:

Q. So Doctor, if I can just ask, do you mean that the pathology was reviewed to determine whether it was lobular or ductal?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and who did that for you?

DR. LAING:

A. When I first called Dr. Elms and I said, you know, explained that the reason was is because it was lobular and that in my discussions with Dr. Hudis, he said, you know, this is rare and we just don't see that, that I said, you know, "can you repeat it?" and when he called me

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back, when he got the slide out, he said "you know, I remember this had some ductal features," but he didn't change--you know, when he looked at it and I believe that he told me that he looked at it with some of the other pathologists, that they still called it lobular.

CHAYTOR, Q.C.:

Q. That it was still lobular?

DR. LAING:

A. Yeah, they didn't change that it was lobular at that time.

CHAYTOR, Q.C.:

Q. Okay, and in 2002, based on Ms. Deane's profile at that time, did it occur to you that it was unusual that she was ER negative?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And the fact that in 2005, Dr. Hudis was saying that he had never seen an ER/PR negative invasive lobular, I take it that hadn't been your experience. You'd seen negatives?

DR. LAING:

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A. That's right. That's right, yeah, and so you know, really getting back to what we've already discussed, that we accepted that there was a high percentage that were ER/PR positive, but this is the first time that I had ever had anybody tell me, in my training or in discussions, that it was all of the lobular patients were ER/PR positive.

CHAYTOR, Q.C.:

Q. So what was -

DR. LAING:

A. At the same time, as well, you know, this was a lady who presented to me with metastatic disease right from the beginning, clearly an aggressive cancer, and so it didn't really, you know, sort of stand out that it should be positive, just based on the fact that it was lobular. And then, of course, the other issue is, you know, looking back, if I had have known that she was hormone receptor positive, this was someone who had metastatic disease at that time, was a young patient with clearly an aggressive cancer, who had liver metastases. So it is likely that I would have treated her with chemotherapy still as the

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initial treatment.

What we often do with patients who are hormone receptor positive, but yet we feel that they require chemotherapy because of the aggressiveness of their cancer, the age, where it is, all those other reasons is we give them chemotherapy and then when that chemotherapy is finished, we put them on Tamoxifen or an aromatase inhibitor, some sort of hormonal therapy, and it's hoped that we can extend the time to progression, if you will, between chemotherapy agents, by giving a hormone. So that's what I would have done differently at the time, but when I think back to when I first saw her and there wasn't anything that, at that time, made me question the fact that she was ER/PR negative, having an aggressive disease, metastatic at presentation, and you know, I certainly have had patients subsequently and continue to have patients who are hormone receptor positive who don't have an upfront response to hormonal therapy, unfortunately, when we give it to them, because the overall response rate is just 60 percent, which means 40 percent of patients,

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even known to be hormone receptor positive on their primary cancer, will not respond to that sort of treatment.

CHAYTOR, Q.C.:

Q. Doctor, what was your reaction upon reading what Dr. Hudis had to say?

DR. LAING:

A. I remember looking at it and saying, "oh, okay." That's, you know, a pretty definitive statement, and not my sort of what I would consider. I actually subsequently had an opportunity to have a further discussion with him regarding this point.

CHAYTOR, Q.C.:

Q. And I take it Dr. Hudis is known--is he known to be a breast oncologist?

DR. LAING:

A. Yes, he is.

CHAYTOR, Q.C.:

Q. Okay, and he's well known?

DR. LAING:

A. Oh yeah. Yes, he is.

CHAYTOR, Q.C.:

Q. And perhaps then, tell us what was your subsequent discussion with him, and was it

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around the same time period?
DR. LAING:
A. It was after this, and certainly to the point after this that I, you know, we were well underway with the review, sort of getting ready to do the tumour panel, that I would have seen him again.
CHAYTOR, Q.C.:
Q. So by then, Ms. Deane would have already -
DR. LAING:
A. So sometime in the fall, October of 2005.
CHAYTOR, Q.C.:
Q. - and Ms. Deane would have already passed on?
DR. LAING:
A. Yes. Yes, she would have, and I saw him at a meeting and spoke to him and said "remember I had talked to you about that lady?" and you know, explained to him that we did retest her, that her results came back as positive. That we treated her with hormonal therapy, but she didn't really have any significant response, and that, you know, it led to us deciding to this review, and then he subsequently said to me that they had done a review where they had looked back at lobular samples, so tumour

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samples of lobular breast cancer, and they had retested them in the lab and that, you know, using the new antibodies, that they had actually, all of the lobular cancers had tested positive.
CHAYTOR, Q.C.:
Q. And they being, this is Sloan Kettering?
DR. LAING:
A. Yeah. Now, so of course, I was quite interested in that, because I said "well, what did you do? Was this related to patients?" and he said no, many of these large cancer centres have tumour banks where they have anonymous tumour samples from different sorts of cancers, including breast cancers, that they do research studies on in the lab, and it was on these tumour samples that they reran the immunohistochemistry testing for the lobular samples. So this wasn't a patient based or a patient centred review. This was something that was done only in the laboratory on tissue samples.
CHAYTOR, Q.C.:
Q. And were these tissue samples that had previously been tested and had ER/PR results?

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DR. LAING:
A. They would have been, because they would have come from, obviously they would have come from patients, and so what they did was that they-- using their current antibodies and things, they had rerun the lobular samples that they had had in their tumour bank from over the years and all of them, he told me, came back as being hormone receptor positive.
CHAYTOR, Q.C.:
Q. And did he indicate how that compared to what the original test on those samples had been?
DR. LAING:
A. No, because these were again samples that they had had, that they had gathered, but they didn't necessarily--they weren't necessarily tied back and they wouldn't have necessarily always had the patient data related to them. So I'm not sure that he would be able to tell me had these been people that had been--you know, what had their original result been. This was sort of done in a laboratory setting with these blocks of lobular specimens, and I was quite interested, because I thought well, was this something that you would--you know,

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that you then had to communicate back to patients, and he said "no, this was not a patient centred review." And that was really the last time that we've spoken about this.
CHAYTOR, Q.C.:
Q. You've never had a discussion with him on this issue since?
DR. LAING:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and that discussion took place in the fall, sometime after October 2005 or around October?
DR. LAING:
A. Around that time.
CHAYTOR, Q.C.:
Q. Around that time period.
DR. LAING:
A. Yeah, I was at a meeting in--a European conference and I believe that that's when it would have been.
CHAYTOR, Q.C.:
Q. And Doctor, after receiving Dr. Hudis' e-mail and being somewhat surprised by the content yourself, did you discuss it with any other

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oncologists?
DR. LAING:
A. Yes, I discussed it with Dr. McCarthy.
CHAYTOR, Q.C.:
Q. Okay, and what was discussed between you and Dr. McCarthy?
DR. LAING:
A. Well, I initiated the discussion with Dr. McCarthy because, as I said, we were both really thinking about what we were going to do next with this patient, Peggy Deane. When we got the result come back and it changed, the result that we got was--Dr. Elms had called us. He said that they're both positive and we started the patient on the Tamoxifen. Then we said, well, you know, this is really the case, then you know, should we be thinking about looking at our lobular patients? You know, what should we do about this? And we just had a--we had a discussion at that time, and she said to me "well, I'll give Dr. Cook a call" and so she called Dr. Don Cook and that, you know, was sort of the start of that whole process. And then, of course, there were some other events that had happened, in terms of

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some other patients with lobular who we asked to be retested.
CHAYTOR, Q.C.:
Q. Yes, and I'll take you to those. I just want to stick with Ms. Deane's case for a moment. So you discussed the matter after getting this e-mail. You discussed it with Dr. McCarthy. Was she equally surprised by what Dr. Hudis had to say?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and when you talked to Dr. Elms and you explained to him that you were looking for a retest, and I take it you told him it was because --
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Of what Dr. Hudis had told you?
DR. LAING:
A. That's correct.
CHAYTOR, Q.C.:
Q. All right, and did Dr. Elms indicate to you whether he was aware that other patients ER/PR

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tests had previously been retested and experienced a change result?
DR. LAING:
A. Not at that time, no.
CHAYTOR, Q.C.:
Q. At any point in time has Dr. Elms had that discussion with you?
DR. LAING:
A. Not--no, no.
CHAYTOR, Q.C.:
Q. Has anyone brought that, in the way of a pathologist, brought that to your attention?
DR. LAING:
A. You mean prior to --
CHAYTOR, Q.C.:
Q. That there were prior tests before Peggy Deane's ER/PR test that had been repeated and resulted in a change result?
DR. LAING:
A. No, I don't remember having those conversations with--prior to this incident, no.
CHAYTOR, Q.C.:
Q. So, for example, the examples that I've shown you today, other than your own --

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DR. LAING:
A. So the examples you showed me about Dr. Zaidi's patients.
CHAYTOR, Q.C.:
Q. Yes, and there are others, yes.
DR. LAING:
A. And the other ones --
CHAYTOR, Q.C.:
Q. But those that I've shown you, there's been no discussion since with you about, well, perhaps we had a similar situation back in 2002 or 2003?
DR. LAING:
A. No, that discussion came out after this, in the early discussions we had with Dr. Cook, as I indicated, that they said there may have been a problem in the lab in 2002.
CHAYTOR, Q.C.:
Q. And when did you have that discussion with Dr. Cook? When was it brought to your attention that perhaps Peggy Deane was not the first?
DR. LAING:
A. Oh, that would have been in--now getting into July of 2005.
CHAYTOR, Q.C.:

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Q. Okay.
THE COMMISSIONER:
Q. Ms. Chaytor, wherever you can find a convenient spot, we'll take the afternoon break.
CHAYTOR, Q.C.:
Q. Okay. Doctor, upon Peggy Deane's case coming to light and the retest, and this time period with receiving Dr. Hudis' e-mail, did you do any research? Did you look into the issue yourself and look back through the literature?
DR. LAING:
A. Not a whole lot. You know, at this point, really we were looking at this particular case, we had some discussion about--some early discussion with Dr. Cook about where we went from here. We had identified in the clinic a couple of more patients who we retested. You know, I remember sort of going and sort of doing a literature search looking at, you know, sort of lobular disease to see if I could find some reference to saying that it was 100 percent. I remember taking out my big oncology textbook and seeing if I could look in there and see, and I couldn't find a

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reference anywhere that gave actually 100 percent. You know, there were statements like, you know, the majority or most, but certainly I didn't find anything that said "all".
CHAYTOR, Q.C.:
Q. So this would have been a textbook that you had from the time that you were in med school or in your residency?
DR. LAING:
A. Yes. It's a textbook that still exists and gets updated, The DeVita. So that's our --
CHAYTOR, Q.C.:
Q. And why would you have looked back to that as opposed to currently literature?
DR. LAING:
A. Oh, no, it's a current book. It's updated regularly.
CHAYTOR, Q.C.:
Q. It's updated.
DR. LAING:
A. Oh, yes, yes.
CHAYTOR, Q.C.:
Q. So you would have an updated version of it?
DR. LAING:

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A. Oh, yes, yes, certainly.
CHAYTOR, Q.C.:
Q. That makes more sense.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. Like, edition who know what, probably 12 now. These textbooks are updated.
CHAYTOR, Q.C.:
Q. Pretty close to a 2005 edition?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And there was no reference to it being 100 percent?
DR. LAING:
A. 100 percent, right.
CHAYTOR, Q.C.:
Q. What did it say on that issue?
DR. LAING:
A. Oh, they didn't even give a percentage. Most of what I looked at was again what we had said, you know, most--there wasn't anything

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that said 100 percent or that had said "all" lobular tumours.
CHAYTOR, Q.C.:
Q. Other than discussing this with Dr. McCarthy, the information that has been forwarded on to you by Dr. Hudis, did you discuss it with any of the rest of the oncologists?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Who else did you discuss it with?
DR. LAING:
A. We would have had a discussion as an entire group of medical oncologists. We actually are together once a week. On Tuesday mornings, we do our in-patient ward rounds together, and afterwards we always have an informal meeting and we talk about lots of different issues. So, I mean, even down to Dr. Rorke, who doesn't treat breast cancer, you know, knew all about what was going on because, of course, he had been the attending looking after Peggy while she was in the hospital. So, you know, this was something that we really talked about really initially as an

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isolated case, and then went on to think about this--I think in the early days our mindset was really around that this was going to be something related to lobular tumours, and it wasn't until the events unfolded over the next little while that we realized that this was something that was beyond just this being something that we were seeing in lobular patients.

CHAYTOR, Q.C.:

Q. So, Doctor, in your Tuesday morning then get together, you chatted about this particular case?

DR. LAING:

A. That's right.

CHAYTOR, Q.C.:

Q. In your Tuesday morning oncology get togethers, had it previously ever come up, for example, the cases I showed you in 2003?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. That issue had never come up?

DR. LAING:

A. No.

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CHAYTOR, Q.C.:

Q. And the issues back in 2002, 2003, or any change results back in that time period, had they ever come up in the tumour board rounds with the pathologists?

DR. LAING:

A. Not that I was present for, and not that I have any knowledge of, no.

CHAYTOR, Q.C.:

Q. And you've subsequently heard that that has happened. Has anyone ever told you that there may have been a discussion back in that time period at the tumour board rounds?

DR. LAING:

A. Yes, there was some reference made--I'm not sure if it was by Dr. Greenland or someone back in 2002 or 2003, that someone could recall somebody saying about it, but that was the only thing that I have ever heard subsequently.

CHAYTOR, Q.C.:

Q. And when did you learn about that?

DR. LAING:

A. Oh, after this had all developed.

CHAYTOR, Q.C.:

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Q. So into July or August, 2005 period?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. After it became the subject, the discussion --

DR. LAING:

A. Sure, yeah.

CHAYTOR, Q.C.:

Q. And when you had your first Tuesday morning meeting of oncologists after Dr. Hudis' communication to you, at that point in time did any other oncologist mention any issues that had happened in the past, any issues of changes in ER/PR results?

DR. LAING:

A. Not that I recall, no. It was--you know, it probably wasn't the very next Tuesday, but it would have been within the weeks after this once we had the results come back from Peggy's retesting, and then subsequently once we go the next results back.

CHAYTOR, Q.C.:

Q. Thank you. Commissioner, this would be a convenient point.

THE COMMISSIONER:

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Q. All right then, take the afternoon break.

(BREAK)

THE COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. If I could have, please, C-0167. Doctor, this is a discharge summary related to Mrs. Deane, and the admission date is April 12th, 2005, discharged April 20th, 2005, "Repeat testing of her ER/PR receptor status changed its status to ER/PR positive, and thus she was started on treatment with Tamoxifen, and also given Zoladex injections after laboratory parameters showed that she was pre-menopausal". I take it her change in treatment by this point in time before she was discharged on April 20th, she had already been started on Tamoxifen?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And her test had already been repeated?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

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Q. If I could have, please, C-0168. This progress note again is in relation to Mrs. Deane. It's May 3rd, 2005, and this refers to your discussion with--your e-mail, sorry, with Dr. Clifford Hudis?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. "When I had sent an e-mail to Dr. Clifford Hudis in the United States asking him if he had any trials that Peggy might be eligible for, he commented that it would be unusual for lobular carcinoma to be ER/PR negative. For this reason, I had asked for her pathology to be reviewed, and interestingly, it came back saying that it was a ductal cancer, but when they did stain it for ER/PR, it was positive for both. Because of this, we started Peggy on Tamoxifen as she still had evidence of an-- if you could help me with that word.

DR. LAING:

A. Oh, that's Estradiol. So she was still pre-menopausal.

CHAYTOR, Q.C.:

Q. Okay, and you spoke about that before.

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DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. And you go on to say, "She has been tolerating the Tamoxifen well with no difficulties". Doctor, this information here that, "You asked for the pathology to be reviewed, and interestingly it came back saying that it was a ductal cancer", where did that information come from?

DR. LAING:

A. That was what I had understood for when I initially had the first discussion with Dr. Elms was that he said that there was some ductal features about the tumour, but that he would review that, and, in fact, when the final pathology report came out, which was subsequent to this note, they did not change the histology diagnosis, it remained a lobular cancer.

CHAYTOR, Q.C.:

Q. Yes, but didn't the original pathology also indicate that it was lobular with ductal features?

DR. LAING:

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A. Yes, yes. So when I had spoken to Dr. Elms, he said that he would like to sort of have a look at it and review it again, and--see at this point, we were going with what Dr. Hudis had said. So if we were to assume and to keep that it was still absolutely lobular, then, you know, we would have sort of said, well, we're pretty sure it's going to be positive, but when he took it out and said, no, I'd like to review this and make sure that I would still call it a lobular and that wouldn't change, this is why we waited for the retesting to come back, and I had misunderstood what he had said to me on the phone initially when he said that, oh, wait now, it has some ductal features, we'll have a look at that again and see if there's any change. I had thought that he meant it had been ductal, but, no, in fact, when the final pathology report comes back, it stays as lobular, and I've subsequently--around that time, and, of course, since I've talked to Dr. Elms about it, and there was not a change in the histological diagnosis, it remained a lobular cancer.

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CHAYTOR, Q.C.:

Q. And was there any indication on the addendum that came back to you that there was ever even any review of the original diagnosis?

DR. LAING:

A. No, the--the only addendum that came said that the ER/PR were both positive.

CHAYTOR, Q.C.:

Q. Yes, and have you subsequently in your discussion with Dr. Elms, discussed whether or not he, in fact, did review the original diagnosis?

DR. LAING:

A. Yes, he came back to me and said, no, when I looked at the slides again, it was a lobular then and I would still call it a lobular now, and so it didn't change to a ductal, and I knew this shortly after this note was dictated.

CHAYTOR, Q.C.:

Q. Okay. So what you're saying is this note is dictated and at the time that you dictated it, you had asked for her pathology to be reviewed, so not just her ER/PR, you had asked for the --

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DR. LAING:
A. I didn't ask for a pathology review, no.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. What had happened was when I had initially called Dr. Elms and said, you know, we've got this e-mail, it indicates that because this lady's pathology is lobular, that, you know, Dr. Hudis felt that she should be ER/PR positive, and he had said to me--you know, I remember that this--he looked at the slides. He said, yes, it was lobular, but it had ductal features, and I had misunderstood that to mean that he was thinking that it was, in fact, a ductal cancer, but what he had said was that it had ductal features, he was going to look at it again, and when he signed out the final report, he did not change his histological type of this tumour. It remained a lobular cancer.
CHAYTOR, Q.C.:
Q. Okay, and when a pathologist tells you, because I'm assuming that's something that you would read on a pathology report from time to

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time, when you're told that it's lobular with ductal features --
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. You still understand that it would be a lobular cancer?
DR. LAING:
A. Yes, and there are some cancers that actually come back as mixed ductal and lobular because you see both types of patterns of histology present.
CHAYTOR, Q.C.:
Q. So this here, "Interestingly, it came back saying that it was a ductal cancer", Dr. Elms never called you back and said I've reviewed it and it, in fact, is a ductal cancer?
DR. LAING:
A. No, no, no.
CHAYTOR, Q.C.:
Q. And in your discussions subsequently with Dr. Elms more recently, did he, in fact, confirm that he had reviewed her original diagnosis in terms of this issue of was it ductal, was it lobular?

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DR. LAING:
A. Oh, yes, and even then when--so subsequent to this dictation note, which was the first time that I had seen Peggy in the clinic after her discharge from the hospital, I did get the addendum after and it eventually came through the mail and made it to me, and put on her chart, that, no, there was no change in her histological diagnosis, she remained a lobular.
CHAYTOR, Q.C.:
Q. And --
DR. LAING:
A. And that's important because that formed the basis of some of the other patients that we decided to retest.
CHAYTOR, Q.C.:
Q. Okay, and if we could see, please, C-0156. This is the addendum?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And it's not entered until May 31st, 2005.
DR. LAING:
A. Yes.

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CHAYTOR, Q.C.:
Q. But it--I've taken you to the discharge summary which indicates that the retest was actually done sometime in April.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And immunohistochemical staining for ER and PR has been repeated on this tissue using Ventana automated systems. Stains for both receptors are positive", and that's the only addendum in 2005. Do you know was Mrs. Deane's case ever repeated by Mount Sinai as part of the review?
DR. LAING:
A. Not that I know of.
CHAYTOR, Q.C.:
Q. Okay.
DR. LAING:
A. I have no idea. I've never seen a result come back from Mount Sinai that I can recall.
CHAYTOR, Q.C.:
Q. And why would her case not have been--her original ER negative specimen not have been retested by Mount Sinai?
DR. LAING:

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A. I'm not certain.
CHAYTOR, Q.C.:
Q. Doctor, did Mrs. Deane respond to the Tamoxifen treatment?
DR. LAING:
A. I don't really think so. You know, when we first started it, she had had ascites. So she had fluid within her entero-abdominal cavity. We drained that as we often do for a comfort measure for patients, and when she first started on the Tamoxifen, it seemed that there was maybe a little bit of a longer time between when she needed to be--like, the interval was a little bit longer, and we thought maybe that was a sign of her first starting to respond, but really her condition continued to deteriorate over the next couple of months, and she had other palliative radiations and other admissions, and palliative procedures done, and then she ultimately died of her disease in early August of that year.
CHAYTOR, Q.C.:
Q. And, Doctor, the addendum here just says that both receptors are positive?

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DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And this is in 2005?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. There's no indication of percentages, and at this point in time, I take it, it was usual that percentages would be given?
DR. LAING:
A. It would have been.
CHAYTOR, Q.C.:
Q. Did you have any discussion with Dr. Elms as to whether or not--how positive is she? She was already less than 10 percent on the original test, less than 10 percent PR positive.
DR. LAING:
A. Yes. No, I don't know what her actual numbers would have been, and I can't recall if he would have said when we spoke to him, because, of course, the first verbal report of the change in receptor status was communicated through to Dr. Rorke who started her on the

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treatment. Perhaps at some point he did tell me what the numbers are, but I wouldn't be able to remember now what they were.
CHAYTOR, Q.C.:
Q. If you had received this result in 2002 at the time of her original diagnosis, would Mrs. Deane have been placed on hormonal therapy at that time?
DR. LAING:
A. Looking back, and looking at my practice at that time, I suspect I would have given her upfront chemotherapy, and then following that I would have given her hormonal therapy for her metastatic disease.
CHAYTOR, Q.C.:
Q. If we could have P-0046, please. This is a report, October 17th, 2005, from BC Cancer Agency from Dr. Banerjee, and this is just his cover letter.
DR. LAING:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And there's a report, and, Doctor, when did you first--when did you first see this report?
DR. LAING:

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A. I've never read this report in its entirety.
CHAYTOR, Q.C.:
Q. You've never read it in its entirety?
DR. LAING:
A. No.
CHAYTOR, Q.C.:
Q. When did you see any portion of this report for the first time?
DR. LAING:
A. It would have been--as I said, I've never sat down and read this report. This was something, as you know, that was done as part of a peer review process and then that whole issue was subsequently changed. So when Dr. Banerjee attended and did the review, I did not have an opportunity to meet with him, nobody had requested that I spend some time with him, and this was really a review of the pathology in the laboratory. You know, I don't--I haven't read through this report.
CHAYTOR, Q.C.:
Q. Did you know Dr. Banerjee?
DR. LAING:
A. No.
CHAYTOR, Q.C.:

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Q. You've never met him?
DR. LAING:
A. I searched back in my mind to try and think if I can remember him when I was in my BC days, but--perhaps if I saw a picture of him, I would remember, but he's not one of the pathologists that I recall interacting with a lot when I was a resident there. In fact, I'd have to go back and look at his CV to see if he was, in fact, there when I was a resident.
CHAYTOR, Q.C.:
Q. My original question then, when did you see, read, any portion of his report of October 17th, 2005?
DR. LAING:
A. I've never read this in its entirely.
CHAYTOR, Q.C.:
Q. No, any portion of it?
DR. LAING:
A. I may have had some discussions with Dr. Cook and Dr. Denic subsequently as to the content of this report, but this would not be something that I have sat down and seen or read.
CHAYTOR, Q.C.:

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Q. So, Doctor, is it correct to say that you have never read or seen any portion of this report?
DR. LAING:
A. Not that I can recall, no.
CHAYTOR, Q.C.:
Q. Doctor, of course, this report is a public exhibit here at the inquiry, and have you--even since its become a public document, you've never read it or reviewed it, any portion of it?
DR. LAING:
A. No. We discussed it last week in preparation for my being here this week, and--but it wasn't something that I had--there was a lot of other material that I had reviewed, and I've not read it.
CHAYTOR, Q.C.:
Q. And it's not long, it's four pages really--well, maybe five pages because the first page is the cover page, or page two is the cover page. So upon it becoming a public document even, you didn't read it?
DR. LAING:
A. I've never gone to the website and read any of the documents related to the inquiry.

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CHAYTOR, Q.C.:
Q. Uh-hm, and Dr. Banerjee says at page three, I believe it is, of his report, he talks about the index case and four other patients previously tested as negative in 2002.
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Uh-hm. There's a portion here I wanted to take you to. Right here under the "Incident problem case".
DR. LAING:
A. Oh, okay.
CHAYTOR, Q.C.:
Q. The case is that a patient with invasive lobular carcinoma whose tumour was tested in 2002 on the DAKO immunostainer and reported as negative for ER and PR, and when retested in 2005 on the Ventana Benchmark was strongly positive for both receptor proteins. So he's indicating that she was, in fact, strongly positive?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:

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Q. "It should be noted that invasive lobular carcinomas are frequently ER positive", and he puts in brackets, 92 percent.
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. "Thus the initial negative result should have been questioned".
DR. LAING:
A. I'd like to just mention that this is the only part of this report--not that I see where this is coming, I have seen this page, not the full report, but I did look at this last week, and I'm sorry I didn't realize that this was something that was in the body of his report. Certainly Dr. Banerjee is speaking as a pathologist and, you know, as a medical oncologist, as I said, unless there was something else about an ER/PR negative invasive lobular cancer, I--you know, I wouldn't think that I would question each one of those results, knowing that there's certainly--the percentage he gives 92 percent and a reference, I'm not sure what that reference is to, but it's probably appended to

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his report.
CHAYTOR, Q.C.:
Q. Yes, it is.
DR. LAING:
A. So, you know, that's really --
CHAYTOR, Q.C.:
Q. And he was asked about that. I can fill you in on that.
DR. LAING:
A. Okay.
CHAYTOR, Q.C.:
Q. He was asked about that in his evidence because the reference that he gave was to a 2005 journal article.
DR. LAING:
A. Okay.
CHAYTOR, Q.C.:
Q. And that he was asked, well, what about in 2002 because he's saying that it should have been noted.
DR. LAING:
A. Sure.
CHAYTOR, Q.C.:
Q. And his response to that was that it was well known in 2002 that invasive lobular carcinomas

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are virtually 100 percent ER positive, and when he was also asked who should have noted this, he responded the pathologist and the oncologist, and that's Dr. Banerjee's evidence, so I wanted to offer you an opportunity then to respond to that?
DR. LAING:
A. Well, certainly, as I said, that's his opinion as a pathologist. My training and what I had been taught was that it was 85 to 90 percent. I've certainly had this discussion with other colleagues of mine who have certainly indicated a similar amount. Perhaps this is time we should refer to, we talked a lot about the index case. In fact, as part of Peggy's course they asked for to be seen by Maureen Trudeau, who we've spoken about. Dr. Trudeau is a medical oncologist at Sunnybrook. There was a letter, a referral letter sent by Dr. McCarthy as that was when I was on my maternity leave. I have subsequently read the consultation note back from Dr. Trudeau which was dictated by one of her fellows and very clearly in that do they acknowledge the fact that this was a lobular tumour and do they

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acknowledge the fact that it was ER/PR negative and it wasn't questioned then. This is certainly something that, as you can imagine, I have discussed with my colleagues to say that, you know, what was your understanding. And, you know, people said we understood that there was a high proportion but not that it was 100 percent.
THE COMMISSIONER:
Q. Not that it was 100 percent or not that it was 92 percent?
DR. LAING:
A. That it was not 100 percent and that it was, you know, my teaching, as I said, had been that it was somewhere around 85, 90 percent.
THE COMMISSIONER:
Q. So are you saying that what the other oncologists have said to you were consistent with your training or did they have another number entirely?
DR. LAING:
A. No, it was consistent with that. It would usually be around 90 percent would be what the people that I spoke with certainly said.
THE COMMISSIONER:

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Q. Thank you.
CHAYTOR, Q.C.:
Q. And you're saying that Dr. Trudeau would have been clear in any communications to her that the ER/PR status on the original tumour was ER negative?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And PR positive, less than ten percent?
DR. LAING:
A. Yes, in the consultation note back, they indicate that it was ER/PR negative.
CHAYTOR, Q.C.:
Q. And have you subsequently discussed that with Dr. Trudeau?
DR. LAING:
A. No, I have not.
CHAYTOR, Q.C.:
Q. Okay. Doctor, the decision then to go further in the aftermath of Peggy Deane's case and to test further, well, first of all, within the first days or couple of weeks following Peggy Deane's situation and so back in, I guess that would take us into late April, early May, was

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this a subject of much discussion amongst the oncology department?

DR. LAING:

A. I would say it was a subject of discussion amongst Dr. McCarthy and I, Dr. Rorke. I cannot remember who else may have in the very, very early days, that is, in the first few weeks, have weighed into this discussion. But certainly as time went on, over the next couple of months, it was a discussion that was had by, as I said, by all of the medical oncologists. And I would think, as I said earlier, it was probably within about three to four weeks of that initial, you know, of April that we would have had this discussion informally amongst the medical oncologists.

CHAYTOR, Q.C.:

Q. And, Doctor, so what happened after that, when did--what was the impetus for looking beyond and questioning other patient's results?

DR. LAING:

A. Right. So subsequent to that over the next few weeks, so into May, late May and early June, there were some other patients that both Dr. McCarthy and I had identified in our

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practice who we had asked for retesting to be done on. Perhaps I'll speak first to the two patients that I had asked for retesting on.

CHAYTOR, Q.C.:

Q. Okay.

DR. LAING:

A. The first was a lady who I had seen previously and treated for breast cancer in the adjuvant setting. She had a poorly differentiated lobular tumour. The initial ER/PR testing was negative, I believe it said one to two percent, which again at that point we considered to be negative. I gave her a short course of adjuvant chemotherapy but did not offer her hormonal therapy. She happened to have a follow-up visit with me in May of 2005 and at the beginning of all of my notes of my patients I dictate just a little, you know, two or three summary line of their diagnosis, relevant information and the treatments that they have received.

CHAYTOR, Q.C.:

Q. Do you normally put their ER/PR status in there?

DR. LAING:

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A. Yeah.

CHAYTOR, Q.C.:

Q. And most of those progress notes I see are diagnosis, impression and plan?

DR. LAING:

A. Yes. So the first thing would be when I dictate a note, I say the date and then I say diagnosis and I, you know, it's a standard sort of. For the adjuvant patients, it doesn't change; for the metastatic patients, it sort of changes as they go on and have different therapies. In any event, this particular patient, when I looked at the chart, I noticed that she had invasive lobular cancer and it said that it was ER/PR negative. So I then decided, well, I should ask if we could recheck this particular patient, so I did, and it was reviewed and it came back to be positive. Because of that I called the patient and asked her to come back to the clinic. And this would have been in very early June. And the note sort of indicates I saw this lady, we had some information that there may be reason for us to believe that because she was lobular that she should be ER/PR

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positive, I've asked for it to be reviewed, and, in fact, it did come back as positive. So I brought her in to the clinic and disclosed that information to her and then explained what I thought it meant in terms of her care and commenced her on hormonal therapy at that time.

CHAYTOR, Q.C.:

Q. Okay. And if we could have, please, C-0244? And, Doctor, we're going to refer to this patient as patient number two.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. Okay. And we've had some communication before this through your solicitor that there would be a number of patients that we would refer to. So this is patient--in this manner, so this is patient number two. And do you believe this to be the patient that we just-- that you just discussed?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And you'll see that most of this clinic

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note, most of this clinic note has been redacted. And under "Clinical diagnosis" is "Poorly differentiated lobular carcinoma."

DR. LAING:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And you see her on May 6th, 2005. I'll just scroll down so you can see that, that's your signature. And ER/PR negative with staining only in one to two percent?

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. "I had a look at her pathology today. It is interesting that it was said to be lobular, but there was evidence of DCIS and the ER/PR was essentially negative with only one to two percent staining. Reviews have suggested that most lobulars should be ER/PR positive. I'm going to have the pathology review this for me. I will see her back in six months." So, Doctor, you've written here, "Reviews have suggested that most lobulars should be ER/PR positive." And what are you referring to there?

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DR. LAING:

A. I'm referring to the communication that I received from Dr. Hudis.

CHAYTOR, Q.C.:

Q. Okay. And that communication would have been a review that Sloan Kettering did which indicated on tumour bank--anonymous tumour bank -

DR. LAING:

A. I wouldn't have had any of that information at this time.

CHAYTOR, Q.C.:

Q. You didn't have that at that time?

DR. LAING:

A. No, no, no.

CHAYTOR, Q.C.:

Q. Oh, okay.

DR. LAING:

A. This was just only after, you know, I get this e-mail from Dr. Hudis suggesting that, you know, as I--you know, as we read that the number shouldn't be what I had always thought, that perhaps it even should be 100 percent, which is why I thought, okay, you know, here's a case that just happens to be coming into the

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clinic and that I decided, well, maybe I'll ask to have this reviewed and see if that changes or not.

CHAYTOR, Q.C.:

Q. Um-hm. And the idea, though, of any review, when we look at Dr. Hudis' e-mail, there's certainly no indication of any review at that point in time?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. Okay. And so "Reviews have suggested that most lobulars should be ER/PR" where does that come from out of what Dr. Hudis had told you up to this point in time?

DR. LAING:

A. I can only say that, you know, looking at what I've written there and knowing what I knew at the time, it was based on what he had told me.

CHAYTOR, Q.C.:

Q. Doctor, you, in your own training, have told us that you were aware that most lobulars should be ER/PR positive?

DR. LAING:

A. That's correct.

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CHAYTOR, Q.C.:

Q. So this wasn't recent knowledge, that was something that you knew, that most lobulars should be ER/PR positive?

DR. LAING:

A. Right. It was his statement that he had never seen an invasive that was negative. So never seen invasive lobular that was negative would translate to me to be that they were 100 percent positive. And as I said, that was the first time I had had any indication was when he sent me that e-mail that all lobulars, ie, 100 percent, were potentially positive. So, you know, this was in the early days so I had said, you know, this is a lobular, I had this information and that was the rationale I had placed in the chart at that time for asking for the review.

CHAYTOR, Q.C.:

Q. Yes. And Dr. Hudis had indicated that he had never seen -

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. - is exactly what he said?

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DR. LAING:
A. That was his exact words.
CHAYTOR, Q.C.:
Q. He had never seen it?
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. The idea that you're going to have her pathology reviewed and you're going to see her back in six months.
DR. LAING:
A. So she would have been on a six-month follow-up.
CHAYTOR, Q.C.:
Q. Okay. And I take it if you're going to have her pathology reviewed and there were any change, you'd see her back sooner than six months?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And, Doctor, did you, in fact, do that, did you have then her pathology reviewed and, if so, what happened?
DR. LAING:

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A. I had it reviewed, yes, and the results changed and I brought her back.
CHAYTOR, Q.C.:
Q. And, Doctor, it indicates from our review that, I believe, May 20th, 2005, Dr. Cook did an addendum to her pathology report indicating that she was both ER/PR strongly positive?
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. Did you--after having her in on May 4th, I'm sorry, May 6th, after having her in on May 6th, after having her in on May 6th I take it you made contact with Dr. Cook?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. And what exactly did you explain to Dr. Cook as to why you wanted this patient redone?
DR. LAING:
A. I'd have to look at her chart to know if I sent a consult or if I spoke to him directly. I can't recall at this point which one it was.
CHAYTOR, Q.C.:
Q. Okay.

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DR. LAING:
A. Most often -
CHAYTOR, Q.C.:
Q. So you don't know if you spoke to him or just sent along a requisition?
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay. And having her retested and then having a change in her result, you then had her back?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. On June 10th. And think, as I said, it was May 20th that the addendum was placed on her chart. You indicate here that "She returns to clinic today for review. I saw a month ago. At that time on reviewing her chart I noted that she had a lobular cancer which was said to be ER/PR negative. I had this reviewed and in fact it did come back as being ER/PR positive with staining that was strongly positive. I called her and told her this news and asked her to come in and speak to me today."

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DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. So I take it patient number two, you contacted her on the phone and told her this?
DR. LAING:
A. Yes, I told her that I had change in her result and would she come in and we would sit down and talk about it.
CHAYTOR, Q.C.:
Q. Okay. And "We now know that her tumour was ER/PR positive."
DR. LAING:
A. That's right.
CHAYTOR, Q.C.:
Q. "Had we known that at her initial diagnosis I would have placed her either on Tamoxifen or Arimidex at that time. However, because we believed her to be ER/PR negative, that was not done. These has been some literature which does support late starting of Tamoxifen. I have talked to some of my colleagues across the country about this situation and they felt it was reasonable at this time now that she is just over two years from when we would have

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started her Tamoxifen to offer her this."
DR. LAING:
A. Right.
CHAYTOR, Q.C.:
Q. So I take it that refers to your discussion you mentioned earlier today with Dr. Kathy Pritchard?
DR. LAING:
A. With Doctor--that's right, yeah.
CHAYTOR, Q.C.:
Q. Okay. And did you speak with anyone else other than Dr. Kathy Pritchard about that situation?
DR. LAING:
A. No. Actually, when I did have that conversation with Dr. Pritchard, I was at a meeting with, you know, probably half a dozen medical oncologists that deal with breast cancer from across the country and I brought up the issue and Dr. Pritchard said, oh, yes, you know, there's a paper and it was--she then asked to have it sent to me, she asked her assistant to e-mail it to me, which is--or e-mail me the reference, so that's how I first got that particular paper.

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CHAYTOR, Q.C.:
Q. And, Doctor, do you know whether or not this patient was also--this is early on days now, this is May 20th that her retest was done and noted on her chart. Do you know whether or not she was also sent or her sample was sent Mount Sinai for further retesting?
DR. LAING:
A. I am not certain.
CHAYTOR, Q.C.:
Q. And I can indicate that her review of her chart would indicate that there was a repeat at Mount Sinai and she was found to be 80 to 20 percent positive, 80 percent ER -
DR. LAING:
A. 80 for ER -
CHAYTOR, Q.C.:
Q. - and 20 percent PR.
DR. LAING:
A. Okay, fair enough, yeah.
CHAYTOR, Q.C.:
Q. And she in fact was reviewed by your panel.
DR. LAING:
A. Yes. And I believe the panel letter says that she had already been contacted and already

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started on Tamoxifen.
CHAYTOR, Q.C.:
Q. Yes.
DR. LAING:
A. That's right.
CHAYTOR, Q.C.:
Q. And she's reviewed in December, December 18th, 2005, there's a panel letter -
DR. LAING:
A. Okay, so then she would have had -
CHAYTOR, Q.C.:
Q. - for her.
DR. LAING:
A. Yeah.
CHAYTOR, Q.C.:
Q. And it indicates she is already on Tamoxifen so no need of any--no impact, I believe, is what it says. The letter says "There's no impact on the patient's treatment and no treatment follow-up required."
DR. LAING:
A. Because I had already disclosed it and started her on the appropriate therapy.
CHAYTOR, Q.C.:
Q. Okay. So in terms of indicating at the end of

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the day the number of people who would have required a change in treatment, people such as patient number two who had been started because of your review back in the early days, May and June of 2005, who had a treatment change at that point, were they counted in the numbers who at the end of the day were disclosed as having a change in treatment?
DR. LAING:
A. I would have to say yes. That would be if you were to ask me which category I would place this lady in, it certainly would be the ones in which the new information had an impact and resulted in a treatment change, she would belong in that category.
CHAYTOR, Q.C.:
Q. Okay. She would belong to that category?
DR. LAING:
A. Yes.
CHAYTOR, Q.C.:
Q. Regardless if her panel letter said that she required a change in treatment or not?
DR. LAING:
A. The number that came from those treatment changes would have been based on the panel

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letters. That would have been a tabulation that was not done by me, but I would think, and the only way I could know would be if I had a list of the patients that were included in that 104, but she would belong in that 104 and which subsequently became 117. But she certainly would have been someone who it just so happened that because of where she was, that she was one that was very early on in the process. She was started on Tamoxifen. You know what, I couldn't even tell you to be sure. She was started on one or the other and remains on that medication to date.

CHAYTOR, Q.C.:

Q. So based on your understanding of -

DR. LAING:

A. Based on my understanding.

CHAYTOR, Q.C.:

Q. You would expect her to be included in the 117 because she was certainly a patient that required a change in treatment as a result of this review?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

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Q. Okay.

THE COMMISSIONER:

Q. My understanding is as follows, in your view number two belongs in any list of persons who required treatment change, you don't know whether, in fact, she is in the list?

DR. LAING:

A. No, but I would assume that she is, but I'd have to see that list.

THE COMMISSIONER:

Q. I understood you didn't compile the list?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And you'd be surprised if her name wasn't on the list?

DR. LAING:

A. I would.

CHAYTOR, Q.C.:

Q. And you would suggest that she be added?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And did you have any input into comprising who was placed on the list of 117 patients?

DR. LAING:

A. The input that I had would be that we felt that the patients who had a treatment change should be the ons who were on that list. That was our definition, if you will. And the reason for that was that as we alluded to this morning, there were several patients who were already treated way back from the time of their initial diagnosis with adjuvant hormonal therapy because of their progesterone receptor status.

CHAYTOR, Q.C.:

Q. Okay. And, Doctor, were you, at this point in time in May and into June of 2005, were other oncologists doing the same thing that you're obviously doing here, people are appearing before you and you're questioning whether or not you should have a look at the ER/PR status, were your colleagues doing the same?

DR. LAING:

A. Yes, so that the other colleague of mine that I know did this was Dr. McCarthy. And when we were asked recently if we could recall which patients may have been in those very, very

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early patients, this is the five patients that we're reviewing now that we could remember back then. And some of them were her patients and some of them were my patients. Some of them were patients that through our maternity leaves that we had both been involved at some point in their care. And three of those patients had lobular histology, which is what tweaked us, if you will, for asking for the repeat. One of those patients, a patient of Dr. McCarthy's had metastatic breast cancer. She had extensive disease, particularly involving her chest wall, which had stopped responding to chemotherapy and the reason to retest her was to see if there might be a therapy, because she had run out of chemotherapy options, to might see if there was a therapy that she could be offered for her metastatic disease. But, in fact, her initial pathology was ductal.

THE COMMISSIONER:

Q. I'm sorry, her initial pathology was?

DR. LAING:

A. Was ductal. Yeah, she wasn't a lobular patient. But, you know, Dr. McCarthy had

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someone sitting in the clinic who had run out of chemotherapy options and thought, well, maybe I'll ask for it to be reviewed to see if there's any change in her status that would at least allow her to offer this lady hormonal therapy for her metastatic disease.

CHAYTOR, Q.C.:

Q. Okay. And I believe that might be patient number three?

DR. LAING:

A. I think it's patient one, but.

CHAYTOR, Q.C.:

Q. Patient one, okay. Well, let's look at patient number one, if we could?

DR. LAING:

A. Oh, wait now.

CHAYTOR, Q.C.:

Q. That's fine.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. Patient number one I think is a lobular.

DR. LAING:

A. It's hard for me to know -

CHAYTOR, Q.C.:

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Q. Yes, she's a lobular, yes, she's a lobular. If we could look, please, at -

DR. LAING:

A. So is patient one a lobular then?

CHAYTOR, Q.C.:

Q. Patient one is a lobular.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. According to my notes.

DR. LAING:

A. Then this lady would be patient number three. And we put these patients in order by looking at what we could determine to be their retest date.

THE COMMISSIONER:

Q. So when you say this lady would be number three, are you talking about the one we have been talking about as number two or the next one?

DR. LAING:

A. No, we're talking about another one. Number is definitely number two.

THE COMMISSIONER:

Q. All right. I'm fine if number two is number

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two. You can work out -

CHAYTOR, Q.C.:

Q. Number two is number two, all right.

DR. LAING:

A. I know that much.

CHAYTOR, Q.C.:

Q. We'll look at number one, yeah, because patient number two is your patient.

DR. LAING:

A. Yeah, patient number two is my patient, that's what I know.

CHAYTOR, Q.C.:

Q. Patient number one is Dr. McCarthy's. C-0243.

DR. LAING:

A. Okay. Let me see if I can figure it out from this.

CHAYTOR, Q.C.:

Q. Okay. And this is a poorly differentiated infiltrating carcinoma, lobular carcinoma.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. And we are calling this one patient number?

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CHAYTOR, Q.C.:

Q. This is patient number one.

DR. LAING:

A. This is patient number one.

THE COMMISSIONER:

Q. Thank you.

CHAYTOR, Q.C.:

Q. And she's seen in clinic by Dr. McCarthy. And we'll get a chance, Commissioner, I'm sure, to hear from Dr. McCarthy on this. But she's seen May 4th, 2005. And I've redacted-- there's no reference that I could see to anything about the review on that date. But then on May 11th.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. Now if we bear in mind that it was May 6th that you saw patient number two. So on May 11th, 2005 this patient is back in, patient No. 1 is back in to see Dr. McCarthy on that date. And she writes on that date, "I do note that her previous cancer was lobular and even though it said that she was ER/PR negative, I think we should repeat this because in 2002

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there were some problems with the assay. We have had a previous case of lobular carcinoma that was read as being negative which was actually positive on review, thus, I will consult pathology urgently today. I will see her again once her CAT scan is done and we will stop chemotherapy for now." And, Doctor, the reference Dr. McCarthy makes here because, ask for a repeat because in 2002 there were some problems with the assay, do you know what she's referring to there, was that discussed between yourself and her?

DR. LAING:

A. I'm not certain, but I suspect that the 2002 may be there because that was the year of Peggy Deane's diagnosis, so I think that that's the reason for 2002.

CHAYTOR, Q.C.:

Q. Okay. And according to this patient's chart on May 13th Dr. Cook did do the retest.

DR. LAING:

A. And I think that's the reason why she got to be patient number one.

CHAYTOR, Q.C.:

Q. Yes. She was actually -

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DR. LAING:

A. We went by the testing date.

CHAYTOR, Q.C.:

Q. Yes, testing date, that's right. So your patient was actually tested on May 20th, whereas this patient was tested May 13th, a week prior, and of course, she did convert, okay.

DR. LAING:

A. Yes, and she was lobular, that's correct.

CHAYTOR, Q.C.:

Q. And she was lobular, that's right. Now patient three, so she would be C-0245, please, and Doctor, we're running a bit short on time, so I won't take you through all five, but I'll take you through number three.

DR. LAING:

A. Right, so this is the real number three.

CHAYTOR, Q.C.:

Q. This is the real number three, and she is a moderately differentiated ductal carcinoma.

DR. LAING:

A. Right, so this is the one that I was talking about.

CHAYTOR, Q.C.:

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Q. So this is the patient you were referring to?

DR. LAING:

A. That's correct.

CHAYTOR, Q.C.:

Q. Yes, okay, and "was originally felt to be ER/PR negative, but recently retested in the past couple of weeks and she is actually strongly positive for both ER and PR," and this again is June 22nd, 2005.

DR. LAING:

A. That's right.

CHAYTOR, Q.C.:

Q. And Dr. McCarthy also writes, under her plan, "I have previously presented her case in tumour board because I do not know how to use the ER/PR positivity information at this time. The group agreed that I would give her Femera with the Herceptin as long as she is responding." And Doctor, do you recall Dr. McCarthy bringing the case of patient number three and the change in her result to the tumour board rounds at that time?

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

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Q. Okay, and so you--and do you recall that there would have been other oncologists and pathologists present at that tumour board round?

DR. LAING:

A. There usually is a group of pathologists and oncologists.

CHAYTOR, Q.C.:

Q. Okay, so and this would have taken place obviously sometime before June 22nd, 2005, because she's stating "I had previously done this." So I take it by the middle of June or certainly by June 22nd, 2005, it was very well known that these issues had arisen and there were changes in results?

DR. LAING:

A. So there would have been some discussion. I'm not certain that I was actually at this specific tumour board round, but this is a lady that I mentioned that I was involved with her care when Dr. McCarthy was on maternity leave, so I know who this lady is and I know her case, and she really had quite extensive chest wall disease that really had stopped responding to treatment and we were really

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looking for something else to be able to give her, which was--because, if you'll note, this is the first retest now that we've done on a ductal cancer.

CHAYTOR, Q.C.:

Q. Yes, and that was, I understood your evidence to be that's because she was basically--you were looking--Dr. McCarthy was looking for anything to potentially help this woman?

DR. LAING:

A. That's right, yeah. That was the reason to retest her. At this particular--I know that I was away on June 22nd, but if this was presented perhaps the week or two weeks before at tumour board round, I may have been present for that discussion, but I do know that Dr. McCarthy and I did discuss this particular lady's care and we did start her on Femara, which I'll remind you is letrazole, which is one of the aromatase inhibitors, and we picked that one because of its higher response rate than Tamoxifen in the metastatic setting.

CHAYTOR, Q.C.:

Q. Doctor, take us forward then from there. How did you then continue to identify other

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patients that should be retested? You now have a ductal carcinoma that has also converted.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. So what happens after that?

DR. LAING:

A. So by this time, you know, we've had the preliminary discussions with Dr. Cook.

CHAYTOR, Q.C.:

Q. And what do you mean by that? Other than requesting retests from him, have you had any other discussion with him?

DR. LAING:

A. Well, there was the phone call between him and Dr. McCarthy, which was earlier than June, and in fact, the -

CHAYTOR, Q.C.:

Q. According to Dr. Cook's note, it was May 11th, according to his letter anyhow.

DR. LAING:

A. Okay, sure.

CHAYTOR, Q.C.:

Q. And I'll take you to that.

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DR. LAING:

A. Yeah, and -

CHAYTOR, Q.C.:

Q. And did you sit in on that telephone conversation?

DR. LAING:

A. I'm not sure if it was the initial one, but there was another time when she did call Dr. Cook and I was in the office with Dr. McCarthy, and she was talking to Dr. Cook at St. Clare's, but I think it might have been a subsequent to that initial phone conversation, because by this time, we both now, in the middle of May, have had patients with new results. But my first patient, patient number two, I wouldn't have been aware of her results until after the 20th of May. So it would have been subsequent to that.

CHAYTOR, Q.C.:

Q. I'm sorry, yes, so he--you would be--as patients are coming before you, you're identifying them or checking the chart at that point?

DR. LAING:

A. Right, so yes.

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CHAYTOR, Q.C.:

Q. Yes, and so is, Dr. McCarthy is doing that?

DR. LAING:

A. Yeah, yeah.

CHAYTOR, Q.C.:

Q. And Doctor, what was it in May, May 6th is the first reference we have with patient number two, that you do that? What is it on May 6th that causes you to start to do that and start to question and look for retests on ER/PR status?

DR. LAING:

A. Oh, it was the index case. It was Peggy's case. It was the discussions with Dr. Hudis, and so really our first clue, if you will, or what was that, I mean, that's what started this whole process. The second one was, of course, we now have two more cases, albeit lobular, that change, and now our first ductal case. I have another lobular who's another one of these patients, and these are the people that we can remember from those early days as being the ones that we either retested by virtue of them having lobular disease that was negative or because they were patients

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really, you know, with metastatic disease who really had no other treatment options.

CHAYTOR, Q.C.:

Q. Doctor, Mrs. Deane's case was retested back in mid April and the first, next retest happens, it appears, May 13th.

DR. LAING:

A. Right.

CHAYTOR, Q.C.:

Q. So what was it--it's not like you went back to your office within, you know, two or three days and sat down and started -

DR. LAING:

A. Oh, you mean why was there that delay between -

CHAYTOR, Q.C.:

Q. Yes, there's a period of two or three, maybe even four weeks.

DR. LAING:

A. I would suspect that it was because during that time period, I didn't come across any patients through my work that raised it. I mean, the next patient that really raised it for me was that lobular chart that I picked up that said, you know, that this was negative,

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and that was the reason -

CHAYTOR, Q.C.:

Q. So it was the next lobular in through the door?

DR. LAING:

A. Yeah. Now certainly, between now and then, in that time, I'm sure there were other charts that I looked at that were lobulars that were positive that were--you know, we still had lots of patients who were -

CHAYTOR, Q.C.:

Q. So were you doing that? Were you pulling your charts in the meantime?

DR. LAING:

A. No, no, I wasn't pulling my charts. These were people that we were seeing as part of our day-to-day clinical practice, and you know, in the run of a day, in a busy clinic, I'll see 15-18 patients, and that would have been three or four days a week. So there would have been a large volume of people that we would have been seeing during that time period. This was in 2005, and every year, in the end of April, I'm gone to usually a week long of national meetings. So I'm certain that at the last

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week in April of 2005, I would have been at these meetings. So really between when we had the index case and when we started sort of--it was pretty much right away that we were looking at things as we were seeing them coming through the door in the clinic.

CHAYTOR, Q.C.:

Q. Now, Dr. McCarthy would have had the patient number one.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Who was also a lobular, infiltrating lobular.

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. She saw her on May 4th, and there was no indication at that time of any review happening or looking at her chart and questioning her pathology on May 4th. On May 6th, that happens for you with patient number two. But Dr. McCarthy saw patient number one on May 4th and it's May 11th, the next time that patient is in, that Dr. McCarthy also

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initiates a retest for her.

DR. LAING:

A. Okay.

CHAYTOR, Q.C.:

Q. So I'm just wondering is there something that happened to trigger this in those--between May 4th, May 6th?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. And it was May 6th when your patient walked in that you -

DR. LAING:

A. Sure.

CHAYTOR, Q.C.:

Q. - you picked up on this and thought "isn't this unusual? I now have another lobular who's negative."

DR. LAING:

A. Right, so that was my thinking.

CHAYTOR, Q.C.:

Q. And then did you relay that to Dr. McCarthy, and is that what caused her to go back and look at patient number one?

DR. LAING:

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A. I'm not sure, not that I can recall. I mean, I think that these discussions had been happening right from the index case, right from Peggy Deane's case, so you know, I don't think that there was any sort of a sentinel event on May 6th that, you know, made Dr. McCarthy do what she did on May 11th. It probably had to do with when the patient was coming to the clinic.

CHAYTOR, Q.C.:

Q. No, she was there on May 4th, that's why I was wondering.

DR. LAING:

A. Yeah, it--you know, the only way you could really know is to sort of read through what exactly was in the clinic note to say if--you know, there are often patients, particularly patients with metastatic disease, that are seen in the clinic on a weekly basis. That would not be an uncommon thing for people on active treatment.

CHAYTOR, Q.C.:

Q. It seemed to be a regular clinic visit, and we did read through the clinic note, but I'll ask Dr. -

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DR. LAING:

A. No, the regular clinic visit that you had for that first patient was all blacked out, so -

CHAYTOR, Q.C.:

Q. Yes, yes.

DR. LAING:

A. - I don't know. Oh, you read through it.

CHAYTOR, Q.C.:

Q. Yes, I've read it.

DR. LAING:

A. Sorry, you read through it at the time, okay.

CHAYTOR, Q.C.:

Q. We've read it.

DR. LAING:

A. Okay, fair enough.

CHAYTOR, Q.C.:

Q. But well, obviously, you and Dr. McCarthy, if you wish. That's why I'd given the names of the patients. I thought perhaps it would have been reviewed beforehand, but that's all right.

DR. LAING:

A. No, we actually came up with these, when we had the request last week.

CHAYTOR, Q.C.:

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Q. Yes, and I indicated that I'd be asking questions about them, so I--but that's okay.

DR. LAING:

A. We did look at them, but you know, I can't remember any reason why--what we did is remembered their names. We pulled them up on our patient computer system, on our OPUS system, and I asked them to print out--asked the secretaries in Health Records, to print out the first clinic note that had any mention of ER/PR retesting and the note that corresponded to the disclosure to the patients, and then we got the pathology reports and printed those off. So, but you know, as to what had happened before or after, or you know, why Dr. McCarthy didn't indicate it on the May 4th as opposed to just one week later.

CHAYTOR, Q.C.:

Q. You haven't reviewed that, that's fine. I'll ask Dr. McCarthy.

THE COMMISSIONER:

Q. Doctor, while we're looking at it, so I can understand the proper context of this.

DR. LAING:

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A. Yeah.

THE COMMISSIONER:

Q. Peggy Deane's case occurs, it's a big surprise and you and your colleagues talk about it.

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. Is it a case of because Peggy Deane is in your mind, the next person who walks through the door who is a lobular and who has a negative ER, you remember, or did you start out with the idea "I am going to check every lobular that now walks through my door to see if they're negative or positive"? How did it occur in that sense?

DR. LAING:

A. So what I would tell you -

THE COMMISSIONER:

Q. I'm trying to figure out what Peggy Deane's case meant to you.

DR. LAING:

A. So what Peggy Deane's case meant to me, back in those days, was that this was a change in a lobular histology. That it was because it was lobular that it was different. So it

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certainly meant that I was going to be looking at the results for my patients, in terms of their ER/PR testing, if they had been lobular, yes, and so the first person that I came in contact with in my day-to-day clinical practice was patient number two.

THE COMMISSIONER:

Q. Okay.

DR. LAING:

A. And so, you know, as I said that's written at the top of the chart, so I was making a conscious effort to look at and to see if there were people there who were lobular who had said to be ER/PR negative.

THE COMMISSIONER:

Q. And do you have any knowledge of whether or not other oncologists who were all of--all of the oncologists in the province would be operating out of the same institution that you were operating out of. Would you have any knowledge as to whether or not all of the oncologists in your shop, as it were, would set out to look at their charts in the same way?

DR. LAING:

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A. Certainly after--maybe not right then, but certainly within the next few weeks, after we started to have more and more people, then yes, other people were looking at lobulars. Because as I said, this was now a discussion that was had within the larger group of oncologists, outside for just Dr. McCarthy and I.

CHAYTOR, Q.C.:

Q. And was there a direction given to the oncologist that they, in fact, do that?

DR. LAING:

A. Was there a specific direction given?

CHAYTOR, Q.C.:

Q. Yes.

DR. LAING:

A. No, not at that time, other than to say that if there were patients that were being seen in the course of our clinical practice that they wanted to have the ER/PR testing repeated, that we would send a consult to pathology and that they would do those--that retesting for us. At this point, that retesting was being done on the Ventana System. So there were requests for retesting to be done and that

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was, you know, those--that was carried out, and that --

THE COMMISSIONER:

Q. I'm taking what you're saying to say that at some point you communicated to other oncologists that if they wanted repeat tests done, I presume in the context of lobulars that were negative --

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. To make the order and that would be done by pathology. At what point would that have been done?

DR. LAING:

A. I'm thinking that it was sometime towards June, but I can't tell you exactly when that was. I'm trying to think of when the first retesting summary results came back, and I believe that was sometime towards the end of June, 2005, that Dr. Cook would have written a summary note to Dr. McCarthy with the retesting that had been done so far. So it was in the days sort of leading up to and after that. In fact, that was a process that was

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allowed to continue all through the review, that if any time one of the oncologists, one of the treating oncologists had a patient who had not been retested as part of the review, and they felt that there was something about that case that they wanted to have it done, then we would send a specific consult to pathology and ask for that to be done at that time.

THE COMMISSIONER:

Q. I'm sure we'll get into this tomorrow, but to make sure that I have timing straight. Peggy Deane's case occurs. You and at least your colleague, Dr. McCarthy, are then--have a heightened awareness.

DR. LAING:

A. That's right.

THE COMMISSIONER:

Q. Of the question of lobular and negative ER results.

DR. LAING:

A. Yes.

THE COMMISSIONER:

Q. You, at least then as patients come through the door, check your charts whether it's a

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lobular, to see what the result was.
DR. LAING:
A. Uh-hm.
THE COMMISSIONER:
Q. And the first of these patients comes up here in our little group.
DR. LAING:
A. That's right.
THE COMMISSIONER:
Q. Dr. McCarthy has some similar kind of experience.
DR. LAING:
A. Yes.
THE COMMISSIONER:
Q. What I'm interested in now is when this hits a wider number of oncologists. When I asked you about when the other oncologists knew that they could similarly order retests, you seem to go back to after what I would describe as the first group of retests were done, and that grouping was one of three in their relatively early stages.
DR. LAING:
A. Right.
THE COMMISSIONER:

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Q. But still much--still beyond this sort of first part of May.
CHAYTOR, Q.C.:
Q. It's June 29th that the first list is done and sent back to Dr. McCarthy.
DR. LAING:
A. Right. So on that list of patients, there would have been some that were my patients and some that were Dr. McCarthy's patients. I'd have to see that list to know if there might have been some--I don't think that list indicates who the attending oncologist was or who had requested the repeat.
THE COMMISSIONER:
Q. But are you suggesting that that list contains only patients who had been identified by you and Dr. McCarthy?
DR. LAING:
A. No, there may have been patients who had been identified by other oncologists at that time.
THE COMMISSIONER:
Q. And are you suggesting that those--the people on that list were people that were identified as they came through the door as opposed to as a result of a meeting between you and

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pathology, you and perhaps Dr. McCarthy and pathology?
DR. LAING:
A. The very first list, and I'm not sure if we have it there, has a--because I know when I looked at it prior to coming here last week, it contains the surgical numbers. So I can tell by looking at that that they are all different years. So they were various patients from various different time periods, and certainly the early discussions, Dr. McCarthy's initial phone call with Dr. Cook were kind of in the middle of May, and then subsequent to that, there are some further discussions with Dr. Cook, and there are these --this kind of retesting that's happening as the patients are being identified by the oncologists.
THE COMMISSIONER:
Q. Okay.
DR. LAING:
A. And then there is a decision, and I believe by that time we're into the middle of July, to do a wider retest of not just patients who we've sort of identified in the process in the

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clinic, but actually to include patients from 2002, and so the subsequent list has quite a number of patients, if not all of the patients, have a surgical number of 2002.
THE COMMISSIONER:
Q. Okay, back to my original point which is sort of when the oncologists beyond you and Dr. McCarthy got involved in this process, and I'm still not sure when that is. Can you be a little more precise with me about when that might be?
DR. LAING:
A. It's hard for me to tell you that it was an exact date. I can tell you --
THE COMMISSIONER:
Q. Let's try a month.
DR. LAING:
A. Then I would say it was--I would say, if I was to pick a month to be the most accurate, I would say it was in June.
THE COMMISSIONER:
Q. Thank you.
DR. LAING:
A. You're welcome.
CHAYTOR, Q.C.:

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Q. Doctor, was there any way in your system of-- in the system that you used for you to have been able to identify all your lobular patients?

DR. LAING:

A. No, none whatsoever.

CHAYTOR, Q.C.:

Q. And is there currently any way in which those records are kept which would enable you to do that?

DR. LAING:

A. No.

CHAYTOR, Q.C.:

Q. I just want to understand in terms of the oncologists, the other oncologists, there was no specific direction given to them to start to try and identify patients, but by some time in June they're aware that this is happening and they start to identify patients as well, is that right?

DR. LAING:

A. I mean, I can tell you that in terms of the index case, this was something that we talked about as a group. Everybody knew what had happened. As we started to find these early

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retests from May, I know that people were aware of that, and certainly both Dr. McCarthy and I were telling our colleagues that, you know, we're retesting these people who are coming through the door, and that that's something that is possible and something that we can do. Whether that was something that happened towards the end of May or whether it wasn't until early June, it's difficult for me to recall, to put an exact date on it. I can only tell you what Dr. McCarthy and I were doing simply because I have pulled these files and we can see that activity from there, and also because, you know, right from the index case, this was something that Dr. McCarthy and I had talked about on a regular basis.

CHAYTOR, Q.C.:

Q. And, Doctor, on Peggy Deane's case, when you spoke to Dr. Ford Elms --

DR. LAING:

A. Yes.

CHAYTOR, Q.C.:

Q. Did he ever offer you any explanation as to how her test could convert?

DR. LAING:

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A. No, we didn't talk about that at the time.

CHAYTOR, Q.C.:

Q. Did you ask him how could this be, how could this happen?

DR. LAING:

A. No, I think at that time, you know, my main-- we were so anxious to have those results back to offer this lady a therapy, that, you know, this was something that, you know, looking back to those early days, was something that we felt was related to her being lobular, and then we weren't sort of thinking about this as turning into something that was going to impact so many more patients. So, you know, I don't recall at the time having said to Dr. Elms, why do you think this was, you know, this was just--certainly as time went on, there were discussions had regarding these issues, as you're aware, but not at that time. I think at that time, you know, I can honestly tell you I didn't, and I don't think anybody else thought that this was something that was going to play out the way that it did. You know, thinking about--as I try and answer these questions, I'm trying to place myself in

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my clinic in May and June of 2005. You know, we had the index case. To her--to us at that time, she wasn't an index case, she was one of the patients under our care. It wasn't until, you know, time went on and things evolved over the summer. So, you know, when I look back at that time, it's sometimes difficult to remember exactly what happened at exactly what time, but I think that your comments regarding the fact that we certainly had a heightened awareness, that, yes, you know, we were looking at the lobular people and reading it, and certainly there were a number of people that I would have read lobular that were positive, you know, and when I've gone back and thought about this, I can come up with three patients with lobular cancer that I can remember. There may be more within the panel review, but I can't remember their names, and these were the ones that we've talked--well, except for number five, the ones that we have addressed thus far.

CHAYTOR, Q.C.:

Q. And after speaking to Dr. Elms, did you-- about Peggy Deane's case, did you think to

contact Dr. Cook and speak to him about this?

DR. LAING:

A. After --

CHAYTOR, Q.C.:

Q. About Peggy Deane's case. After speaking to Dr. Elms, realizing her case has changed, did you have any discussion with Dr. Cook about Peggy Deane's case?

DR. LAING:

A. No, no.

THE COMMISSIONER:

Q. Ms. Chaytor, we'll break wherever you're ready.

CHAYTOR, Q.C.:

Q. That's fine then, perhaps that'll be a good place, Commissioner.

THE COMMISSIONER:

Q. All right then, 9:30 in the morning. Thank you.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 9th day of September, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 9th day of September, A.D., 2008

Judy Moss

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