

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">September 9, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C. Commission Co-counsel</p> <p>Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury Doctors Kara Laing et al</p> <p>Daniel Simmons Eastern Regional Integrated Health Authority</p> <p>Laura Brocklehurst. Members of the Breast Cancer Testing Class Action</p> <p>Mark Pike NL Medical Association Jennifer Newbury Canadian Cancer Society (NL Division) Blair Pritchett/ David Eaton, Q.C. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>Exhibit entered and marked C-0243 Pg. 106 Exhibit entered and marked C-0244 Pg. 106 Exhibit entered and marked C-0245 Pg. 106</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. KARA LAING (CONT'D) Examination by Sandra Chaytor, Q.C. Pgs. 4 - 365</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 DR. KARA LAING, EXAMINATION BY SANDRA CHAYTOR, Q.C. 2 (CONT'D) 3 THE COMMISSIONER: 4 Q. Ms. Chaytor. 5 CHAYTOR, Q.C.: 6 Q. Good morning, Commissioner. Good morning, Dr. 7 Laing. 8 DR. LAING: 9 A. Good morning. 10 CHAYTOR, Q.C.: 11 Q. If we could have, please, P-2610? Doctor, 12 this is a PowerPoint presentation and I 13 understand you're going to take us through 14 this. I understand you gave a version of this 15 presentation dealing with--or throughout the 16 ER/PR issue. Do you recall when that would 17 have been? When would you have given this 18 presentation? 19 DR. LAING: 20 A. This was a presentation that I initially gave 21 in November of 2006 and that was to the 22 medical staff. So it was the pathologists, 23 laboratory personnel, oncologists and surgeons 24 from across the province. We did it as a 25 teleconference and that was in November of</p>

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<p>1 2006, in preparation for the media briefing, 2 which was to occur that December. 3 CHAYTOR, Q.C.: 4 Q. Okay, thank you, and then perhaps you could 5 just continue on then and take us through the 6 presentation. 7 DR. LAING: 8 A. Shall I advance the slides then myself? 9 CHAYTOR, Q.C.: 10 Q. Sure, you can do that. 11 DR. LAING: 12 A. Okay. Well, first of all, I'd like to thank 13 you for letting me do this presentation at 14 this time. I thought that it may be valuable 15 to go through the same information that I 16 would--that I presented then and that I would 17 present to patients in the clinic, really to 18 try and help people understand the rationale 19 for hormone therapy for breast cancer, and I 20 thought it was important that we just 21 highlight the epidemiology of this disease and 22 to talk about the difference between adjuvant 23 therapy and treatment for metastatic breast 24 cancer, and talk about the various ways we now 25 have in the clinic to target the hormone</p>	<p>1 update it every year, and you know, back in 2 2000, the number would have just been breaking 3 300 at that time. So as you can see, there's 4 certainly been a steady increase. 5 This is the 2006 statistics, and I think 6 it's interesting because you can see that if 7 you go from west in British Columbia to east, 8 that the incidents of breast cancer is similar 9 and varies by province, but if you look at 10 mortality, then the outcomes are actually 11 better in the rest of this country and worse 12 in the east. Part of that reason may be 13 explained by an older, more established 14 screening and treatment program as we alluded 15 to yesterday in our discussions. 16 When we talk about the treatment of 17 breast cancer, there's really quite a 18 continuum of care. I include here early 19 breast cancer and advanced breast cancer, but 20 if you think about it, really you can go even 21 to the left of the screen and that's where you 22 would place prevention and screening. But the 23 core of what we do within cancer care programs 24 would be to provide treatment for early stage 25 breast cancer, which includes adjuvant</p>
<p>Page 6</p> <p>1 receptor and to explain, if you will, how 2 things have changed over the years, in terms 3 of treatment of patients with hormone receptor 4 positive breast cancer. When I gave this 5 presentation initially in November, I had 6 included some discussion of the impact that 7 this had on clinical management, and I thought 8 it was important to leave that as part of this 9 presentation and go through that at the end. 10 The incidents of breast cancer has 11 continued to increase in this country over the 12 last several years, but we're happy to report 13 that mortality has decreased and the decline 14 in mortality is due to improvement in adjuvant 15 therapies, but also to improvement in 16 screening, and we feel that about 50 percent 17 of the improvement is from each of those. 18 We've had a steady increase in the incidents 19 of breast cancer in this province and in 2007, 20 based on the Canadian Cancer statistics, we 21 saw 370 new cases. This would include 22 invasive cancers of all histologies, as well 23 as in situ cancers, and this number certainly 24 has increased. This is a slide that I often 25 use in breast cancer presentations and I</p>	<p>Page 8</p> <p>1 treatment, that we'll talk about in a minute. 2 Neo-adjuvant simply refers to treatments that 3 are given prior to definitive surgery and 4 extended adjuvant is a term that we use to 5 talk about treatment beyond five years from 6 initial diagnosis. In advanced or metastatic 7 breast cancer, we talk about lines of therapy, 8 and the first therapy that a patient would 9 receive would be first line, second line, 10 third line and so on. 11 This is a summary of hazard rates which 12 look at the probability of recurrence at each 13 year after initial diagnosis. This is a 14 summary of several different graphs for 15 various patient population, so premenopausal, 16 post-menopausal, those that had chemo, who 17 didn't, had hormonal therapy, didn't, and what 18 we can see is that there is an early peak in 19 recurrence of breast cancer in the first three 20 years, the first two to three years, but that 21 unlike other malignancies, at the five-year 22 mark, the risk of recurrence of breast cancer 23 does not go away. It's less, but it does not 24 go to zero, and in fact, we often see patients 25 who recur in the five to ten-period, and even,</p>

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1 I have patients in my practice who have
 2 recurred 20 and 30 years later.
 3 For patients with hormone receptor
 4 positive disease, it's felt that about 60
 5 percent will recur in the first five years,
 6 but up to 40 percent may have a recurrence in
 7 the five to ten-year period, and this is the
 8 reason for the trials looking at treatment
 9 beyond five years of Tamoxifen, and this, of
 10 course, was a factor that played into our
 11 decision about treating patients who may have
 12 been more than five years from their initial
 13 diagnosis when their new ER/PR test results
 14 were available.
 15 When we look at various factors about
 16 breast cancer, we divide them into prognostic
 17 factors and predictive factors. The most
 18 important prognostic factors in breast cancer
 19 are, number one, whether or not there's lymph
 20 node involvement. The second is the size of
 21 the tumour, the grade, with poorly
 22 differentiated tumours having a worse
 23 prognosis. And the histology, with some less
 24 common histology such as tubular, medullary
 25 cancers having a better prognosis.

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1 Lymphovascular invasion, which means the
 2 presence of cancer cells in the tiny blood
 3 vessels and lymph vessels surrounding the
 4 tumour is also known to be a marker for
 5 increased risk of recurrence.
 6 Younger patients with breast cancer have
 7 a worse prognosis and ethnicity is felt to
 8 play a role as well, and in the U.S.
 9 population and U.S. studies, there's certainly
 10 evidence that African American women have a
 11 worse prognosis with this disease.
 12 Prognostic factors are something that
 13 tell you how someone is going to do with their
 14 disease, irrespective of what treatment that
 15 they receive. These are the things that are
 16 important in breast cancer. For example, in
 17 lung cancer, weight loss is a very important
 18 prognostic factor. If we see a patient who's
 19 lost more than ten percent of their weight,
 20 then we know that they have a worse prognosis,
 21 even if they have the same stage, same
 22 diagnosis as another person who hasn't lost
 23 weight. A predictive factor, however, is
 24 something that tells you how likely somebody
 25 is to respond to a certain treatment, and in

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1 breast cancer, the predictive factors that we
 2 use every day in the clinic are estrogen and
 3 progesterone receptors, the hormone receptors,
 4 and HER2 expression.
 5 CHAYTOR, Q.C.:
 6 Q. And wouldn't ER and PR status also be a
 7 prognostic factor?
 8 DR. LAING:
 9 A. It's a very weak prognostic factor. So if you
 10 look at what's called a multi-variant analysis
 11 or if you put all these things into the
 12 equation, the ones that come out most strongly
 13 are the ones that I have listed there, and so
 14 we really consider ER/PR to be a weak
 15 prognostic factor, but more so a predictive
 16 factor in this disease.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, thank you.
 19 DR. LAING:
 20 A. So adjuvant therapy are additional treatments
 21 that are given after potentially curative
 22 surgery. So we talk about this in breast
 23 cancer. The same is true in lung cancer,
 24 colorectal cancer, and we know that in a
 25 certain number of patients that we see with

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1 breast cancer, that they have a chance of this
 2 disease coming back and recurring somewhere
 3 outside the breast. The most common places
 4 are the lungs, the liver and the bone, and in
 5 order for that to happen, then there must be
 6 cells at the time of the initial diagnosis
 7 that get away from the breast cancer primary
 8 that's removed by the surgeon, that get away
 9 from the lymph nodes that are removed by the
 10 surgeon and are there, and so the goal of this
 11 adjuvant therapy is to get rid of those, to
 12 kill those cells before they have a chance to
 13 spread and grow and cause metastatic disease.
 14 Unfortunately, we don't have any special
 15 blood test or x-ray or scan when we see a
 16 patient. We can only estimate the probability
 17 of them having micrometastatic disease, based
 18 on their prognostic factors.
 19 So the goal of these treatments, and how
 20 we know that these work is that we see a
 21 decrease in recurrences and we see an
 22 improvement in overall survival, and that's
 23 often a question that the patients ask me in
 24 the clinic. "Well, how are you going to know
 25 that this is working?" Because we don't do

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1 scans for this. We don't do special blood
2 tests. And we say "we'll know over time when
3 we see what happens."
4 CHAYTOR, Q.C.:
5 Q. And do you keep track of, here in your clinic,
6 recurrence rates and survival rates, overall
7 survival rates? Is there any tracking or any
8 measurement of that, in terms of your patient
9 population?
10 DR. LAING:
11 A. The only data that we would have would be what
12 would come from our registry and what we get
13 from the statistics from the Canadian Cancer
14 Society, because we don't have a specific
15 database. It's more difficult for us to track
16 that. And recurrence is not something that's
17 as easily captured by the tumour registry,
18 because recurrence in breast cancer is most
19 often a clinical diagnosis, although we're
20 trying to capture that better.
21 CHAYTOR, Q.C.:
22 Q. And that's something you spoke about
23 yesterday, in terms of looking at a database
24 such as what was used in BC when you trained
25 there?

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1 DR. LAING:
2 A. Yeah. The fact that lymphatic and vascular
3 invasion is an important prognostic factor
4 came at looking at that information in the BC
5 breast cancer database. They were able to go
6 back and identify patients who had that
7 feature and then they could follow them. You
8 know, they had this follow up over many years
9 and were able to show that to be a negative
10 prognostic factor.
11 So in terms of the types of adjuvant
12 therapy that we offer patients, radiation
13 therapy is part of the local control of breast
14 cancer, so surgery and radiation. And then in
15 terms of the systemic therapies or the drug
16 therapies, they include chemotherapy, targeted
17 therapy, which now includes the--okay, do you
18 want me to -
19 CHAYTOR, Q.C.:
20 Q. I'm sorry, Doctor. Go ahead.
21 DR. LAING:
22 A. So targeted therapy, which includes Herceptin
23 or trastuzumab, which we've had for metastatic
24 disease in the clinic since 1999 and since
25 2006 for adjuvant treatment, and hormonal

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1 therapy. But really, when you think about it,
2 hormonal therapy is the oldest targeted
3 therapy that we've had in breast cancer
4 treatment, way back to the 19th century when
5 somebody's ovaries were removed and it showed
6 that they responded.
7 So currently, we use adjuvant hormonal
8 therapy for patients with hormone receptor
9 positive disease. It is currently given to
10 both pre and post menopausal patients, and
11 prior to 1998-1999, it was only therapy
12 offered to post menopausal patients.
13 CHAYTOR, Q.C.:
14 Q. And was that true across the country?
15 DR. LAING:
16 A. Yes, and it's given after adjuvant
17 chemotherapy. So if we determine that a
18 patient requires both adjuvant chemotherapy
19 and adjuvant hormonal therapy, the hormonal
20 therapy is given afterwards, and that's
21 because of some trials that suggest a better
22 outcome than if you give the two concurrently.
23 CHAYTOR, Q.C.:
24 Q. And are there any circumstances in which it
25 would be given prior to the chemotherapy?

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1 DR. LAING:
2 A. No. And again, as I mentioned earlier, these
3 treatments have shown in several studies to
4 show a significant improvement in both disease
5 free survival and overall survival.
6 This is a slide that shows that about 75
7 percent of all breast cancers are ER and/or PR
8 positive and that the likelihood of having
9 hormone receptor positive disease increases
10 with age.
11 Currently, in 2008, our breast cancer
12 guidelines used the consensus from the 10th
13 St. Gallen's Conference on the primary therapy
14 of breast cancer. So this was a summary
15 report from that meeting in March of 2007, and
16 they divide endocrine responsiveness, so
17 hormone receptor positivity, if you will, into
18 three groups. The first are those patients
19 who are ER and are PR strongly positive. The
20 second are the ones that are negative, so
21 that's with less than one percent staining.
22 So they recommend that these patients not
23 receive any endocrine therapy. And then
24 there's this group now that we call the
25 endocrine response uncertain group. So this

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1 one to ten percent. Because many of the
 2 clinical trials that were done used ten
 3 percent as a cut-off, it's not really certain
 4 as to how much benefit patients with low
 5 expression of ER derive from these adjuvant
 6 hormonal therapies.
 7 It's interesting, we're doing a--
 8 participating in a large international phase
 9 three trial that's looking at a medication
 10 called bevacizumab or avastin in breast
 11 cancer, and it's looking at patients who are
 12 estrogen progesterone receptor negative and
 13 HER2 negative, and that's now what we call
 14 triple negative breast cancer. In that trial,
 15 patients who have ER/PR between one and ten
 16 percent are eligible for the trial. So they
 17 can go on study, and interestingly, if the
 18 investigator chooses to, they may offer the
 19 patients with one to ten percent staining a
 20 hormone as part of their adjuvant therapy. So
 21 it just speaks to the fact that this is still
 22 an area of uncertainty worldwide in breast
 23 cancer.
 24 CHAYTOR, Q.C.:
 25 Q. Doctor, just a question before you leave this

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1 slide. You've indicated that the endocrine
 2 response uncertain, between over one percent
 3 and ten percent, so between one and ten
 4 percent.
 5 DR. LAING:
 6 A. That's right.
 7 CHAYTOR, Q.C.:
 8 Q. For ER, but PR negative. What about the
 9 patients who would fall in that range but
 10 would be PR positive also within that range?
 11 DR. LAING:
 12 A. So still most of the times that you see low
 13 expression of the estrogen receptor, you do
 14 not see expression of the progesterone
 15 receptor. There's a move to further classify
 16 breast cancer into groups that include luminal
 17 A and luminal B. Luminal A's are the ones
 18 that are very strongly estrogen and
 19 progesterone receptor positive. Luminal B's
 20 are the ones that have lower expression and
 21 certainly those that don't express the
 22 progesterone receptor as well, and it's felt
 23 that perhaps if you have estrogen receptor
 24 expression, but not progesterone receptor
 25 expression, that you're less likely to respond

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1 to hormones and there's a signal that this may
 2 be a group that may benefit more from the
 3 aromatase inhibitors, although most of this
 4 work has been done retrospectively. So it's
 5 not common for us any more to see patients who
 6 have low expression of estrogen and are
 7 progesterone receptor strongly positive. Most
 8 often now, when we get our results, if we have
 9 very low expression of estrogen, there is no
 10 or very low expression of progesterone and
 11 they would fall into this group as well. So
 12 between one and ten for both receptors.
 13 CHAYTOR, Q.C.:
 14 Q. And how does that compare to what you were
 15 seeing in the past, in terms of the results
 16 that were coming to you?
 17 DR. LAING:
 18 A. When we did the review and when we did the
 19 tumour panel, we noticed that there was a fair
 20 number of patients who were estrogen receptor
 21 negative, but progesterone receptor positive,
 22 and that was something that, you know, again,
 23 when we were seeing this individually, it
 24 wasn't--you know, it wasn't something that
 25 really stood out to us, but when we actually

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1 sat down and put together everybody from the
 2 tumour panel and looked at those numbers, we
 3 certainly had a higher than expected number of
 4 patients who were ER negative PR positive. On
 5 their retesting from Mount Sinai, some of
 6 those patients ended up being ER positive, PR
 7 completely negative. So it was almost as if
 8 the two had been reversed. And some ended up
 9 coming back to be positive for both.
 10 If you look at large clinical trials and
 11 they summarize the patient characteristics,
 12 for example, if you look at the trial that had
 13 upfront aromatase inhibitors versus Tamoxifen,
 14 and they show you the breakdown of patients,
 15 what you'll notice is about 70 percent, 60 to
 16 70 percent, will be ER and PR positive. About
 17 25 percent will be ER positive PR negative,
 18 and still in those large trials, there's about
 19 a three to five percent reporting of patients
 20 who are ER negative PR positive.
 21 Some pathologists would argue that you
 22 shouldn't have expression of your progesterone
 23 receptor unless your estrogen receptor is
 24 expressed in those cells. But you know,
 25 that's something that people are still looking

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<p>1 at.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. And in your own practice now, and I hear what</p> <p>4 you're saying, that you're not seeing that any</p> <p>5 more, the trend that you're able to detect</p> <p>6 when you looked at them on review.</p> <p>7 DR. LAING:</p> <p>8 A. Yes.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. What if you did? What if today you were to</p> <p>11 get a result which said ER negative and PR</p> <p>12 positive? What would you do?</p> <p>13 DR. LAING:</p> <p>14 A. We've had just one instance that I can recall</p> <p>15 where we had a patient who was ER negative and</p> <p>16 PR was five percent positive, and it was a</p> <p>17 result that came from Mount Sinai. So we</p> <p>18 asked for it to be reviewed and the same</p> <p>19 result was given.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Okay, and so I take it your practice then</p> <p>22 today would be if you were to get that, you</p> <p>23 would request a repeat of the test today?</p> <p>24 DR. LAING:</p> <p>25 A. In some situations, yes. The other thing that</p>	<p>1 after finishing their chemotherapy. So, you</p> <p>2 know, our experience to date in the clinic has</p> <p>3 been that these very low expressers are not,</p> <p>4 you know, many of them don't seem to be</p> <p>5 deriving benefit from the hormones. If you</p> <p>6 think about it and if you consider, you know,</p> <p>7 that you have--sometimes when I think about</p> <p>8 percentages, I think about a hundred of</p> <p>9 something, so if I think about patients, I</p> <p>10 think about if I had a hundred patients. When</p> <p>11 I try explaining this to patients, I say, you</p> <p>12 know, if there was 100 breast cancer cells</p> <p>13 left in your body and on or two of them seem</p> <p>14 to be dependent on estrogen for their growth,</p> <p>15 then I can give you a hormone to try and deal</p> <p>16 with those ones, but the other 98, 99 percent</p> <p>17 are not going to pay attention at all to the</p> <p>18 treatment that I've given you, which is why I</p> <p>19 think that you also need chemotherapy.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Okay. And, Doctor, before we leave it, you</p> <p>22 indicated about the results from Mount Sinai</p> <p>23 with ER negative and PR positive and so you</p> <p>24 would request retests. But the other option,</p> <p>25 you could bring it to the tumour board panel</p>
<p>Page 22</p> <p>1 we've done is the patients who fall into this</p> <p>2 grey zone, if you will, and we're not seeing</p> <p>3 very many of those, but we certainly are</p> <p>4 seeing them, we present those patients at our</p> <p>5 tumour board round to have a discussion as to</p> <p>6 whether or not we should offer them endocrine</p> <p>7 therapy, and we make that decision based on,</p> <p>8 you know, what we think their benefit would be</p> <p>9 and how likely we think that their cancer is</p> <p>10 going to recur.</p> <p>11 The last two I've had with very low</p> <p>12 expression of estrogen receptor and</p> <p>13 progesterone receptor negative have had</p> <p>14 locally advanced breast cancer. So they've</p> <p>15 presented and required upfront chemotherapy,</p> <p>16 and I did place those patients on hormonal</p> <p>17 therapy because I felt that their risk of</p> <p>18 recurrence was so high, because they had</p> <p>19 inflammatory breast cancer, which has a more</p> <p>20 than 80 percent risk of recurrence.</p> <p>21 Unfortunately, despite both of those patients</p> <p>22 being treated with Tamoxifen, they were young</p> <p>23 pre-menopausal patients, both to date have had</p> <p>24 a chest wall recurrence in a very short period</p> <p>25 of time, only in a matter of a few months</p>	<p>Page 24</p> <p>1 and have--or your tumour board rounds, sorry.</p> <p>2 DR. LAING:</p> <p>3 A. Right.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. And have it discussed in that forum. I take</p> <p>6 it that's something new that's come out of</p> <p>7 this, that's recent practice?</p> <p>8 DR. LAING:</p> <p>9 A. Yes. The reason to bring it to tumour board</p> <p>10 is to have a group discussion about whether or</p> <p>11 not we should offer that person hormonal</p> <p>12 therapy or not. If someone had a very good</p> <p>13 prognosis tumour that, you know, had a very</p> <p>14 small risk of recurrence, then we may decide</p> <p>15 that the potential toxicities from the hormone</p> <p>16 would not be worth sort of saying to the</p> <p>17 patient in front of you, I think we should</p> <p>18 give it a try. When the risk of recurrence is</p> <p>19 very high, it's easier to make a case to offer</p> <p>20 treatments with more toxicities because, of</p> <p>21 course, you're always looking at your</p> <p>22 risk/benefit ratio for that patient.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Yes. And, Doctor, when you sat down with the</p> <p>25 results in front of you from the tumour board</p>

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<p>1 and had the benefit of seeing a large number</p> <p>2 of patients, you were able then to see this</p> <p>3 trend as a lot of ER negatives and PR</p> <p>4 positives -</p> <p>5 DR. LAING:</p> <p>6 A. Yes, positives, yeah.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. I take it that would have been of assistance</p> <p>9 to you in picking up on an unusual trend or a</p> <p>10 trend that wouldn't be in keeping with the</p> <p>11 literature if that kind of tracking had been</p> <p>12 kept back through the years?</p> <p>13 DR. LAING:</p> <p>14 A. Yes, yes. And that was--through the process</p> <p>15 of the tumour panel we would often pick up a</p> <p>16 chart and say, you know, this is someone and</p> <p>17 we'd look at their--we'd start with their</p> <p>18 pathology and then when we'd open the chart,</p> <p>19 we'd say, oh, look, you know, this patient has</p> <p>20 been treated with Tamoxifen or another</p> <p>21 aromatase inhibitor or some sort of hormonal</p> <p>22 therapy and we'd look and we'd say it was</p> <p>23 because they may have been ER negative but</p> <p>24 their PR was very strongly positive.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. A database?</p> <p>3 DR. LAING:</p> <p>4 A. - new database. And the work on the</p> <p>5 preliminary discussions and that about that</p> <p>6 have started already with Eastern Health.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. Yes, okay. Thank you. Sorry to interrupt.</p> <p>9 DR. LAING:</p> <p>10 A. No, no, I think that's -</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. Is that -</p> <p>13 DR. LAING:</p> <p>14 A. That's exactly what I want -</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. - more helpful from the last question -</p> <p>17 DR. LAING:</p> <p>18 A. Yes, yes.</p> <p>19 CHAYTOR, Q.C.:</p> <p>20 Q. - as we're going, okay.</p> <p>21 DR. LAING:</p> <p>22 A. So there's various ways that you can target</p> <p>23 the estrogen receptor. One is that you can</p> <p>24 block the production of what binds the</p> <p>25 receptors, so you can take away estrogen. One</p>
<p>1 Q. Yes, okay.</p> <p>2 DR. LAING:</p> <p>3 A. And I guess we'll talk about it as time goes</p> <p>4 on because that's part of the numbers that we</p> <p>5 saw at the end of the day, there was quite a</p> <p>6 significant number of those patients.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. Who didn't require a change in treatment</p> <p>9 because -</p> <p>10 DR. LAING:</p> <p>11 A. Because they had already been on hormones.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. - they were treated on the basis on their PR</p> <p>14 positivity?</p> <p>15 DR. LAING:</p> <p>16 A. Yes, yes.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. That's right, okay. And are those, are those</p> <p>19 statistics now being kept by anyone in terms</p> <p>20 of if someone is ER negative, PR positive, is</p> <p>21 that being kept or is that what you hope to</p> <p>22 develop in terms of -</p> <p>23 DR. LAING:</p> <p>24 A. That's what we hope to be able to put into our</p> <p>25 -</p>	<p>1 is that you can block the interaction between</p> <p>2 the estrogen and its receptor. And the third</p> <p>3 way is that you can do something to the</p> <p>4 receptor itself, so you can turn it off or</p> <p>5 what we call down regulate it, so not have it</p> <p>6 there and expressed within the cells.</p> <p>7 This is a cartoon of what the estrogen</p> <p>8 receptor looks like. And over the years I've</p> <p>9 had several different pictures and I find this</p> <p>10 one to be one that helps patients and other</p> <p>11 people understand. So this is a breast cancer</p> <p>12 cell. Do we have an arrow? Yes. So estrogen</p> <p>13 and progesterone receptors are actually</p> <p>14 steroidal receptors, so they actually sit</p> <p>15 inside the cell, so they sit in the nucleus of</p> <p>16 the cell. And this small green box here</p> <p>17 depicts the estrogen receptor. Estrogen or</p> <p>18 estradiol are these yellow puzzle pieces,</p> <p>19 almost, they look like, that come and bind to</p> <p>20 that receptor.</p> <p>21 What a drug like Tamoxifen does, which</p> <p>22 belongs to a class of medicines known as a</p> <p>23 selective, estrogen receptor modulator is that</p> <p>24 it binds to the estrogen receptor shown here</p> <p>25 at pink, so that the estrogen cannot bind. So</p>

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<p>1 you have the receptor, Tamoxifen gets in there 2 instead and so you can't cause the downstream 3 or you can't cause the effects of the binding. 4 They're called selective estrogen receptor 5 modulators because they cause different action 6 in different tissues, so they have a negative 7 or an antagonistic effect in breast cancer, in 8 breast tissue and breast cancer cells, but 9 they have a positive effect or an agonistic 10 effect or they work just like estrogen in 11 things like the bone.</p> <p>12 Up above on the top of the cartoon it 13 talks about how the aromatase inhibitors work. 14 So in pre-menopausal patients the ovaries are 15 functioning and the majority of estrogen 16 actually comes, as one would expect, from the 17 ovaries. In a postmenopausal patient there is 18 still estrogen made and that estrogen comes 19 from conversion of male-like hormones into 20 estrogen, and one of those is this hormone up 21 here called androstenedione. It's made by the 22 adrenal glands. Some testosterone made, as 23 well. And the enzyme called aromatase turns 24 those into estrogen, so that's where a 25 postmenopausal woman still gets the last</p>	<p>1 turn off the ovaries, called luteinizing 2 hormone releasing hormone agonists. And, of 3 course, many of these are done now in clinical 4 trial settings to look at ovarian ablation and 5 we actually are participating in a clinical 6 trial that's looking at ovarian ablation plus 7 Tamoxifen versus Tamoxifen alone versus 8 ovarian ablation and aromatase inhibitor for 9 pre-menopausal patients.</p> <p>10 For a very, very long time Tamoxifen was 11 the gold standard and still remains a very 12 important drug in the treatment of hormone 13 receptor positive breast cancer. It was found 14 to have an optimal duration of five years, and 15 this was because trials showed that five years 16 was better than two years but that ten years 17 was actually inferior. And as I said, it's 18 still the main endocrine therapy for our pre- 19 menopausal patients.</p> <p>20 In breast cancer we're very fortunate to 21 have something called the Oxford Overview. 22 And what it is is it's a summary of the 23 world's literature in breast cancer which is 24 done as a meta-analysis so all the data from 25 various individual trials are taken and put</p>
<p>1 little bit of estrogen that they have around. 2 The aromatase inhibitors block that. So when 3 I explain it to patients, I say it takes away 4 that last little bit of estrogen in your body, 5 which means that you have the receptors there, 6 but you don't have anything to bind to it. 7 And it also explains some of the side effects 8 that we see from the aromatase inhibitors. 9 For pre-menopausal patients the main treatment 10 that we use and still is the main treatment 11 that we use is Tamoxifen. Because the 12 aromatase inhibitors won't work because the 13 ovaries are still making lots of estrogen.</p> <p>14 There are studies going on now that look 15 at what we call ovarian ablation, so that 16 means turning off or stopping the ovaries from 17 making estrogen. That often happens in our 18 older pre-menopausal patients as a result of 19 chemotherapy. However, in some patients this 20 can be done surgically by removal of the 21 ovaries. Many years ago and not so much now 22 and not ever in my practice radiation to the 23 ovaries was a technique that was used. And 24 there are medications similar to medications 25 that we use to treat prostate cancer which</p>	<p>1 together in a meta-analysis so that you can 2 have more strength, if you will, in looking at 3 effects. This has been--and this is usually 4 updated every five years. This is from 1998, 5 but if you look at these numbers in the most 6 recent update in 2005, they're very similar.</p> <p>7 So what it shows is two things. It shows 8 how adjuvant Tamoxifen works in reducing the 9 risk of breast cancer recurrence in the first 10 column and then how it helps to reduce the 11 risk of dying from breast cancer in the second 12 column. And it looks at it by age group, less 13 than 50, 50 to 59, 60 to 69 and greater than 14 70. And as you can see, these are relative 15 risk reductions. And what a relative risk 16 reduction is looks at the magnitude of the 17 benefit but doesn't look at the absolute 18 benefit to an individual patient. So, for 19 example, if I have a patient that I'm seeing 20 in the clinic who has a 30 percent risk of 21 recurrence based on their prognosis, then 22 Tamoxifen would decrease that by about 40 23 percent. So instead of their risk being 30, 24 it would come down to about 17 or 18 percent. 25 And the same as you think about a risk of</p>
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<p>1 death being 30 percent, you would decrease 2 that by a third, so it would take it to 20 3 percent. So the absolute benefit to the 4 patient is dependent on what their prognosis 5 is. If someone has a 95 percent chance of 6 being cured from their breast cancer, then the 7 absolute benefit for any of these treatments 8 is extremely low and in some situations less 9 than one percent. 10 I'll ask you just to look at this number 11 here. So if you look at the relative 12 reduction in the odds of death for someone age 13 60 to 69, it's 33 percent, because that will 14 be important later when we look at the 15 adjuvant on line example. 16 CHAYTOR, Q.C.: 17 Q. Doctor, if I could, could we just look at that 18 slide again? 19 DR. LAING: 20 A. Certainly. Previous, okay. 21 CHAYTOR, Q.C.: 22 Q. Previous, yeah. Thank you. This is the 23 efficacy of five years of adjuvant - 24 DR. LAING: 25 A. Adjuvant Tamoxifen.</p>	<p>1 towards the delay in initiating treatment. 2 DR. LAING: 3 A. Oh, okay, I understand what mean now. 4 CHAYTOR, Q.C.: 5 Q. So instead if it being immediately following 6 your diagnosis. 7 DR. LAING: 8 A. The only--so, of course, when we were faced 9 with our situation of what are we going to do 10 now with these patients, we did find a 11 publication and that looked at late initiation 12 of Tamoxifen. And that was a trial that was 13 done in a time period where Tamoxifen wasn't 14 routinely offered to pre-menopausal patients 15 and then, you know, in the late 1990s it was 16 evidence that it was beneficial. So they took 17 patients who are at least two years from their 18 initial diagnosis who had not received 19 hormonal therapy and they randomized those 20 patients to receive Tamoxifen or not and then 21 they followed them over time. And what they 22 found was that even with the late initiation 23 of therapy that there was a benefit, that 24 there was a benefit in terms of disease-free 25 survival and there was a benefit in terms of</p>
<p>Page 34</p> <p>1 CHAYTOR, Q.C.: 2 Q. - Tamoxifen. Immediately, I take it, 3 following diagnosis and other chemo treatment? 4 DR. LAING: 5 A. Yes. 6 CHAYTOR, Q.C.: 7 Q. Is there any similar study as to the efficacy 8 up to ten years out from diagnosis? 9 DR. LAING: 10 A. The initial trials for--I guess I'll answer 11 that in two ways. The trials that looked at 12 five years versus ten years of Tamoxifen, 13 there was a Scottish trial and there was a 14 NSABP, so that's the National Surgical 15 Adjuvant Breast and Bowel Program, so that's a 16 cooperative group that does clinical trials in 17 the United States had a B-14 trial, both of 18 which showed no advantage to treating patients 19 in a five to ten years, so showed no advantage 20 of ten years of Tamoxifen over five years of 21 Tamoxifen. And in fact, in one of the trials 22 there was the suggestion that there may be a 23 worse prognosis. 24 CHAYTOR, Q.C.: 25 Q. Okay. I think my question was more geared</p>	<p>Page 36</p> <p>1 overall survival, but that the benefit in 2 terms of overall survival was--and disease- 3 free survival were most significant in the 4 patients who had node positive disease, which 5 makes sense because they would have the higher 6 risk of recurrence. And that was the paper 7 that we found. Back in the fall of 2005 when 8 we were first starting this, I had spoken to 9 Dr. Kathy Pritchard, who's a medical 10 oncologist at Sunnybrook Hospital, who's a 11 colleague and a friend of mine and asked her 12 if she had any idea of had there been any 13 experience in the literature and she was the 14 one who forwarded me this article. But you're 15 very correct, that in the overview these are 16 people who were given up-front treatment. 17 CHAYTOR, Q.C.: 18 Q. Okay. And the benefit that article speaks of 19 for those with the late introduction of the 20 therapy, while it is a benefit, is it--is 21 there any difference in terms of the 22 percentages from what you would have seen had 23 they received the treatment in the beginning? 24 DR. LAING: 25 A. They were similar in magnitude of reductions,</p>

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1 yeah.

2 CHAYTOR, Q.C.:

3 Q. Okay. Thank you.

4 DR. LAING:

5 A. I'll get--there's another point that I'll

6 make, but I'll make it as I get to that, to

7 that -

8 CHAYTOR, Q.C.:

9 Q. Okay, sure.

10 DR. LAING:

11 A. To the relevant section. So I think one of

12 the things that's important to realize about

13 Tamoxifen as a treatment is that it does have

14 some side effects. I usually tell my patients

15 that it has some serious side effects and

16 those include endometrial cancer, and the risk

17 is two in 1000 patients who are treated with

18 Tamoxifen. The risk is more if you're older.

19 There's also a risk of thromboembolic disease,

20 which includes blood clots in the legs, do

21 deep vein thrombosis, and also includes

22 potential for these to travel to the lungs,

23 what we call pulmonary embolism which is very

24 serious and sometimes fatal, and it also

25 includes a risk of stroke. That risk also

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1 increases with age. And if you look at

2 someone who's greater than the age of 70, then

3 that risk in that age group of severe

4 thromboembolic disease related to Tamoxifen

5 approaches five percent. Vasomotor symptoms,

6 so the hot flashes are probably the most

7 commonly reported and most problematic side

8 effect to the patients themselves and occurs

9 in about 30 percent of patients. Some of them

10 are able to tolerate these quite well and they

11 settle down over time, but for other patients

12 they are very severe, interfere significantly

13 with their quality of life and we may try

14 various medications to lessen those, but I

15 still have patients in my practice who are not

16 able to continue on Tamoxifen because of side

17 effects. We know that it can cause premature

18 cataract formation. It can cause aches and

19 pains in the legs. Most patients complain of

20 muscle cramps, particularly at night time.

21 It's been shown to cause weight gain, which is

22 a concern for some patients, particularly

23 because many of these patients will have

24 finished adjuvant chemotherapy at a time when

25 they've already had some weight gain related

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1 to the steroids and to their chemotherapy and

2 are not as active and, you know, have concerns

3 about their body image because they've lost

4 their hair and may have had a mastectomy, so

5 weight gain can be of concern to these

6 patients. It can cause mood alteration, and

7 we've seen significant depression. And it can

8 cause, very rarely, some increases in the

9 liver enzymes and lowering of the blood count,

10 so we monitor for that.

11 There are some good side effects, if you

12 will, or some benefits of Tamoxifen. It has a

13 positive effect on bone and lipids. It has

14 been shown to reduce the risk of breast cancer

15 in the opposite breast in patients with a

16 breast cancer diagnosis. And there are two

17 large trials showing a benefit to Tamoxifen in

18 breast cancer prevention. And because we've

19 known about and have studied Tamoxifen for

20 over 30 years, we know that it has something

21 called a "carry-over effect". If you look at

22 the slides from the overview, what happens is

23 you see a separation of the curves, so that

24 the people who get Tamoxifen are doing better.

25 And that doesn't stop at five years, it

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1 doesn't stop at ten years, that continues to

2 be separated. So we think that there's an

3 ongoing benefit even beyond the duration of

4 the Tamoxifen. And we're not certain that

5 that is going to be the same for the aromatase

6 inhibitors because they've only been included

7 in the last overview.

8 So then on to the other types of

9 medications that are key for hormonal therapy

10 of breast cancer. So these are the aromatase

11 inhibitors. When I was a fellow, we had an

12 aromatase inhibitor called aminoglutethimide,

13 which was a first generation aromatase

14 inhibitor and it was used to treat metastatic

15 breast cancer but not in the adjuvant setting.

16 It blocked estrogen production, but it also

17 blocked production of several of other

18 important hormones in the body, so that it was

19 very problematic to give to patients. Then

20 these third generation aromatase inhibitors

21 came out and were initially tested and shown

22 to be superior to Tamoxifen in treatment

23 metastatic breast cancer, and that was in the

24 mid to late 1990s.

25 The thing to remember about these

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<p>1 medications is, as I said, they are only 2 effective if the patients is postmenopausal. 3 That can be natural or it can be as a result 4 of ovarian ablation, as we've talked about. 5 There are three of these drugs. Two are 6 called non-steroidal inhibitors and those are 7 the drugs Letrozole and Anastrozole, and 8 there's one that's a steroidal inactivator and 9 that's a drug called Exemestane and they vary 10 slightly in how they work. 11 So once these drugs had been shown to be 12 very active in metastatic breast cancer, the 13 next natural progression was to test them in 14 the adjuvant setting, and this has been done 15 in three different ways. First of all has 16 been to give these drugs instead of Tamoxifen 17 as the up front treatment, so as you said, 18 right at the time of diagnosis after their 19 chemotherapy if they're going to need it. 20 These patients were randomized to get 21 Tamoxifen or to get these medications. So far 22 the largest of these trials, the ATAC trials, 23 has shown an improvement in disease-free 24 survival but not overall survival yet for the 25 aromatase inhibitors.</p>	<p>1 that away, and you also take away the 2 estrogen. So there's a rationale for the 3 sequence of aromatase inhibitor after 4 Tamoxifen. Those are called the switch trials 5 and there are a few of those. Then when these 6 drugs first came out, of course, there was a 7 population of patients who had finished their 8 five years of Tamoxifen, and we knew that 9 giving them Tamoxifen for a longer duration 10 wasn't going to help, but we also knew that 11 the risk of cancer recurrence was still there, 12 and that was the rationale for the NCIC MA17 13 trial which was the study that looked at 14 Letrozole, one of the aromatase inhibitors 15 after five years of Tamoxifen. 16 The important thing to remember about 17 this situation is that patients had to make it 18 to the five years without having a recurrence. 19 So, of course, you would have had people that 20 had recurrence in that five years who then 21 wouldn't have been eligible for this study. 22 That also--this is a point I had wanted to 23 make. That also was helpful to us in deciding 24 what to do with some of the patients that we 25 reviewed that were in the five to ten year</p>
<p>1 The second strategy is to start with 2 Tamoxifen and then to switch patients after 3 two to three years to an aromatase inhibitor. 4 The rationale for that is extensive, but the 5 two important points of that are if you 6 remember back to the curve I showed you, that 7 there's a peak of recurrence at two to three 8 years. So that was the rational for looking 9 at a switch earlier than five years, because 10 investigators felt, well, if that's when the 11 peak is, should we try and get a potential 12 drug that overcomes resistance to Tamoxifen in 13 sooner in the adjuvant setting than later. 14 The second is that one of the mechanisms that 15 was thought to be responsible for Tamoxifen 16 not working after five to ten years is because 17 it can be estrogen-like or anti-estrogen, 18 depending on what tissue it's in, and it's 19 thought that if you chronically inhibit the 20 receptor in breast cancer cells, over time 21 those cells may actually start to see 22 Tamoxifen as estrogen, and there's some basic 23 science work done to support that. So the 24 rationale for that sequence meant that if your 25 Tamoxifen starts to act to estrogen, you take</p>	<p>1 period, so we did have some evidence that 2 treating in the five to ten year period was 3 beneficial. This study was so positive, the 4 MA17 trial, that it was stopped early at the 5 first interim analysis. So you had a 6 situation where you had patients who had five 7 years of Tamoxifen. They were then randomized 8 to get the active medicine or to get a 9 placebo. We didn't know, as the 10 investigators--this was a trial that we 11 participated in, it was a Canadian led study. 12 We didn't know if those patients were taking 13 the active drug or if they were taking a 14 placebo. When the trial showed such a benefit 15 to the treatment in the five to ten year 16 period with the active drug, the Letrozole, 17 the study was stopped early and the patients 18 were unblinded. Half of the patients on the 19 trial would have been getting the placebo, and 20 then it was up to the patient, with some 21 discussion with their physician, to decide at 22 that point if they wanted to go on that study. 23 So then we had patients who had Tamoxifen for 24 five years, who had nothing, no adjuvant 25 treatment for two to three years, who elected</p>

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1 to go on Letrozole at that point. They have
 2 analyzed those patients and those patients who
 3 decided to go on late Letrozole also got a
 4 benefit. So that was helpful to us --
 5 CHAYTOR, Q.C.:
 6 Q. So even with the gap in treatment?
 7 DR. LAING:
 8 A. Because of the gap, yes, yes. It wasn't until
 9 2004 that the American Society of Clinical
 10 Oncology recommended aromatase inhibitors as
 11 part of adjuvant hormonal therapy for post
 12 menopausal patients. They have not updated
 13 that guideline since. That still remains
 14 there. However, they point out, and this is
 15 the case, that there's none of those three
 16 drugs, nor any of those three strategies that
 17 are known to be superior to each other because
 18 they've not been compared head to head, and
 19 that, of course, you need to consider the
 20 potential side effects and the risk of relapse
 21 for the patient.
 22 Aromatase inhibitors have side effects as
 23 well. They're somewhat different than the
 24 Tamoxifen side effects. Because they take away
 25 that last little bit of estrogen, there is a

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

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

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1 aromatase inhibitor, and also HER2 probably
 2 plays a role. There's certainly a lot of
 3 interaction between the HER2 receptor and the
 4 estrogen receptor that people are trying to
 5 understand better.
 6 I think it's important to understand as
 7 well that when we see somebody in the clinic,
 8 the decision to offer them hormonal therapy
 9 depends more than just on the results of the
 10 estrogen/progesterone receptors. The most
 11 important first thing is what's the prognosis.
 12 Someone has an extremely good prognosis, we
 13 may decide that they don't require any extra
 14 treatments. The next, of course, is the
 15 estrogen and progesterone receptor status.
 16 Menopausal status helps us to decide what
 17 drugs, and, of course, what other health
 18 problems they may have. If I have a 70 year
 19 old lady who has severe hypertension, ischemic
 20 heart disease, a diabetic, and who has had a
 21 stroke, then she's not going to get Tamoxifen.
 22 If I have someone who is small framed, doesn't
 23 exercise, is a smoker and has already had a
 24 pathological fracture in their spine, then I'm
 25 not going to be as keen on giving that person

<p style="text-align: right;">Page 49</p> <p>1 an aromatase inhibitor.</p> <p>2 Patient preference is something that</p> <p>3 comes into the discussion. I have some</p> <p>4 patients who come in and had a friend or a</p> <p>5 neighbour or a sister who took Tamoxifen and</p> <p>6 they sit down and say there's no way I'm</p> <p>7 taking that medication, I saw what--and there</p> <p>8 are other people who I talk about the</p> <p>9 aromatase inhibitor, but their sister who had</p> <p>10 breast cancer had Tamoxifen and they're more</p> <p>11 comfortable to start with that medication</p> <p>12 first. So that certainly plays a role.</p> <p>13 Then, of course, drug coverage.</p> <p>14 Tamoxifen is a generic medication, it's been</p> <p>15 around for 30 or more years and it costs about</p> <p>16 \$20.00 a month. The aromatase inhibitors are</p> <p>17 relatively new and they cost about \$180.00 a</p> <p>18 month. So for many of our patients, we have</p> <p>19 to discuss with them what their drug coverage</p> <p>20 is.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. Doctor, the patient preference issue, I take</p> <p>23 it that's true on whatever therapies that you</p> <p>24 offer to your patients?</p> <p>25 DR. LAING:</p>	<p style="text-align: right;">Page 51</p> <p>1 terrified of needles to the point that they</p> <p>2 can't even imagine having a needle, and so we</p> <p>3 usually try and work through that. Patients</p> <p>4 certainly are very informed. I think breast</p> <p>5 cancer patients, as a group, tend to be very</p> <p>6 well informed, and I think it's because</p> <p>7 there's a lot of resources out there for them.</p> <p>8 When a patient in this province is diagnosed</p> <p>9 with breast cancer, before they ever come to</p> <p>10 the cancer clinic, they get something called</p> <p>11 the Purple Lupin Kit, which is a kit that</p> <p>12 contains a lot of very helpful information</p> <p>13 about all aspects of breast cancer, their</p> <p>14 diagnosis, their surgery, lymphedema. So many</p> <p>15 people already know, they've heard about</p> <p>16 chemo, they've heard about Tamoxifen, they've</p> <p>17 heard about the aromatase inhibitors. The</p> <p>18 Cancer Society provides a lot of helpful</p> <p>19 information, very general information, what is</p> <p>20 chemotherapy, what is radiation, and those</p> <p>21 sorts of things. So, yes, I'd agree with you</p> <p>22 that patients are very well informed.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And I take it you encourage that?</p> <p>25 DR. LAING:</p>
<p style="text-align: right;">Page 50</p> <p>1 A. Absolutely.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. That there's a dialogue with the patient and</p> <p>4 input from them, and are you finding more and</p> <p>5 more that patients are well informed and</p> <p>6 educated on those things before they ever even</p> <p>7 come to you to speak about this issue?</p> <p>8 DR. LAING:</p> <p>9 A. Yes. You know, that's true for chemotherapy.</p> <p>10 There are patients who we recommend</p> <p>11 chemotherapy to who just decide that they</p> <p>12 don't want to take it. What we really try and</p> <p>13 do, you know, as the clinician who's involved</p> <p>14 in their care, is make sure that whatever</p> <p>15 decision that they make is an informed</p> <p>16 decision. So we try and give them as much</p> <p>17 information. If I see someone who says</p> <p>18 there's no way I'm doing such and such a</p> <p>19 thing, there's usually a story behind it, so I</p> <p>20 usually say why is it that you don't want to</p> <p>21 have chemotherapy, and it may be that years</p> <p>22 ago they had experience with a family member,</p> <p>23 and if you try and talk to them and take it</p> <p>24 through and reassure them that we have better</p> <p>25 medications for nausea--some people are</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Yes.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. And do your part to help and assist them in</p> <p>4 what they should be reading and the types of</p> <p>5 literature to concentrate on?</p> <p>6 DR. LAING:</p> <p>7 A. Yes.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. And you encourage them to be involved in those</p> <p>10 decisions about their care?</p> <p>11 DR. LAING:</p> <p>12 A. Absolutely. So for many of our patients--so</p> <p>13 if I think about--this is how I think about</p> <p>14 it. I think about a third of our patients</p> <p>15 have private drug insurance in this province,</p> <p>16 a third of them have coverage through the</p> <p>17 Newfoundland and Labrador Drug Prescription</p> <p>18 Program, and a third of patients have no drug</p> <p>19 coverage. When the aromatase inhibitors first</p> <p>20 came out for treatment of metastatic disease,</p> <p>21 it took us quite some time to have this drug</p> <p>22 funded through the drug prescription program,</p> <p>23 to have it listed as a special access drug.</p> <p>24 In September of 2006, I was asked to go and</p> <p>25 present to the Atlantic Common Drug Review</p>

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

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1 but we don't have the same coverage--every
 2 other province in Canada lets the medical
 3 oncologist who's treating the patient decide
 4 which hormone therapy to use and doesn't put
 5 stipulations on this definite or severe
 6 toxicity from Tamoxifen. So we continue to
 7 work to try and get them to change their mind.
 8 CHAYTOR, Q.C.:
 9 Q. And do you know what's the rationale for that
 10 here in Newfoundland and Labrador?
 11 DR. LAING:
 12 A. They're waiting, they say, for some of these
 13 further updates of the trials that are looking
 14 at the aromatase inhibitors and the upfront in
 15 the switch strategies, and in December there's
 16 going to be a trial come out that's hopefully
 17 going to provide us with some more evidence to
 18 bring back to them again for review.
 19 CHAYTOR, Q.C.:
 20 Q. Doctor, the people who you deal with on that
 21 issue and the people that you have to bring
 22 the evidence back to, do you feel that you are
 23 better informed on the issue or are they?
 24 DR. LAING:
 25 A. The issue of aromatase inhibitors --

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1 CHAYTOR, Q.C.:
 2 Q. Are they--for example, are they treating
 3 oncologists?
 4 DR. LAING:
 5 A. No, no, and so the reason why I had asked to
 6 go to the Atlantic Common Drug Review meeting
 7 that time was that there was no oncologist on
 8 that committee, and yet they were dealing with
 9 the issue of aromatase inhibitors. As you
 10 know or may know, there's a common drug review
 11 --there's a common drug review for this
 12 country, and it deals with new drugs. At that
 13 time, there was a decision within Atlantic
 14 Canada to have an Atlantic Common Drug Review
 15 and they were dealing with new indications for
 16 drugs that already had approval, and, of
 17 course, the aromatase inhibitors fell into
 18 that classification. They listed them for
 19 metastatic disease and the other three
 20 Atlantic provinces, it was up to the
 21 oncologist to decide how to treat the patient.
 22 Here they said that they felt that the patient
 23 had to have a contraindication to Tamoxifen.
 24 So after that September, 2006, meeting we
 25 managed to convince them to list that

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1 restriction on that, the added adjuvant
 2 therapy, but they haven't lifted the
 3 restriction yet on adjuvant therapy.
 4 Currently the process has changed in
 5 terms of drug review in this country, and now
 6 there is a joint oncology drug review that is
 7 operating on an interim basis of which we are
 8 a participating province, but this issue is
 9 done, you know, the rest of the world is
 10 funding --
 11 CHAYTOR, Q.C.:
 12 Q. Moved on?
 13 DR. LAING:
 14 A. Right. So there's never going to be any more
 15 evidence, but we need to go back and again
 16 when we get the update data at the San Antonio
 17 Breast Cancer Conference, we'll prepare
 18 another file and forward it to them and meet
 19 with them again to see if we can lift that
 20 restriction.
 21 CHAYTOR, Q.C.:
 22 Q. And that's coming up shortly.
 23 DR. LAING:
 24 A. I do want to stress, though, that we are
 25 creative, we do get these drugs funded, and we

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1 actually have a lot of compassion access
 2 programs with the pharmaceutical companies.
 3 So if somebody--if we feel that somebody
 4 really needs this medication, we do not let
 5 them go without it.
 6 CHAYTOR, Q.C.:
 7 Q. And the "we", that's the oncologists treating
 8 the patient?
 9 DR. LAING:
 10 A. And our clinical pharmacist who works side by
 11 side with us.
 12 CHAYTOR, Q.C.:
 13 Q. Makes sure that happens?
 14 DR. LAING:
 15 A. Yes.
 16 CHAYTOR, Q.C.:
 17 Q. Thank you, Doctor.
 18 DR. LAING:
 19 A. So this next slide is taken from Adjuvant
 20 Online. Adjuvant Online is a computer program
 21 that was designed a few years ago now by Dr.
 22 Peter Ravdin, which is a medical oncologist
 23 from the United States, and he was trying to
 24 come up with a tool to help physicians assist
 25 their patients in decision making in the

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1 clinic. It reminds me of when I was a fellow,
 2 we only had one way to treat hormone receptor
 3 positive breast cancer, it was Tamoxifen. We
 4 only gave it to post-menopausal patients, and
 5 there was two types of chemotherapy to use,
 6 Type A and Type B. One of the oncologists in
 7 Hamilton made a decision for it, and it was a
 8 great aid for patients to try and decide, you
 9 know, this is the potential side effects of
 10 this treatment and this is the potential side
 11 effect of that treatment.
 12 Since that time, there are several,
 13 several various combinations of chemotherapy,
 14 and as you can see, lots of hormonal therapy
 15 for breast cancer. So Dr. Ravdin's goal was
 16 to try and take this and put it into a system
 17 that could first of all give a prognosis, and
 18 second of all, help patients visualize and see
 19 what the potential benefit to treatments may
 20 be. On the top side here to the left, you put
 21 in patient information. This can all be
 22 changed, okay, so I've just used an example of
 23 somebody who is 63, which would be about the
 24 median age for breast cancer, minor health
 25 problems, you can give them major health

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

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

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<p>1 alive because of the hormonal therapy. Two 2 would be alive because of chemotherapy and 3 four more would be alive because of both. 4 That's very important, and I think it's 5 important for two reasons. One is because it 6 tells us that these hormonal therapies are 7 effective at increasing survival in these 8 patients, but it also tells us that even with 9 these treatments there are still those 10 patients who do not benefit. So if you take 11 that group, nine were going to die, three 12 don't, there's still six that despite getting 13 hormonal therapy, and then the next line, 14 despite getting chemotherapy, and then the 15 last line, despite if I gave these ladies both 16 things, that it doesn't prevent recurrences in 17 all people. We wish that it did, we wish that 18 that or all of our adjuvant therapies did, but 19 they don't. 20 The next patient is going to be almost 21 the same, but I've changed one factor. 22 CHAYTOR, Q.C.: 23 Q. Doctor, I just wanted to ask you one thing. 24 DR. LAING: 25 A. Yes.</p>	<p>1 a program on the same site for colon cancer, 2 for lung cancer. When you go in under this, 3 it suggests that it be used by health care 4 professionals that are involved in cancer 5 care, and that patients should talk to their 6 physicians about using it to make sure that 7 they, I guess, understand what to put in and, 8 you know, the relative risk reductions and the 9 benefits and things. For some of my patients, 10 I do this in the clinic with them. I'll go 11 online, I'll do this, I'll take them out and 12 I'll sit down and show it to them. Not all 13 patients want this degree of information, but 14 certainly some of them do. I find it's really 15 helpful in trying to decide about giving 16 chemotherapy to older patients who have 17 hormone receptor positive disease, and you can 18 see, you know, for some of those patients that 19 the benefit to chemotherapy is quite small, 20 and the benefit to hormonal therapy is 21 actually larger. 22 CHAYTOR, Q.C.: 23 Q. Doctor, where does this factor into your 24 decision making in terms of your patient? 25 DR. LAING:</p>
<p>Page 62</p> <p>1 CHAYTOR, Q.C.: 2 Q. Is this program available to all physicians, 3 all oncologist -- 4 DR. LAING: 5 A. Yes. 6 CHAYTOR, Q.C.: 7 Q. Or all, I should say, physicians who would be 8 treating cancer patients? 9 DR. LAING: 10 A. Yes. It's available online. 11 CHAYTOR, Q.C.: 12 Q. And when did it become available? 13 DR. LAING: 14 A. I would say probably about two or three years 15 ago, yes. 16 CHAYTOR, Q.C.: 17 Q. So it's sometime since or around the 2005 18 mark? It wasn't available, I take it -- 19 DR. LAING: 20 A. No. 21 CHAYTOR, Q.C.: 22 Q. Between 1997 and 2005? 23 DR. LAING: 24 A. No, no. It's available online, it's available 25 for breast cancer, but you can also--there's</p>	<p>Page 64</p> <p>1 A. For a lot of patients, I--you know, this is 2 stuff that I kind of do in my head, if you 3 will. The people that I use it most often for 4 are the people where I know that the benefit 5 is going to be very small, and I think 6 sometimes when we think about chemotherapy, 7 not so much hormonal therapy, but when we 8 think about chemotherapy, we may overestimate 9 the benefit that we think that we're providing 10 to patients by chemotherapy. So if I have a 11 patient in the clinic who's in their late 60s 12 or 70s who has a hormone positive breast 13 cancer, who maybe has one lymph node involved 14 or tumour that's more than two centimetres, or 15 something that puts them into the high risk 16 category, I'll often go and put the numbers in 17 here and sort of see, and I might sort of have 18 in my mind that, oh, they're going to get an 19 absolute benefit of five or seven percent from 20 chemotherapy, and you put it in here and it 21 comes back as one, so--you know, because they 22 derive such benefit from hormonal therapy. So 23 it's when you're--you know, for these 24 borderline cases, I find it really helpful. 25 CHAYTOR, Q.C.:</p>

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<p>1 Q. You would do it as a check?</p> <p>2 DR. LAING:</p> <p>3 A. Yes.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. You make your own determination with respect</p> <p>6 to the patient before you, but then you could</p> <p>7 use this as a check?</p> <p>8 DR. LAING:</p> <p>9 A. Yes.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And you also use it as an educational tool for</p> <p>12 your patients?</p> <p>13 DR. LAING:</p> <p>14 A. Yes, yeah, it's really--we use it a lot in the</p> <p>15 clinic when we're teaching the residents that</p> <p>16 are working with us because you can, you know,</p> <p>17 very easily say, well, look what would happen</p> <p>18 if this patient had nodes involved or look</p> <p>19 what would happen if this person was hormone</p> <p>20 receptor negative, you know, this would be why</p> <p>21 we did something different with another</p> <p>22 patient as opposed to this one. So it's a</p> <p>23 very good educational tool, and for some</p> <p>24 patients, you know, a good tool as well.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 that you might give your client, would you</p> <p>2 consider the degree of positivity?</p> <p>3 DR. LAING:</p> <p>4 A. In--I consider that for the patients who have</p> <p>5 low expression, so the one to ten percent. For</p> <p>6 the patients who are more than 10 percent</p> <p>7 positive, then, no, I would consider that to</p> <p>8 be positive is positive. This whole idea of</p> <p>9 being both estrogen and progesterone receptor</p> <p>10 positive and very strongly positive is</p> <p>11 starting to come out there, and so in some</p> <p>12 instances I'll look at someone and their</p> <p>13 results come back and they're greater than 95</p> <p>14 percent positive for both, they have a well</p> <p>15 differentiated ductal tumour, and they're in</p> <p>16 their late 60s or 70s, and I'll say, great,</p> <p>17 good, you know, this means I can use a hormone</p> <p>18 as part of their treatment. But to use that</p> <p>19 to look at someone who might be ER positive</p> <p>20 and PR negative, and for me to say I'm</p> <p>21 definitely going to give that person aromatase</p> <p>22 inhibitor because of that, we're not there</p> <p>23 yet. So the level of expression, once it's</p> <p>24 into greater than 10 percent, is not as</p> <p>25 important a factor in determining it as some</p>
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<p>1 Q. When did you start using it?</p> <p>2 DR. LAING:</p> <p>3 A. Oh, I've used it for the last couple of years.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. Whenever it became available?</p> <p>6 DR. LAING:</p> <p>7 A. Not right away, but probably for at least the</p> <p>8 last two years.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. And was there a program prior to Dr. Ravdin's,</p> <p>11 a similar program?</p> <p>12 DR. LAING:</p> <p>13 A. No.</p> <p>14 THE COMMISSIONER:</p> <p>15 Q. Excuse me, Dr. Laing, I notice that in respect</p> <p>16 of ER status --</p> <p>17 DR. LAING:</p> <p>18 A. Yes.</p> <p>19 THE COMMISSIONER:</p> <p>20 Q. It says positive. I presume you put in</p> <p>21 positive or negative.</p> <p>22 DR. LAING:</p> <p>23 A. You can put in positive, negative, or unknown.</p> <p>24 THE COMMISSIONER:</p> <p>25 Q. Okay, and in your determination of the advice</p>	<p>1 other things about the patient.</p> <p>2 THE COMMISSIONER:</p> <p>3 Q. Doctor, how would you know the rate of</p> <p>4 positivity?</p> <p>5 DR. LAING:</p> <p>6 A. It's given to us now in the reports.</p> <p>7 THE COMMISSIONER:</p> <p>8 Q. And has that been true historically?</p> <p>9 DR. LAING:</p> <p>10 A. No, it has not been true.</p> <p>11 THE COMMISSIONER:</p> <p>12 Q. And how long have you been getting it in the</p> <p>13 reports?</p> <p>14 DR. LAING:</p> <p>15 A. When we first started changing our thinking</p> <p>16 about the cutoffs, which was in 2001 and then</p> <p>17 into 2002, if the number was not present in</p> <p>18 the pathology report, I would contact the</p> <p>19 pathologists who signed out and say could you</p> <p>20 tell me what the number was, was it zero, as</p> <p>21 in nothing, or was there some staining. Some</p> <p>22 of the reports would come like that, but some</p> <p>23 of the reports would just say positive or</p> <p>24 negative. When we started to get reports in</p> <p>25 2005 from Mount Sinai, then we would always</p>

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<p>1 get reports that actually had the percent 2 staining on the main sheet, and then there 3 would be a summary at the end, and ever since 4 that time when we've gone back to getting the 5 reports from our own lab, they would certainly 6 contain the percent staining for both.</p> <p>7 THE COMMISSIONER:</p> <p>8 Q. And why is it that if this was valuable 9 information in 2001 or 2002, the oncology 10 department wouldn't talk to the pathology 11 department and say this is a useful piece of 12 information, please put that on your reports?</p> <p>13 DR. LAING:</p> <p>14 A. I'm not sure. I know that in my own practice, 15 if it wasn't there, as I said, I would contact 16 the pathologist and ask for that information. 17 The discussions that I would have had with 18 those pathologists, as a medical oncologist, 19 you know, I would say to them, you know, could 20 you tell us that because we sometimes will 21 decide to treat somebody, you know, we'd like 22 to know the number and then make the decision. 23 At that time, I wasn't aware or wasn't part of 24 any discussions that may or may not have gone 25 on between the then heads in oncology and</p>	<p>1 he asked Dr. Siddiqui to be a member of that 2 committee. Looking back on it now, I don't 3 think that was a committee that met very 4 frequently or really followed through. In our 5 new breast disease site group, that certainly 6 is a place where we have had opportunity to 7 discuss issues that are relevant to both 8 pathologists and oncologists. That's where we 9 had the discussions about ductal carcinoma in 10 situ and ER/PR testing and that, that's where 11 we have discussions about lymphedema 12 management, but that's a venue where you have 13 pathologists and oncologists and surgical 14 medical radiation oncologist involved in the 15 care of breast cancer patients where you would 16 be able to have those discussions. Maybe, you 17 know, back then had something like that 18 existed, maybe that would have been a forum 19 that maybe somebody would have said, oh, you 20 know, I notice that this is not happening, but 21 at that time, no, it wasn't something that we 22 did.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And do you recall it actually coming up at the 25 tumour board rounds that the oncologists</p>
<p>1 pathology, but I don't think that there were 2 those types of discussions, but I think that 3 at that time they may have been valuable.</p> <p>4 THE COMMISSIONER:</p> <p>5 Q. Thank you.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. And when you became the Director of Medical 8 Oncology and then into your role of Clinical 9 Chief, as the Director of Medical Oncology, 10 did you embark upon that discussion on behalf 11 of your fellow oncologists?</p> <p>12 DR. LAING:</p> <p>13 A. No, because I think, you know, once we got-- 14 once I became director in 2002, we were doing 15 our tumour board rounds, we were having some 16 discussions then. There was a committee 17 struck, and I can't recall the name of it, but 18 I think you know, sort of a liaison committee 19 between --</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Surgical Pathology Review Committee?</p> <p>22 DR. LAING:</p> <p>23 A. Right, right. I was not a member of that. Dr. 24 Gardiner was then the Medical Director of the 25 Cancer Clinic, of the NCTRF at that point, and</p>	<p>1 raised this with pathologists in that context 2 to say that we need to see this on the 3 reports?</p> <p>4 DR. LAING:</p> <p>5 A. No, I don't recall that.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. You don't recall it coming up?</p> <p>8 DR. LAING:</p> <p>9 A. No.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And I do have one other question arising from 12 the questions of the Commissioner on this 13 issue of positivity.</p> <p>14 DR. LAING:</p> <p>15 A. Yes.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. Is there a difference in how a patient will 18 respond depending on the degree of positivity 19 in the metastatic setting?</p> <p>20 DR. LAING:</p> <p>21 A. Yes, there is, and--would it be okay if I 22 spoke to that because it's coming up.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Sure, yes.</p> <p>25 DR. LAING:</p>

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1 A. Because that's really where we have--that's
 2 where the data comes from because in the
 3 adjuvant setting, all you can sort of say is
 4 does the cancer recur or not, but in the
 5 metastatic setting, you can actually look at
 6 response rates.
 7 CHAYTOR, Q.C.:
 8 Q. So in that situation, it would be even more
 9 important to have the percentage given to you?
 10 DR. LAING:
 11 A. You know, I remember back to when we were
 12 having the discussions about retesting, and,
 13 you know, should we retest just the estrogen
 14 receptor, should we test just the progesterone
 15 receptor, or should we do both, and I think
 16 that, you know, one of the things that this
 17 whole process has really taught us is that
 18 there's so many things that we may not
 19 recognize as being so important today that are
 20 going to be important five years from now, and
 21 I think that there will come a time where if
 22 we can be sure that we're getting accurate
 23 measurements of the estrogen and progesterone
 24 receptor, that, yes, you know, if someone's
 25 ER/PR is strongly positive, that's going to

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1 maybe be the most important factor in deciding
 2 about the therapy, that maybe if someone is ER
 3 positive/PR negative, that that's going to
 4 determine how we should treat people, which is
 5 why we felt that we needed to retest both and
 6 we needed to have as accurate information as
 7 we could on that patient's chart because over
 8 time that may be very important, and we may be
 9 able to really know that these are reliable
 10 predictive factors to determine the type of
 11 hormonal therapy that we offer a patient.
 12 CHAYTOR, Q.C.:
 13 Q. Doctor, just before we leave this, and I know
 14 you have a similar screen to show us, but
 15 under ER status where the program says either
 16 positive or negative or unknown --
 17 DR. LAING:
 18 A. Yes.
 19 CHAYTOR, Q.C.:
 20 Q. Do you know how does Dr. Ravdin define
 21 positive?
 22 DR. LAING:
 23 A. It's--I don't believe that it's defined on
 24 this. There's no--it doesn't say greater than
 25 or less than or anything. It just says

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1 positive.
 2 CHAYTOR, Q.C.:
 3 Q. Whether it's one percent or ten percent --
 4 DR. LAING:
 5 A. No.
 6 CHAYTOR, Q.C.:
 7 Q. You don't know.
 8 DR. LAING:
 9 A. No. It's interesting because, you know, I
 10 have looked back through various different
 11 things, if you will. For example, I've looked
 12 back at some protocols from clinical trials
 13 just to sort of say, I wonder, you know, how
 14 they define positivity. Some of them very
 15 clearly stated it was 10 percent, and others
 16 said it was institutional, so it was whatever
 17 that referring lab, if you will, used to
 18 determine positivity, and, of course, that
 19 varies from lab to lab, as you know.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, thank you.
 22 DR. LAING:
 23 A. So the only difference that I made in the next
 24 screen was that I changed the prognosis of the
 25 patient, and I said that she had four to nine

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1 lymph nodes positive. Everything else stays
 2 the same. So it's hormone receptor positive,
 3 grade one, same size tumour, but you can see
 4 that just by virtue of having lymph nodes
 5 involved that this person now has a much
 6 higher risk of having breast cancer
 7 recurrence, and as opposed to 80 people being
 8 alive without any further treatment, it's now
 9 changed to 60, and that 30 percent or 30
 10 people would die of breast cancer and 10 would
 11 die of other causes. Because your prognosis
 12 is worse when you have lymph nodes involved,
 13 then we know that your risk is higher, and you
 14 can see that your absolute benefit instead of
 15 being 2.6 percent with hormonal therapy is now
 16 8 percent. So this just shows that the higher
 17 your risk, then the more benefit that you're
 18 going to derive from your treatments, but
 19 again if you look at this, and I think about
 20 this as 100 patients with breast cancer, 30 of
 21 them are going to die of breast cancer; if
 22 they receive adjuvant Tamoxifen, eight of
 23 those people will not, but it does not--you
 24 know, there's still 20 people there who would
 25 have death as a result of breast cancer.

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

17 CHAYTOR, Q.C.:

18 Q. Sure.

19 DR. LAING:

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

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

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

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

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

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

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

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

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

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

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

9 There have been some publications in the
 10 literature where people have gone back and
 11 looked at their institutional experience in
 12 this setting. The most recent one that I've
 13 seen presented was last year at the Canadian
 14 Association of Medical Oncology meeting where
 15 one of the residents in Toronto went back and
 16 looked at paired samples. So if had a sample
 17 from the metastatic disease, plus they looked
 18 at the original pathology and to see how often
 19 the ER/PR status--they also looked at HER2,
 20 but I'll focus on ER/PR, how often it changed
 21 from, so it went from being positive on the
 22 initial tumour to being negative on the
 23 metastatic disease, and that happens in about
 24 20 to 25 percent of the cases. And the
 25 rational or the reason for that is that as

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

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

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<p>1 or bulk of disease that we really need a quick 2 response. Because a response to hormonal 3 therapy can take up to three months, whereas a 4 response to chemotherapy, particularly if it's 5 a rapid growing tumour, can be much quicker, 6 because of course, chemo kills cells that are 7 growing and dividing quickly, that's how it 8 works.</p> <p>9 CHAYTOR, Q.C.: 10 Q. So, Doctor, before we leave that, so over time 11 the cancer will evolve? 12 DR. LAING: 13 A. Yes. 14 CHAYTOR, Q.C.: 15 Q. I'll use the word "evolve" it's probably not-- 16 it's probably too positive of a word, but 17 it'll evolve so the person will go from being 18 hormone dependent to hormone independent or - 19 DR. LAING: 20 A. Yes. 21 CHAYTOR, Q.C.: 22 Q. - the disease will be hormone resistant as 23 you've said here. Can it ever happen the 24 other way around, can you go from actually 25 being negative to positive?</p>	<p>1 Q. Um-hm. 2 DR. LAING: 3 A. There's always a possibility that you may pick 4 a clone of cells that is estrogen receptor 5 positive and you may sample a lymph node and 6 it might be estrogen receptor negative cells 7 in it, so there's always that possibility. 8 Each cancer cell is different from each other. 9 I explain it to my patients by saying that, 10 you know, cancers grow and divide very 11 quickly. By the time you get to a one 12 centimetre lump of cancer, you've had about a 13 billion divisions. And think about your own 14 family members, you know, these cells from 15 cancer cells are called their daughter cells. 16 You know, if I think of myself and my four 17 sisters, we're all very different. So, and 18 they continue to be different, so, you know, 19 you can start with one cell in the lab and 20 after a few divisions, you have a cell that 21 you're looking back at a cancer that is very 22 different than the first one. So the 23 heterogeneity of your cancer cell populations 24 is what makes metastatic disease still a 25 disease we can't cure. When we get excited</p>
<p>1 DR. LAING: 2 A. No. If you look at a normal breast cell of a 3 normal breast tissue, then it's estrogen 4 receptor positive. As it goes on and develops 5 into cancer, as it becomes more aggressive, 6 then it loses that positivity. If you look at 7 these reviews and if you look at the patients 8 who went from being negative to positive, you 9 usually see one or two cases and usually what 10 it is is either your initial result was a 11 false negative or your second result is a 12 false positive. So, no, the cells don't go 13 back and gain - 14 CHAYTOR, Q.C.: 15 Q. There's something wrong with your test if that 16 happens? 17 DR. LAING: 18 A. The only thing that sometimes weighs in is 19 this whole idea of, you know, when you take a 20 biopsy and when you do the testing and the 21 pathologists certainly speak to this better 22 than I can, but, you know, you're looking for 23 the most representative sample of your tumour 24 to do the testing on. 25 CHAYTOR, Q.C.:</p>	<p>1 because the CAT scan looks better and things 2 are shrinking, it means that the cells that 3 are sensitive to that chemotherapy die off. 4 The ones that are left behind are the ones 5 that are resistant and then they are the ones 6 who grow up again and then repopulate the 7 tumour. If we could come up with a way that 8 we could kill all of the cells, you know, no 9 matter what made them grow or--then we would 10 get rid of that disease. And we can do that 11 in some malignancies. Leukaemia is a 12 wonderful example of--lymphomas, testicular 13 cancer, there's lots of cancers that are 14 metastatic that are curable by chemotherapy, 15 but unfortunately breast cancer is yet - 16 CHAYTOR, Q.C.: 17 Q. Not there yet? 18 DR. LAING: 19 A. - is not one of them. Not there yet. 20 CHAYTOR, Q.C.: 21 Q. Okay. So, Doctor, on that question about 22 going from negative to positive, as an 23 oncologist receiving such a report where your 24 primary tumour, your original was negative and 25 then, as you say, you would do another test at</p>

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<p>1 the time of the metastatic disease and you get 2 the ER test or ER/PR test then and it's 3 indicating that it's positive at that point, I 4 take it that would cause you to call into 5 question - 6 DR. LAING: 7 A. The original test. 8 CHAYTOR, Q.C.: 9 Q. The original test? 10 DR. LAING: 11 A. Yeah. Unless you explained it by some sort of 12 clonal thing, but it's, you know, my first 13 indication would be I wonder if maybe the 14 initial test wasn't correct. 15 CHAYTOR, Q.C.: 16 Q. And in reviewing the cases through the panel 17 in the aftermath of the retesting did you, in 18 fact, were there patients who had been 19 originally tested ER negative and the--on the 20 tests on their primary tumour and then their 21 metastatic tests showed ER positive? 22 DR. LAING: 23 A. I can recall one such case. It wasn't a 24 patient of mine, but it was a patient who had 25 had a chest wall recurrence shortly after</p>	<p>1 from the primary to metastatic, because I 2 think that other case we're going to talk 3 about is actually the same tumour? 4 DR. LAING: 5 A. Yes. 6 CHAYTOR, Q.C.: 7 Q. But this situation which I was just asking 8 about is a situation where primary had been 9 one---had been, one result had been positive 10 and then the metastatic had gone negative. So 11 there was one such case that you found in the 12 review? 13 DR. LAING: 14 A. Right, but it was all during the middle of 15 this. When I think back, I cannot come up 16 with a similar case. I wonder, though, as I 17 sit here and think about it, may it have been 18 because if someone was initially said to be 19 ER/PR negative, we may not have--it may not 20 have been repeated on the metastatic disease. 21 Because really, the reason to check it again 22 when you're faced with a recurrence is to 23 reassure yourself that you're giving--by 24 giving them a hormone for chest wall disease, 25 that you're going to treat. Do you know what</p>
<p>1 their initial diagnosis and the repeat, the 2 repeat test was positive and that patient had 3 been started on one of the aromatase 4 inhibitors. But this was all during--when we 5 presented this patient at the tumour panel, 6 this was after we were already sort of along 7 the process. Prior to that I did have a 8 patient who had a differing result from their 9 initial biopsy and their mastectomy specimen. 10 CHAYTOR, Q.C.: 11 Q. Yes. 12 DR. LAING: 13 A. And I did ask for a repeat on the mastectomy 14 specimen. 15 CHAYTOR, Q.C.: 16 Q. And I'd like to get into that with you - 17 DR. LAING: 18 A. So, yeah, we can talk about that - 19 CHAYTOR, Q.C.: 20 Q. Yeah, because I'd like to talk to you about 21 that case in some detail. 22 DR. LAING: 23 A. Sure, yeah, and we can do that. 24 CHAYTOR, Q.C.: 25 Q. So in the review, though, in terms of going</p>	<p>1 I mean? So if someone was ER positive to 2 begin with, they have something that's easily 3 accessible to biopsy, such as a lymph node or 4 a chest wall disease, you ask for it to be 5 repeated to make sure that it's still 6 positive. I wonder if maybe there was 7 instances, and this is just me thinking, that 8 if someone was negative all along, that you 9 may not have asked for it to be redone because 10 you're not thinking about using hormonal 11 therapy. 12 CHAYTOR, Q.C.: 13 Q. But you do recall one case where - 14 DR. LAING: 15 A. Yeah. 16 CHAYTOR, Q.C.: 17 Q. - there were the conflicting the report? 18 DR. LAING: 19 A. Yes. 20 CHAYTOR, Q.C.: 21 Q. And had you been the treating oncologist in 22 that case, you would have questioned the 23 original test? 24 DR. LAING: 25 A. It's hard to say because that's when we were</p>

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

8 CHAYTOR, Q.C.:

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

11 DR. LAING:

12 A. If someone has--if, so -

13 CHAYTOR, Q.C.:

14 Q. If your metastatic is not consistent with -

15 DR. LAING:

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

20 CHAYTOR, Q.C.:

21 Q. No, I'm -

22 DR. LAING:

23 A. They would retest somebody.

24 CHAYTOR, Q.C.:

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

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

5 DR. LAING:

6 A. Yes, absolutely, absolutely.

7 CHAYTOR, Q.C.:

8 Q. And is that a written policy now?

9 DR. LAING:

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

12 CHAYTOR, Q.C.:

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

14 DR. LAING:

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

16 CHAYTOR, Q.C.:

17 Q. Yes.

18 DR. LAING:

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

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1 the threshold for positivity, the changes in
 2 the patients who were offered hormonal therapy
 3 and getting to the pre-menopausal patients.
 4 It's interesting because I finished my
 5 training in Vancouver in 1998 and we didn't
 6 routinely give Tamoxifen to pre-menopausal
 7 patients. In fact, we put them on a study
 8 called MA 12, which was one of the NCIC trials
 9 that's actually coming out with it its ten-
 10 year follow-up. It's going to be published
 11 very soon. And what that trial showed was
 12 that for the patients who were randomized to
 13 Tamoxifen after chemotherapy, so they all got
 14 chemotherapy, they're pre-menopausal patients,
 15 they all got chemotherapy and then they were
 16 randomized to Tamoxifen or not. But actually
 17 30 percent of patients came off Tamoxifen
 18 because of toxicities or patient choice. So I
 19 don't know the final results now, but I know
 20 that it's coming out soon, that they're not
 21 actually that robust, but part of the reason
 22 that it's felt for that is because of the non-
 23 compliance of patients, and then, of course,
 24 in the change in the agents that we had
 25 available. We looked at cases from 1998,

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1 1999, 2000, 2001 where if they couldn't
 2 tolerate Tamoxifen, there wasn't another
 3 option. It wasn't really until 2004 that the
 4 aromatase inhibitors were something that we
 5 had available to us in the clinic.

6 CHAYTOR, Q.C.:

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

13 DR. LAING:

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

22 CHAYTOR, Q.C.:

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

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<p>1 DR. LAING: 2 A. Some of the references that I found 3 subsequently were from around 2001, 2002, 4 yeah. 5 CHAYTOR, Q.C.: 6 Q. Okay. And are there some before that? 7 DR. LAING: 8 A. Not that I know of, no. 9 THE COMMISSIONER: 10 Q. I'm sorry, I don't think I followed the 11 question. You were asking when it was--when 12 the ten percent? 13 CHAYTOR, Q.C.: 14 Q. When the literature indicated ten percent or - 15 THE COMMISSIONER: 16 Q. Well, the discussion was about the literature, 17 not about when it was actually implemented? 18 CHAYTOR, Q.C.: 19 Q. Yes, not when it was actually implemented in 20 St. John's. 21 THE COMMISSIONER: 22 Q. All right. 23 CHAYTOR, Q.C.: 24 Q. When the literature discussed that. And I'm 25 wondering whether or not you're aware of any</p>	<p>1 patients chemotherapy and postmenopausal 2 patients Tamoxifen and didn't look routinely 3 at the estrogen and progesterone receptor 4 staining. And the ATAC trial that I told you 5 about, which was Arimidex versus Tamoxifen was 6 run both in North America and in Europe. And 7 in the European trial almost 50 percent of the 8 patients are estrogen receptor unknown, 9 because it wasn't something that was routinely 10 done. And of course, this was during the 11 change over and people trying to establish, 12 you know, what would be an appropriate 13 threshold in relation to the Ligand binding 14 assay. You know, as a resident, as a fellow, 15 and as a junior oncologist, this wasn't 16 something that, you know, that we were reading 17 about or, you know, looking at ourselves in 18 the literature. So if there were things 19 before that, I'm not aware of it. 20 CHAYTOR, Q.C.: 21 Q. Wasn't anything that was taught specifically 22 to you during your training? 23 DR. LAING: 24 A. No. 25 CHAYTOR, Q.C.:</p>
<p>1 studies which would have indicated ten percent 2 or back perhaps lower, prior to 2001, 2002? 3 DR. LAING: 4 A. There were, in terms of studies, then, you 5 know, as I said, some of--when I went back and 6 looked at some of the actual trials that 7 looked at treating with hormonal therapy, some 8 would say positive greater than a certain 9 amount, some would say just institutionally 10 positive. The NIH came out with a consensus 11 conference in 2000 that talks about hormonal 12 therapy and they indicate any level of 13 positivity but they don't use a cutoff. They 14 don't say does that mean greater than ten 15 percent or does that mean, you know, what that 16 means by any level of positivity. At the same 17 time they talk about pre-menopausal patients 18 and that's, you know, similar to when--that 19 would have been around the same time that that 20 recommendation was coming out to offer 21 hormonal therapy to pre-menopausal patients. 22 The other thing that we haven't touched 23 upon that's interesting is that the Europeans 24 for years never did estrogen and progesterone 25 receptor testing. They gave pre-menopausal</p>	<p>1 Q. Okay. And the 2000 study, the National 2 Institute, did that say one percent? 3 DR. LAING: 4 A. No, it doesn't say. If you read that, it 5 wasn't a study - 6 CHAYTOR, Q.C.: 7 Q. Any degree of positivity? 8 DR. LAING: 9 A. - it's a consensus--it's a consensus 10 statement. 11 CHAYTOR, Q.C.: 12 Q. Yes, yes. 13 DR. LAING: 14 A. And I know I did review it sometime in the 15 last week or so in preparation and it just 16 sort of says that any degree of positivity, 17 but it doesn't sort of come out and say--you 18 know, because as I said, there's different 19 ways people do it. Some labs would report 20 threshold, some labs would report a number, 21 some would look at its intensity and give a 22 score and--but, you know, our lab used 30 23 percent initially and then, you know, then as 24 time went on as we as the oncologists started 25 to change our thinking, we didn't have any</p>
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<p>1 formal process, as I said, it was really just 2 by dialogue directly with individual 3 pathologists. 4 CHAYTOR, Q.C.: 5 Q. And the wording, and we don't have that study 6 readily in front of us, but any degree of 7 positivity could mean something other than one 8 percent? 9 DR. LAING: 10 A. Sure. 11 CHAYTOR, Q.C.: 12 Q. In your interpretation? 13 DR. LAING: 14 A. Yeah. 15 CHAYTOR, Q.C.: 16 Q. Yes, okay. All right, I'm sorry, Doctor. 17 DR. LAING: 18 A. And then, of course, we discussed the impact 19 that this had on the patients. And certainly 20 there were people who should have received 21 adjuvant or metastatic treatment with hormonal 22 therapy that did not. We touched very briefly 23 on the issue of, you know, were there some 24 people who you may not have offered 25 chemotherapy to and most of those discussions</p>	<p>1 made. So I think maybe we'll leave that for 2 when we come to that discussion, if that's 3 okay with you? 4 CHAYTOR, Q.C.: 5 Q. Sure. 6 DR. LAING: 7 A. And then really just to say that, you know, 8 the story's not over, in terms of hormonal 9 therapy, be it adjuvant or metastatic, that 10 you know, as time goes on, we really need to 11 better know how to use these predictive 12 factors, and when you say that, then the next 13 thing that you have to say is that if you're 14 going to use them, then you need to be assured 15 that the results that you're getting from the 16 pathologists are as accurate as they can be. 17 Because if you're going to start to get into 18 looking at degree of expression, HER2 and 19 ER/PR linking together, all these sorts of 20 things, then you know, then you need to be 21 sure that not only is it there staining 22 there, but if we're going to start using 23 thresholds then that information needs to be 24 as accurate as possible. That there's all 25 sorts of--I could sit here for an hour and</p>
<p style="text-align: right;">Page 102</p> <p>1 we had with patients on an individual basis. 2 But just to say that in many instances 3 patients get both chemotherapy and hormonal 4 therapy. That the flip of what we want to 5 happen with adjuvant therapy, of course, meant 6 that there were patients who, because of not 7 getting hormonal therapy were at increased 8 risk of relapse and increase risk of death 9 from breast cancer. That we appreciated the 10 stress that this caused to all of the 11 patients, even in people who were hormone 12 receptor negative to being with and stayed 13 hormone receptor negative; that we felt that 14 we really needed to say that this was 15 something that we were dealing with with all 16 patients, and not just people whose results 17 changed, and I would argue maybe not even just 18 breast cancer patients, because it certainly 19 did have an impact on all of the people that 20 we were seeing in the clinic, and of course, 21 the very difficult issue with uncertainty 22 about their care. 23 And then I think we'll talk about this 24 later, about the tumour panel and how we did 25 that and why and the recommendations that we</p>	<p style="text-align: right;">Page 104</p> <p>1 tell you about all the trials that are going 2 on looking at various combinations and 3 permutations of hormonal therapy. 4 My suspicion is that we're going to start 5 to leave patients on hormonal therapy for a 6 much longer period of time. That, you know, 7 now we're doing the ten-year trials and maybe 8 we'll be doing the 15-year trials and on and 9 on we'll go. And I think the main thrust of 10 that is that we do still see these late 11 recurrences and if we can find treatments to 12 give to people to prevent cancer recurrence 13 that are not detrimental to their other 14 health, such as their bone health and that 15 sort of thing, that you know, keeps their 16 cancer away until they--as I always say to my 17 patients, until you get to live to be old and 18 cranky and die of something else, then that's 19 certainly worthwhile. And that, you know, we 20 try and provide as much ongoing support and 21 education for our patients. I think the 22 breast cancer retreat in this province is a 23 prime example of excellent work being done 24 there, and that you know, we do this because 25 we want to continue to have that mortality</p>

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1 line go down. We're not happy with where it
 2 is today. We're happy that it's coming down,
 3 but we would like to eventually get to a point
 4 where, through prevention and screening and
 5 effective adjuvant treatments, that we
 6 wouldn't have breast cancer be a cause of
 7 death for patients. And I believe that that's
 8 the end.
 9 CHAYTOR, Q.C.:
 10 Q. Okay. Thank you, Doctor.
 11 THE COMMISSIONER:
 12 Q. Ms. Chaytor, would you like to take the
 13 morning break before you continue? Because
 14 we're about a couple of minutes away from
 15 that.
 16 CHAYTOR, Q.C.:
 17 Q. Okay, sure. Thank you.
 18 THE COMMISSIONER:
 19 Q. We'll take 15 minutes.
 20 (BREAK)
 21 THE COMMISSIONER:
 22 Q. Ms. Chaytor.
 23 CHAYTOR, Q.C.:
 24 Q. Thank you, Commissioner. Commissioner, I have
 25 three new exhibits that I would ask, please,

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1 to have entered. It's C-0243, C-0244 and C-
 2 0245.
 3 THE COMMISSIONER:
 4 Q. 243, 44 and 45?
 5 CHAYTOR, Q.C.:
 6 Q. Yes.
 7 THE COMMISSIONER:
 8 Q. Entered.
 9 EXHIBITS ENTERED AND MARKED C-0243, C-0244, C-0245
 10 CHAYTOR, Q.C.:
 11 Q. Thank you. Doctor, I just want to clarify a
 12 couple of things from the presentation. You
 13 mentioned that there are 350 new breast cancer
 14 patients each year or approximately. I think
 15 it's up to 370 now the presentation said.
 16 DR. LAING:
 17 A. That's right.
 18 CHAYTOR, Q.C.:
 19 Q. And those included in situ as well as
 20 invasive?
 21 DR. LAING:
 22 A. That's correct.
 23 CHAYTOR, Q.C.:
 24 Q. In situ disease as well as invasive.
 25 DR. LAING:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And that would be ductal, I would take it,
 4 DCIS, as well as lobular in situ?
 5 DR. LAING:
 6 A. Yes.
 7 CHAYTOR, Q.C.:
 8 Q. And are DCIS cases and lobular in situ cases
 9 currently tested for ER/PR?
 10 DR. LAING:
 11 A. No.
 12 CHAYTOR, Q.C.:
 13 Q. They're not, and about how many, what number
 14 of the new breast cancer patients would fit
 15 into that category?
 16 DR. LAING:
 17 A. I'd actually have to go look at the numbers,
 18 but I would think that lobular carcinoma in
 19 situ would be an uncommon presenting for us to
 20 see at the Cancer Centre. So I would say out
 21 of that 370, maybe ten at the most. Ductal
 22 would probably be about 50 or 60. I don't
 23 believe that I looked at the actual breakdown
 24 for 2007, but in other years, it would be a
 25 similar number. The incidents of ductal

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1 carcinoma in situ is actually going up because
 2 of mammographic screening, because these are
 3 the ones that are picked up easily on
 4 mammograms, because of the calcification.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, and so ER/PR tests then are done on all
 7 other breast cancer patients?
 8 DR. LAING:
 9 A. That's correct.
 10 CHAYTOR, Q.C.:
 11 Q. There are no other categories that are
 12 excluded?
 13 DR. LAING:
 14 A. No, there isn't.
 15 CHAYTOR, Q.C.:
 16 Q. Okay. So there'd be, according to that,
 17 there'd be about approximately 300 tests?
 18 DR. LAING:
 19 A. To 320, I'd say.
 20 CHAYTOR, Q.C.:
 21 Q. ER/PR tests?
 22 DR. LAING:
 23 A. That's correct.
 24 CHAYTOR, Q.C.:
 25 Q. That would be done if it were happening here

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1 in St. John's?
 2 DR. LAING:
 3 A. Yes.
 4 CHAYTOR, Q.C.:
 5 Q. Yes, okay. The importance or significance of
 6 the ER/PR test in determining the treatment
 7 that a patient will receive, and you've taken
 8 us through some detail in terms of hormone
 9 treatment, does the result also determine or
 10 affect the type of chemotherapy that the
 11 patient may receive, whether or not the
 12 patient would, in fact, receive chemotherapy,
 13 duration of chemotherapy and the timing of the
 14 chemotherapy?
 15 DR. LAING:
 16 A. No, it doesn't determine what type of
 17 chemotherapy that someone would receive, nor
 18 the duration. In terms of timing of all the
 19 systemic therapies that we use, chemotherapy
 20 comes first. Hormonal therapy and Herceptin
 21 come second and radiation comes third. The
 22 reason for doing systemic therapy,
 23 chemotherapy, specifically prior to radiation,
 24 is that if it's done in the opposite sequence,
 25 there's a higher risk of systemic failure. So

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

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

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

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1 there were some patients who we did discuss,
 2 you know, and they said to me, quite out and
 3 out, "Dr. Laing, if you had known this, would
 4 you have still offered me chemotherapy?" and
 5 for many of those patients, I said "yes, I
 6 still would have" and for some of those
 7 patients, I said "no, perhaps I would not have
 8 given you chemotherapy for your stage one,
 9 node negative, one and a half centimetre
 10 tumour had I know that it was ER/PR positive."
 11 Yeah.
 12 CHAYTOR, Q.C.:
 13 Q. Okay. So there were some of those cases. So
 14 what the review indicated, and the impact of
 15 all of this on the patients, it's not only
 16 that there were patients who missed out on the
 17 opportunity to have hormonal therapy earlier,
 18 there are also some patients who perhaps had
 19 treatment that otherwise would not have been
 20 indicated had the treating oncologist known
 21 the correct ER status in the first place?
 22 DR. LAING:
 23 A. Yes.
 24 CHAYTOR, Q.C.:
 25 Q. Yes, okay. Doctor, the point too that you

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1 made about at the tumour board and obviously
 2 you would have your own patients, you would
 3 have your independent recollections other than
 4 what's written in the chart and I'm sure that
 5 varies over time and with the volume of
 6 patients that you have, but you would have at
 7 least some recollection of discussions beyond
 8 that. Was there any consideration given along
 9 the way for any of those oncologists who were
 10 still with you, and I appreciate that there
 11 has been a turnover as well, but inviting them
 12 to attend tumour board or the physician review
 13 panel while their patients were being
 14 considered?
 15 DR. LAING:
 16 A. No, we didn't think about that at the time.
 17 The physicians who participated in the tumour
 18 panel were myself, Dr. McCarthy, Dr. Zulifqar,
 19 Dr. Ahmad on a few occasions, and some of the
 20 patients, as you know, were cared for
 21 initially by those oncologists. There were an
 22 awful lot of patients though, particularly in
 23 the '97, '98, '99 and even in early 2000, who
 24 were not--that their oncologist simply wasn't
 25 around any more and wasn't available. So the-

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1 -when the letter was written to that attending
 2 oncologist, if they were still somebody who
 3 was practising and working with us, then you
 4 know, on some occasions they would come up and
 5 say, you know, "I got your letter from tumour
 6 panel. I know you talked about such and such
 7 a patient, and you know, what did you say? I
 8 get this recommendation. I'm going to see her
 9 next week," or whatever, you know, and we
 10 would review the discussion with them on a
 11 more in-depth basis. But you know, at the
 12 time, there were very few of us around who
 13 were able to do that work and really trying to
 14 get everybody together was--you know, trying
 15 to come up with a time and trying to ensure--
 16 we wanted, at each tumour panel, for there to
 17 be at least two medical oncologists there, so
 18 that there could be a balanced discussion back
 19 and forth.
 20 CHAYTOR, Q.C.:
 21 Q. Yes, and I'll talk to you about that too, yes,
 22 because there are times obviously that you
 23 weren't able to achieve that as well. Doctor,
 24 so in terms of consulting with the treating
 25 oncologist, if he or she were still within

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1 Eastern Health, there were times when you did
 2 have discussions with them about what was
 3 recommended in the letter. Prior to the
 4 recommendation going forward, were there ever
 5 any times when the panel tried to consult with
 6 the oncologist, the treating oncologist?
 7 DR. LAING:
 8 A. No, not that I can recall. We would have had
 9 the notes there and the notes from most of
 10 the--from the oncologists that were still
 11 there, would often be detailed enough that we
 12 could know that those discussions had
 13 happened. It was some of the older notes
 14 that, you know, there were--that the actual
 15 discussion about what was talked with the
 16 patient were not as detailed.
 17 CHAYTOR, Q.C.:
 18 Q. And I take it then, those oncologists were no
 19 longer within Eastern Health and you couldn't
 20 consult or there was no attempt made to try
 21 and consult with them?
 22 DR. LAING:
 23 A. No.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. And I'll ask you some more questions

<p style="text-align: right;">Page 117</p> <p>1 about that whole process. I'd like to get 2 into some detail on that in a little while, 3 but in terms of ER/PR, are there certain types 4 of cancer that are known--breast cancers, that 5 are known to be more likely considered hormone 6 receptor positive? 7 DR. LAING: 8 A. Yes. So lobular cancers are more likely to be 9 hormone receptor positive. Well 10 differentiated cancers are more likely to be 11 hormone receptor positive. 12 CHAYTOR, Q.C.: 13 Q. And how long have you known that? 14 DR. LAING: 15 A. About lobular cancers being more likely to be? 16 CHAYTOR, Q.C.: 17 Q. Yes. 18 DR. LAING: 19 A. Since my training. 20 CHAYTOR, Q.C.: 21 Q. Okay, and what about the other types, the - 22 DR. LAING: 23 A. Ductal? 24 CHAYTOR, Q.C.: 25 Q. Yes, the--no, not ductal, the well</p>	<p style="text-align: right;">Page 119</p> <p>1 DR. LAING: 2 A. Yes. 3 CHAYTOR, Q.C.: 4 Q. Okay, and again, Doctor, in doing the tumour 5 board or physician panel review, I think 6 that's what I'll call it, physician panel, so 7 we don't confuse tumour board. 8 DR. LAING: 9 A. Okay, yes, so we don't confuse it with our 10 usual ones. 11 CHAYTOR, Q.C.: 12 Q. Yes, and I believe that, in fact, is what it 13 was called for the purpose of your minutes. 14 It was physician review panel. 15 DR. LAING: 16 A. We called it the panel, yeah. 17 CHAYTOR, Q.C.: 18 Q. All right, the panel. So in doing the 19 physician or the review panel, were there a 20 number of lobular cancers which had been 21 originally tested as ER negative? 22 DR. LAING: 23 A. In the very beginning, when--you know, and I'm 24 sure that we'll discuss that with the index 25 case.</p>
<p style="text-align: right;">Page 118</p> <p>1 differentiated. I'm sorry, what did you--what 2 was your second type that you gave? 3 DR. LAING: 4 A. Oh no, so if you look at grades of tumour and 5 association with ER positivity, poorly 6 differentiated tumours are more likely to be 7 ER negative and well differentiated tumours 8 are more likely to be ER positive. 9 CHAYTOR, Q.C.: 10 Q. Yes, okay. So and when would you have known 11 that? 12 DR. LAING: 13 A. Since my training as well. 14 CHAYTOR, Q.C.: 15 Q. Okay, and in terms of more likely, what was 16 your understanding--up until say 2005, what 17 was your understanding as to how likely 18 lobular cancers would be ER positive or 19 hormone receptor positive? 20 DR. LAING: 21 A. Right, so we were always taught somewhere 22 around 85 to 90 percent of lobular tumours 23 would be hormone receptor positive. 24 CHAYTOR, Q.C.: 25 Q. 85 to 90 percent?</p>	<p style="text-align: right;">Page 120</p> <p>1 CHAYTOR, Q.C.: 2 Q. With the index case, yes. 3 DR. LAING: 4 A. That was, you know, this is how this all 5 started. The very few set of patients that we 6 asked to be retested, you know, in that, in 7 the spring and early summer of 2005, many of 8 those patients were lobular. At the end of 9 the day, once the whole panel was finished and 10 we had reviewed patients, I've never actually 11 seen the statistics come out of that to know 12 how many of those were lobular, but it was 13 less as time went on, you know. When we 14 started to get the retest results back, many 15 of the patients who had a change in results 16 were in fact ductal, and that probably has to 17 do with the fact that 70 percent of breast 18 cancers are ductal to begin with. 19 CHAYTOR, Q.C.: 20 Q. Yes. 21 DR. LAING: 22 A. So you know, when I think back through the 23 lobular patients of mine who had a change, it 24 wasn't very many of them, and I think you and 25 I are going to talk about those as we go,</p>

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<p>1 yeah.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. Yes, and there were others as well, in terms</p> <p>4 of other oncologists had lobular patients who</p> <p>5 were originally negative as well?</p> <p>6 DR. LAING:</p> <p>7 A. Yeah.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. So again, in terms of pooling the knowledge</p> <p>10 and keeping track of that, and whether or not</p> <p>11 that may have alerted the oncologists to</p> <p>12 anything earlier, do you think that might have</p> <p>13 been a worthwhile endeavour?</p> <p>14 DR. LAING:</p> <p>15 A. You know, when I think of all the people that</p> <p>16 we reviewed at the end of the day on the</p> <p>17 panel, that information has gone into the</p> <p>18 Centre for Health Information database that</p> <p>19 Eastern Health had constructed.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. The type of tumour?</p> <p>22 DR. LAING:</p> <p>23 A. We asked for that to go in, because I think</p> <p>24 that would be worthwhile to look at.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 were ductal, and without a database to go back</p> <p>2 to and say let's look at, say, the last ten</p> <p>3 years before 2005 and see how many of the</p> <p>4 lobular cancers that were reported were</p> <p>5 positive, then I can't really say.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. Right.</p> <p>8 DR. LAING:</p> <p>9 A. In the early days when--you know, after the</p> <p>10 index case came, I had two patients in my</p> <p>11 practice who I identified who were lobular,</p> <p>12 who were said to be ER/PR negative and I had</p> <p>13 those retested, and both of those had a change</p> <p>14 in their results.</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. Okay, and Doctor, I guess my point being that</p> <p>17 on a go-forward basis, the importance of</p> <p>18 tracking that type of information and how it</p> <p>19 may have been helpful in the past -</p> <p>20 DR. LAING:</p> <p>21 A. Yes.</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. - to have had had that type of information</p> <p>24 into a database?</p> <p>25 DR. LAING:</p>
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<p>1 Q. Um-hm.</p> <p>2 DR. LAING:</p> <p>3 A. But I'm not sure that that has been done.</p> <p>4 What I can tell you though is that as time</p> <p>5 went on, the fact that this was something that</p> <p>6 we were seeing only in the lobular cancers was</p> <p>7 not--you know, I can tell you that as part of</p> <p>8 the whole review, that wasn't something that</p> <p>9 stuck out at the end, that these patients</p> <p>10 changed because they were all lobular tumours,</p> <p>11 that was not the case.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. No, not at all.</p> <p>14 DR. LAING:</p> <p>15 A. Not at all.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. But whether or not there were 85 to 90 percent</p> <p>18 of them were positive, that's something--</p> <p>19 whether or not you were fitting within that</p> <p>20 range are you able to say whether or not it</p> <p>21 appeared to be more than 85 to 90 percent?</p> <p>22 DR. LAING:</p> <p>23 A. No, because I think there's two things there.</p> <p>24 One is that of the patients that were</p> <p>25 reviewed, not as many of them were lobular as</p>	<p>1 A. Yeah, I think with a database, you would be</p> <p>2 able to look at trends and you know, you would</p> <p>3 be able to look at what was your overall ER</p> <p>4 positivity rate, knowing that it should fall</p> <p>5 somewhere around 75 percent, looking at what</p> <p>6 your overall positivity rate is. You know, I</p> <p>7 think Dr. Banerjee made a reference to their</p> <p>8 lab in BC, it was 92 percent, you know. So I</p> <p>9 guess with their database, they were able to</p> <p>10 keep track of that. We didn't have that</p> <p>11 ability. In retrospect, when I looked back at</p> <p>12 the cases that I had of patients who were</p> <p>13 lobular, who were said to be ER/PR negative,</p> <p>14 there wasn't anything at the time that I</p> <p>15 looked at that sort of made their case jump</p> <p>16 out and say "wait now. You know, these should</p> <p>17 be patients who are positive," knowing that,</p> <p>18 you know, not everybody is. That if it's 90</p> <p>19 percent, out of every, you know, 100 lobulars</p> <p>20 that you're going to see ten of them should be</p> <p>21 negative. I would imagine that the majority</p> <p>22 of lobulars that we were seeing were in fact</p> <p>23 positive and there was no sort of alarm bells</p> <p>24 raised.</p> <p>25 You know, and I think we'll talk about</p>

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1 this as time goes on, but certainly this is
 2 something that I've thought about. The index
 3 case presented with metastatic disease, very
 4 aggressive cancer, very young patient. The
 5 person who I identified next who just happened
 6 to be coming for follow up who had lobular
 7 disease had a poorly differentiated tumour,
 8 and the other patient had metastatic disease
 9 and had a very aggressive tumour, and in fact,
 10 the pathology was signed out as
 11 undifferentiated. So it was a very aggressive
 12 looking cancer. So you know, these patients
 13 had very advanced disease at presentation,
 14 were said to have poorly differentiated
 15 tumours, had an aggressive course. So there
 16 wasn't anything about the ER negativity
 17 associated with the lobular histology that
 18 really raised any concern with me.
 19 CHAYTOR, Q.C.:
 20 Q. Okay. Doctor, and the issue that we discussed
 21 during your presentation as to the correlation
 22 between ER positivity and PR positivity, was
 23 that also something that you would have
 24 learned during your training?
 25 DR. LAING:

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1 A. No, I think that's something that's been
 2 recognized more of late. You know, we were
 3 certainly taught that there was four different
 4 combinations that you could have,
 5 positive/positive, positive/negative,
 6 negative/positive, negative/negative. The
 7 whole teaching around response rates, you
 8 know, went right back to my residency training
 9 and that information really hasn't been
 10 updated in any way in the literature because,
 11 you know, those were studies that were done
 12 back even in the 80s.
 13 When this whole idea of, you know, the
 14 expression of estrogen being related to the
 15 expression of progesterone is very new, like
 16 in the last couple of years, as people are
 17 really looking at level of expression and what
 18 that means, particularly for, you know, type
 19 of adjuvant therapy that's required, and you
 20 know, the feeling in the oncology community is
 21 that this is something that really needs to be
 22 identified on a prospective basis. So people
 23 need to be gathering that information at the
 24 time of putting patients on clinical trials,
 25 and then following it forward, as opposed to

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1 taking a clinical trial that's already been
 2 done and then retrospectively going back and
 3 looking at ER/PR expression and response to
 4 therapy.
 5 Whenever you use a predictive factor
 6 retrospectively, we consider that to be
 7 hypothesis generating. So this wasn't the
 8 main point of this study. So the studies may
 9 not be powered. They might not have enough
 10 patients in each of those categories to really
 11 make a conclusive statement, and so we
 12 consider those--and there's all sorts of
 13 things that you'll see done, so sort of post
 14 trial analysis that may look at things like,
 15 not just hormone receptors. They might look
 16 at HER2 expression. They may look at nodal
 17 involvement, and really to get some sort of an
 18 idea. But when it's done in a retrospective
 19 fashion like that, we tend to think about it
 20 as being hypothesis generating and really
 21 before it's practice changing, it needs to be
 22 shown prospectively to be a persistent and
 23 robust result.
 24 CHAYTOR, Q.C.:
 25 Q. So the idea of--and some of the literature

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1 that we've seen talking about ER positive if
 2 you're PR positive, 95 or 96 percent or 98
 3 percent, very high percentage then, would also
 4 be ER positive if you're PR positive, you
 5 know.
 6 DR. LAING:
 7 A. Yes, I see what you mean.
 8 CHAYTOR, Q.C.:
 9 Q. It would be less than four or five percent
 10 that would, in fact, be ER negative. That
 11 idea, when did you learn about that?
 12 DR. LAING:
 13 A. Later on, as well.
 14 CHAYTOR, Q.C.:
 15 Q. And what do you mean by later on?
 16 DR. LAING:
 17 A. You know, when I think back to when I was, you
 18 know, a resident and even, you know, a newly
 19 attending oncologist, there wasn't as much
 20 discussion about, you know, level of
 21 expression and what it all meant. It's only
 22 been since we've started to do the adjuvant
 23 trials, looking at the aromatase inhibitors
 24 and really trying to understand better
 25 predictive markers in oncology. So you know,

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1 what's known about the estrogen receptor in
 2 2008 and even 2005, is a lot more than was
 3 known back in 2000. So -
 4 CHAYTOR, Q.C.:
 5 Q. So you didn't know that in -
 6 DR. LAING:
 7 A. You know, it wasn't something that I can tell
 8 you that -
 9 CHAYTOR, Q.C.:
 10 Q. So in 2002, you weren't aware of that?
 11 DR. LAING:
 12 A. It wasn't something that I was aware of. We
 13 mostly -
 14 CHAYTOR, Q.C.:
 15 Q. In 2002?
 16 DR. LAING:
 17 A. - we mostly went by, you know, what the
 18 results were from the lab. Was it positive or
 19 negative? And that's how we based our
 20 decision in the clinic.
 21 CHAYTOR, Q.C.:
 22 Q. And seeing anything in terms of PR positivity
 23 and ER negatives, the idea of that being, you
 24 know, a rare occasion -
 25 DR. LAING:

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1 A. I'm sorry, ER negative PR positives?
 2 CHAYTOR, Q.C.:
 3 Q. ER negative PR positive, yes, sorry.
 4 DR. LAING:
 5 A. Yes.
 6 CHAYTOR, Q.C.:
 7 Q. ER negative PR positive, and seeing that as
 8 being something that should be infrequent,
 9 probably only four or five percent of the
 10 time, did--you weren't aware of that, say in
 11 2001, 2002, 2003?
 12 DR. LAING:
 13 A. I certainly would have had patients that were
 14 ER negative PR positive. I just don't think
 15 that I was seeing enough patients or seeing
 16 enough of that for it to register as a trend.
 17 Certainly we knew that it existed. It was
 18 well described and it's only been recently
 19 that, you know, that the actual percentage of
 20 that that should exist is about five percent.
 21 CHAYTOR, Q.C.:
 22 Q. And what do you mean by recently?
 23 DR. LAING:
 24 A. So if you look at the adjuvant trials for
 25 adjuvant--the new trials for the aromatase

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1 inhibitors, and if you look at the patient
 2 characteristics and sort of see that, you
 3 know, the majority are ER/PR, then there's ER
 4 positive, PR negative, and a smaller
 5 percentage are ER negative PR positive, I mean
 6 that's been in the last four or five years.
 7 There are some--I mean, you have to realize
 8 that, you know, because of this process, I've
 9 probably read and learned more about the
 10 estrogen receptor and that than I probably
 11 would have otherwise.
 12 CHAYTOR, Q.C.:
 13 Q. And that's what I'm trying to understand.
 14 DR. LAING:
 15 A. Right.
 16 CHAYTOR, Q.C.:
 17 Q. Like what would your knowledge level be in,
 18 you know, the time period that the
 19 Commissioner is looking at here?
 20 DR. LAING:
 21 A. You know, in that time period, you know, this
 22 was a new test. The cut off was not well
 23 defined. You know, I have, through the course
 24 of reviewing materials for this, have found
 25 references in 2001 and 2002 from Dr. Allred

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

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

10 CHAYTOR, Q.C.:

11 Q. So that, in terms of the change then in the
 12 cut off here, that would have been later into
 13 2001, after you're back from your maternity
 14 leave?

15 DR. LAING:

16 A. Right, yeah.

17 CHAYTOR, Q.C.:

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

20 DR. LAING:

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

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

12 CHAYTOR, Q.C.:

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

18 DR. LAING:

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

25 CHAYTOR, Q.C.:

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1 Q. Okay.

2 DR. LAING:

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

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

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

22 CHAYTOR, Q.C.:

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

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

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

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1 their residencies in 2001, who thought about
 2 ten percent as a cut off.
 3 THE COMMISSIONER:
 4 Q. Okay. So can we say that whether by osmosis,
 5 whether by informal discussion or at some
 6 point, and you can't--can we really even
 7 identify when in 2001 ten percent became the
 8 cut off?
 9 DR. LAING:
 10 A. I think it's very difficult to put an exact
 11 time on when that changed, and I've thought
 12 about that, and you know, there are times in
 13 medicine where things change just as you
 14 described it, sort of gradually over time.
 15 You know, patterns of practice change. You
 16 know, how we look at things changes over time,
 17 and sometimes -
 18 THE COMMISSIONER:
 19 Q. So couldn't, for example, the change have run
 20 into 2002, for example?
 21 DR. LAING:
 22 A. I think it did.
 23 THE COMMISSIONER:
 24 Q. Could there have been oncologists well into
 25 2002 who might have been using 30 as opposed

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

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1 that information. One is, is it not then
 2 entirely possible that in the retest process,
 3 there were people who were determined to be in
 4 or out of the retest on a basis that did not
 5 apply to them originally?
 6 DR. LAING:
 7 A. That is a very good question, and that is
 8 something that we have had discussions about
 9 in the last several months, and in my own
 10 practice of people that are still following
 11 me, there was one patient who was identified
 12 by that mechanism, because in somewhere after
 13 2001, they had a result that was 20 something
 14 percent, and it was--they were not retested.
 15 CHAYTOR, Q.C.:
 16 Q. And we've heard certainly from one of your
 17 patients here that would have fallen -
 18 DR. LAING:
 19 A. Yes.
 20 CHAYTOR, Q.C.:
 21 Q. - she was 23 percent.
 22 DR. LAING:
 23 A. So we have had some discussions in the last
 24 few months about really making sure that there
 25 weren't those patients who had been missed. I

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

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1 research and that at Eastern Health was
 2 working on getting that information with Mr.
 3 Gulliver, from the lab, to ensure that we
 4 would have a complete data set that said, you
 5 know, what the person's initial--what their
 6 ER/PR was to make sure that there are people
 7 that there may have been flag come. And of
 8 course, that would involve a review of their
 9 cancer patient chart.
 10 CHAYTOR, Q.C.:
 11 Q. And, Doctor, we'll follow up then that with
 12 Mr. Gulliver when he gets here next week. But
 13 originally there was a decision made back in
 14 2005 when the decision was made to do the
 15 retest, the decision was made to use a cutoff,
 16 January 1st, 2001. Anything after that date,
 17 patients were identified based on a ten
 18 percent cutoff.
 19 DR. LAING:
 20 A. Um-hm.
 21 CHAYTOR, Q.C.:
 22 Q. Were you part of that decision?
 23 DR. LAING:
 24 A. I did not make that final decision.
 25 CHAYTOR, Q.C.:

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1 Q. Were you consulted on that decision?
 2 DR. LAING:
 3 A. What I--the conversations that I recall having
 4 with Dr. Williams and Dr. Cook were really to
 5 sort of outline when--what we were using in
 6 the clinic at that time and I spoke to that
 7 from my own practice as an oncologist, that it
 8 was after that San Antonio meeting that we
 9 started to consider ten percent.
 10 CHAYTOR, Q.C.:
 11 Q. So they would have been told that we started
 12 to consider ten percent after the San Antonio
 13 meeting in 2000?
 14 DR. LAING:
 15 A. Yes.
 16 CHAYTOR, Q.C.:
 17 Q. But not that everybody had adopted the
 18 practice as of January 1st, 2001 of using ten
 19 percent cutoff?
 20 DR. LAING:
 21 A. It would be difficult for me to say that
 22 everybody did that without, you know, having
 23 known what each individual oncologist was
 24 doing at that time.
 25 CHAYTOR, Q.C.:

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1 Q. And did you alert that--did you alert Dr. Cook
2 to that?

3 DR. LAING:

4 A. I'm not certain. I cannot recall that
5 conversation to the degree to know whether or
6 not he had spoken with Dr. McCarthy about the
7 same issue or--to be quite honest with you, I
8 don't think at that time that we realized that
9 there may have been some delay in other people
10 adopting that as their practice, if you will.

11 CHAYTOR, Q.C.:

12 Q. But you, yourself, had patients that you
13 hadn't adopted that as the practice. We've
14 seen--at least one of them has been here, so.

15 DR. LAING:

16 A. That actually is, it wasn't that I hadn't
17 adopted that practice, it was there was other
18 factors that weighed into whether or not that
19 patient took the Tamoxifen.

20 CHAYTOR, Q.C.:

21 Q. Okay. And perhaps then we'll discuss her case
22 a little later then and you -

23 DR. LAING:

24 A. Sure.

25 CHAYTOR, Q.C.:

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1 Q. - and you can explain that to us. But you,
2 when did you come back from your maternity
3 leave in 2001?

4 DR. LAING:

5 A. October.

6 CHAYTOR, Q.C.:

7 Q. October. And so it was sometime after you
8 came back from your maternity leave that the
9 change was made. So it would have been--in
10 terms of practice. So it would have been late
11 in 2001. So did you express any concern to
12 Dr. Cook about using a January 1, 2001 cutoff
13 as the time period as opposed to no cutoff,
14 for that matter, going with 30 percent
15 throughout?

16 DR. LAING:

17 A. Yeah.

18 CHAYTOR, Q.C.:

19 Q. Or going late into 2002?

20 DR. LAING:

21 A. Yeah. I wasn't part of that final decision.
22 And as I said, I just, you know, communicated
23 what my practice was. And so, you know, in
24 fact, when I did look specifically at the case
25 that we've briefly alluded to, if you read -

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1 CHAYTOR, Q.C.:

2 Q. Yes. No, I'll come back--I don't mean to cut
3 you off, Doctor, but I'll come back to that
4 particular case.

5 DR. LAING:

6 A. Okay.

7 CHAYTOR, Q.C.:

8 Q. Because I'm not necessarily concentrating on
9 you individually in your individual practice.
10 I'm asking about your discussions with Dr.
11 Cook around coming up with this cutoff.

12 DR. LAING:

13 A. Right.

14 CHAYTOR, Q.C.:

15 Q. And you as director of medical oncology at the
16 time, whether or not you inquired of your
17 other oncologists as to, well, what was their
18 practice and is this a safe thing to be going
19 with, a January 1st, 2001 cutoff knowing that
20 you didn't come back from your maternity leave
21 until late into 2001 and that the discussion
22 around changing the cutoff happened then?

23 DR. LAING:

24 A. Right. No, I didn't have any further
25 discussions other than what I've outlined to

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1 you with Dr. Cook. And, you know, perhaps,
2 you know, in retrospect we should have had a
3 cutoff of less than 30 percent for the entire
4 time period. But, you know, that was a
5 decision that was made once they decided which
6 slides to pull and send after, you know, some
7 consultation with me, but that final decision
8 wasn't one that I made.

9 CHAYTOR, Q.C.:

10 Q. And in the fall of 2001 when the conversations
11 or discussions took place about changing the
12 cutoff for treatment purposes, what
13 discussions would have been had with the
14 pathologists at that point in time?

15 DR. LAING:

16 A. Again, at that time the discussions that we
17 would have had with the pathologists would
18 have been individual discussions between
19 individual medical oncologists and
20 pathologists. I can only speak from my own
21 practice. I wasn't director at that time.
22 But just, you know--and most of the patients
23 that I would have seen, you know, would have
24 been from the same group of pathologists and
25 most of the reports that I would have had

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<p>1 would have had all the necessary information. 2 If there was ever a pathology report that I 3 felt that I didn't have all the adequate 4 information I needed, be it, you know, the 5 percent staining of ER/PR other than just 6 negative, be it the number of lymph node 7 samples, then I would consult the pathologist 8 formally, usually with either a phone call or 9 a formal consultation letter and ask to have 10 that information clarified.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. So was there anything brought up, for example, 13 at the tumour board rounds at that point in 14 time? I know you had told us yesterday there 15 was a period of time, 2001, when there wasn't 16 tumour board rounds?</p> <p>17 DR. LAING:</p> <p>18 A. Right. So they probably started up again in 19 2002.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Okay.</p> <p>22 DR. LAING:</p> <p>23 A. I can't recall any specific discussions, as I 24 mentioned yesterday, about the issue of 25 thresholds or reporting at that time, no.</p>	<p>1 practice there. And you know, at that point 2 we were starting to evolve to be the medical 3 oncologists who got asked to see a lot of the 4 breast cancer patients. And so through some 5 discussions with her, you know, we talked 6 about cutoffs and thresholds. That's not an 7 uncommon thing to happen. We do lots of 8 clinics where they are together and we run 9 things by each other and--but again, there 10 certainly wasn't any formal process in place 11 at that time where I think this information 12 could have been shared and nor do I recall 13 thinking in those days that, you know, maybe 14 we should have any sort of a formal change or, 15 you know, announcement or those sorts of 16 things.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. But there's no--there's only a handful of you, 19 really, as medical oncologists at that point 20 in time?</p> <p>21 DR. LAING:</p> <p>22 A. There's -</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Five--there's seven of you now and there was 25 less?</p>
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<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. And nothing in writing, no memorandum between 3 the cancer care program oncologists and 4 pathologists to say we are now using a ten 5 percent cutoff?</p> <p>6 DR. LAING:</p> <p>7 A. No.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. And how was it communicated amongst the 10 oncologists?</p> <p>11 DR. LAING:</p> <p>12 A. So -</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. That we're now moving to a ten percent or that 15 I've been to this conference, it's indicated 16 that ten percent would be a more prudent 17 marker, how was that communicated to the other 18 oncologists?</p> <p>19 DR. LAING:</p> <p>20 A. Again, the only person that I can recall 21 having specific conversations related to that 22 to would have been Dr. McCarthy. And you 23 know, it would have been as we went into 2002. 24 At that point I had been back from maternity 25 leave and she had already commenced her</p>	<p>1 DR. LAING:</p> <p>2 A. There was less and there were different people 3 and there were people coming and going and, 4 you know, people that did breast cancer and--I 5 mean, still at that time -</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. Well perhaps more important then if that's 8 your situation that you would have something 9 reduced to writing that everybody could 10 follow?</p> <p>11 DR. LAING:</p> <p>12 A. You know, if you sort of sit here and look 13 back at that, you know, I can--yes, you know, 14 I cannot disagree with you. But I think that 15 you need to sort of think about how things 16 were at that time. There was still a large 17 turnover in 2000 and 2001. You know, I had 18 been on maternity leave. One of my colleagues 19 left just as I got back. One of them left 20 shortly after that. We had new oncologists. 21 You know, we were just basically keeping our 22 head above the water to get the patients seen 23 and cared for on a day-to-day basis. There 24 was a lot of concerns about workload, volume 25 and you know. Yes, should we have been</p>

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1 sitting down looking at guidelines and all
 2 that at that time, yes, in the ideal world,
 3 but I can tell you in those days we were just,
 4 you know, we were -
 5 CHAYTOR, Q.C.:
 6 Q. Well, Doctor, even without coming up with a
 7 formal guideline practice, you know, just a
 8 memorandum or an e-mail or any communication
 9 whatsoever with the medical oncologists, did
 10 anything like that happen to say this is now
 11 recommended to be the guideline?
 12 DR. LAING:
 13 A. Not that -
 14 CHAYTOR, Q.C.:
 15 Q. As the cutoff?
 16 DR. LAING:
 17 A. That didn't happen and I can't recall that,
 18 not at all.
 19 THE COMMISSIONER:
 20 Q. Do I take it--going go back to the second of
 21 my questions. And that is you indicated that
 22 for yourself the information that you would
 23 require was primarily on the report that you
 24 would get from the pathologist?
 25 DR. LAING:

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1 A. That's correct.
 2 THE COMMISSIONER:
 3 Q. And if it wasn't, you would look for it?
 4 DR. LAING:
 5 A. Yes.
 6 THE COMMISSIONER:
 7 Q. Do I take it from that that generally speaking
 8 at that time it was your view that
 9 pathologists were reporting the percentages?
 10 DR. LAING:
 11 A. If I think back to that time, and of course,
 12 now having reviewed some of the reports
 13 through the process, but when we would get a
 14 pathology report and when we would sit in the
 15 clinic and see the patient, all of the
 16 important prognostic factors we would need to
 17 be there. And so it was not uncommon for us
 18 to have to talk to pathologists if there was
 19 some other piece of information that we
 20 thought might have been important that wasn't
 21 there. But I don't recall having to do it on
 22 a regular basis in terms of getting the
 23 percent staining for ER/PR. For a lot of the
 24 times it was there and sometimes it was--you
 25 know, there were reports that would say ER

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1 negative and then underneath it would say PR
 2 faint positivity in less than ten percent of
 3 the cells, which would still be considered a
 4 negative result from the clinical point of
 5 view at that time. So, you know, I wouldn't
 6 ask for that to be--you know, because the ER
 7 said negative, it was inferred that that was
 8 zero because the PR would have a qualifying
 9 comment. I can recall, you know -
 10 THE COMMISSIONER:
 11 Q. So whenever it said negative, you were
 12 assuming it was zero?
 13 DR. LAING:
 14 A. Not always. It would depend on how it was put
 15 into the context of the report. And because
 16 if there was a qualifying statement after
 17 something, then it would be--you know, they
 18 would say it was negative, but they might give
 19 a qualifying statement as to that, yes, we're
 20 calling it negative, but in fact, there might
 21 have been a little bit of staining in some of
 22 the cells, that sort of respect. But often
 23 they would say ER negative, five, you know,
 24 five to ten percent faint staining or zero
 25 percent staining or, you know. So for the

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

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1 patient had a medial tumour and if that wasn't
 2 there, I'd send a consult to the pathologist.
 3 Even though I called them, we would always
 4 follow-up with a written consult note because
 5 we'd want to identify the specimen number, so
 6 that, you know, that we were sure that they
 7 were looking at the right case and the right
 8 patient. So you know, when I think back to
 9 those days, the majority of time, you know,
 10 the information there, if it wasn't, then we
 11 spoke to the pathologists.
 12 THE COMMISSIONER:
 13 Q. So if the report came back simply negative or
 14 simply positive, you would call?
 15 DR. LAING:
 16 A. If it was--yes, if it just said ER negative,
 17 PR negative, and nothing else, then I would
 18 call and say, you know, what do you mean by
 19 negative, is there some staining there or not.
 20 THE COMMISSIONER:
 21 Q. All right. And if it said ER negative and
 22 then PR positive in less than something or
 23 another, because it said positive in less than
 24 ten percent, then you would make assumptions
 25 about what ER negative meant?

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1 DR. LAING:
 2 A. Yeah. But they would actually--most often
 3 what they would say would be ER negative and
 4 then they would actually say PR negative, not
 5 PR positive, but they'd say PR negative, and
 6 then in a bracket would be a comment about
 7 things like faint staining seen in less than
 8 five percent or ten percent or some percentage
 9 -
 10 THE COMMISSIONER:
 11 Q. So if I go back through the reports in the
 12 time frame that we're talking about, I should
 13 expect to find, for the most part, not just
 14 positive and negative, but some kind of
 15 comment which would indicate to you what the
 16 pathologist saw as being negative or positive?
 17 DR. LAING:
 18 A. And the ones that I really, you know, would
 19 question were the ones that they still used
 20 the reference to the 30 percent cutoff. And
 21 the thing to remember, too, is is that, you
 22 know, this was what I was--my thinking during
 23 those days and my practice. Now I can think
 24 about pathology reports that we read as part
 25 of the tumour panel that had differing ways

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1 of, you know, writing things and expressing
 2 things and qualitative things after it. And
 3 certainly there were still reports that we saw
 4 from the 2002 time period, as we've discussed
 5 already, where they may have said that. The--
 6 you know, if I got a pathology report that
 7 said ER is ten to 15 percent positive and PR
 8 is negative and they still gave that
 9 reference, then that was fine because I still
 10 had the number so then I could base how I
 11 wanted to treat that patient in the clinic
 12 based on the number that was there. So the
 13 most important thing was to have the number
 14 so that we could--to make that decision based
 15 on that. But again, I need to stress that
 16 that's one of the factors. There are lots of
 17 people who are ER/PR strongly positive who we
 18 decided not to give hormonal therapy to.
 19 Maybe it was because their prognosis was so
 20 good, maybe there was a contraindication -
 21 THE COMMISSIONER:
 22 Q. That wasn't the point, Dr Laing. The point of
 23 the question is a communications one.
 24 DR. LAING:
 25 A. Yeah.

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1 THE COMMISSIONER:
 2 Q. And frankly, the impression I'm getting from
 3 you and the one I got from the pathologists
 4 who have given evidence so far is different.
 5 I'm not seeing your versions of the
 6 communication the same. So what they thought
 7 they were telling you might be different than
 8 what you thought you were getting is my
 9 problem.
 10 DR. LAING:
 11 A. Okay.
 12 THE COMMISSIONER:
 13 Q. But that's my problem. So carry on.
 14 DR. LAING:
 15 A. Is there something else that I can -
 16 THE COMMISSIONER:
 17 Q. No. I think you've told me what you -
 18 DR. LAING:
 19 A. Okay, all right, okay, fair enough.
 20 THE COMMISSIONER:
 21 Q. - believe the situation to be.
 22 DR. LAING:
 23 A. Okay.
 24 CHAYTOR, Q.C.:
 25 Q. And, Doctor, I just want to clarify a couple

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<p>1 of points, too, regarding the decision that 2 was made in 2005 on retesting. 3 DR. LAING: 4 A. Um-hm. 5 CHAYTOR, Q.C.: 6 Q. To use that ten percent as the cutoff as of 7 January 1. 8 DR. LAING: 9 A. Yeah. 10 CHAYTOR, Q.C.: 11 Q. What you're telling the Commissioner is that 12 Dr. Cook consulted you on it? 13 DR. LAING: 14 A. Yeah. 15 CHAYTOR, Q.C.: 16 Q. You told him about your own practice? 17 DR. LAING: 18 A. Yeah. 19 CHAYTOR, Q.C.: 20 Q. And you may or may not have told him in terms 21 of when you came back from leave and when you 22 think in 2001 those discussions took place in 23 terms of changing the practice? 24 DR. LAING: 25 A. Um-hm.</p>	<p>1 not we should revisit that area, you know, I 2 guess the difficulty is is trying to 3 determine, one, do I think that those patients 4 exist and the answer would be certainly it is 5 possible. And do I think there are people 6 that may not have been identified through 7 review of their clinicians afterwards. I 8 think that that is possible. I think that 9 number is probably extremely small. It would 10 be interesting to see at the end of the day if 11 we do find anybody who falls into that 12 category, but - 13 CHAYTOR, Q.C.: 14 Q. And the whole thing being if there's one 15 patient - 16 DR. LAING: 17 A. And that was - 18 CHAYTOR, Q.C.: 19 Q. - I take it that's - 20 DR. LAING: 21 A. That was the discussion, you know, that was 22 the decision - 23 CHAYTOR, Q.C.: 24 Q. So even if it is extremely small number? 25 DR. LAING:</p>
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<p>1 CHAYTOR, Q.C.: 2 Q. You did not consult the other oncologists in 3 terms of what their practice may have been or 4 relay any information to Dr. Cook about the 5 other oncologists practice. Ultimately you 6 did not make the final decision? 7 DR. LAING: 8 A. Right. 9 CHAYTOR, Q.C.: 10 Q. Were you aware of the final decision that was 11 made? 12 DR. LAING: 13 A. Yes, subsequently I was aware of the final 14 decision, which brings me back to the comment 15 that I had started to make earlier regarding 16 the patient who was--and the 20 something 17 percent. 18 CHAYTOR, Q.C.: 19 Q. Did the final decision cause you any concern, 20 Doctor, the decision to use the ten percent as 21 of January 1st, 2001? 22 DR. LAING: 23 A. Not at that time, no. And when, you know, 24 when we finally sat down and, as I said, 25 recently, and had discussions about whether or</p>	<p>1 A. Yeah. 2 THE COMMISSIONER: 3 Q. I take it that is an ongoing project? 4 DR. LAING: 5 A. That is an ongoing project, that's correct. 6 CHAYTOR, Q.C.: 7 Q. And when was this initiated? 8 DR. LAING: 9 A. I'm just trying to recall. It was we had 10 some--I'll tell, it was in about April. 11 CHAYTOR, Q.C.: 12 Q. April - 13 DR. LAING: 14 A. Just this past year. 15 CHAYTOR, Q.C.: 16 Q. 2008? 17 DR. LAING: 18 A. Yeah. And the reason why I remember that is 19 that we did have some discussions about, you 20 know, doing that and going back, because this 21 is going to--this is sort of part of what I 22 think, you know, can be done as part of the 23 database. In fact, when we went to those 24 meetings, I said, you know, this is a great 25 opportunity for us to really put all this</p>

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<p>1 information into a database because I think-- 2 and I think you need more than just the 3 pathology information in there. I think you 4 need to have the outcomes, and that's going to 5 involve going to the clinic charts to 6 determine that. But I also--at that time we 7 did have some discussions with Dr. Maureen 8 Trudeau who Eastern Health contacted to have 9 an opinion from her as to, you know, whether 10 or not, what she thought about this potential 11 that could there have been some people missed 12 in the retest during this what I would 13 probably call the grey period. And there was 14 actually a conference call that we had with 15 her shortly after our NCIC meetings which were 16 in April. And then Mr. Miller, who is in 17 charge of research and that, it's been given 18 the task to--or had been working with the 19 Newfoundland and Labrador Centre for Health 20 Information really to put together this 21 database. But there's an incredible amount of 22 information that I think is going to even make 23 this picture clearer. I mean, your questions 24 regarding how many of these people ended up 25 being lobular, when I think of that as time</p>	<p>1 did she bring anything relevant to bear on 2 that discussion? 3 DR. LAING: 4 A. The discussion really revolved around could 5 there have been patients who were in that 6 period of time between going from 10 to 30 7 percent was the first part of the discussion, 8 and then the second part of the discussion 9 comes back to -- 10 CHAYTOR, Q.C.: 11 Q. Let me stop you at the first part. How could 12 Maureen Trudeau assist in that first part of 13 the discussion, whether or not patients had 14 been missed in the 10 to 30 percent? She 15 wouldn't know -- 16 DR. LAING: 17 A. No, no, there's a second part to it. 18 CHAYTOR, Q.C.: 19 Q. Okay, sorry. 20 DR. LAING: 21 A. That's okay. 22 CHAYTOR, Q.C.: 23 Q. Go ahead. 24 DR. LAING: 25 A. And then the second question really comes back</p>
<p>Page 166</p> <p>1 went on, it was less, less and less. And even 2 seeing, you know, how many people decided to 3 take late adjuvant therapy, how are these 4 people doing. I think there's a lot of 5 information that can be derived from this 6 experience that is going to be helpful to more 7 than just us here in Newfoundland and 8 Labrador. 9 CHAYTOR, Q.C.: 10 Q. Doctor, why was Maureen Trudeau, as a breast 11 oncologist in Toronto, why would she be 12 consulted on the issue as to whether or not 13 patients may have been missed? 14 DR. LAING: 15 A. I have no idea. I only found out they 16 consulted her when we were at a meeting 17 together. 18 CHAYTOR, Q.C.: 19 Q. Okay, you didn't sit in on that conference 20 call? 21 DR. LAING: 22 A. I did, but I didn't know that Eastern Health 23 had asked her to weigh in. 24 CHAYTOR, Q.C.: 25 Q. And how--what did Dr. Trudeau have to say, how</p>	<p>Page 168</p> <p>1 to a lot of the discussions we had this 2 morning would be would the percent of 3 positivity change, you know, so would you have 4 someone who is sitting in a clinic who, for 5 example, was just border--just made 6 positivity, 10 percent, 24 percent, 30 7 percent, you know, would that factor into the 8 patient's decision, would it factor into the 9 oncologist's decision to then turn around and 10 say, oh, look, you're 95 percent positive for 11 both, would you have a different--either, you 12 know, would the medical oncologist be more or 13 less likely to offer hormonal therapy in that 14 instance, and secondly, would the patient be 15 more willing to accept to it, albeit we think 16 that there's a benefit. You know, the 17 response rate data comes from metastatic 18 disease, but there's--you know, there may be, 19 as I say, some emerging data that suggests 20 that the level of positivity may impact on the 21 likelihood of benefit in the adjuvant setting. 22 So I think that's why they had asked Dr. 23 Trudeau to weigh in on the discussion, just as 24 a medical oncologist from a--just another 25 opinion from an outside medical oncologist was</p>

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<p>1 how I had interpreted that to be. It was 2 interesting because in the discussions with 3 Dr. Trudeau one of the things that came out 4 was, well, just go to your database and pull 5 them out, and we had to say again we do not 6 have a database. It is incredibly difficult 7 for us to identify these patients, you know, 8 to be able to say, well, can we go back now 9 and find all the patients from 2002 who had 10 receptors at this particular level and who 11 were offered treatment. You're going to have 12 to review--pull all the pathology, pull all 13 the clinical charts.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. So I just want to understand then. I guess I 16 can see now then why the consult or the role 17 that Dr. Trudeau would have played in it.</p> <p>18 DR. LAING:</p> <p>19 A. Uh-hm.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Before the decision was to be made as to 22 whether or not the effort would be expended to 23 go through the pathology reports to identify 24 those potential patients that are missed --</p> <p>25 DR. LAING:</p>	<p>1 category, and my answer to that now would be, 2 "I think so, because there's all sorts of 3 people that we're still discovering", you 4 know, that there's still patients that are 5 being identified that, you know, for whatever 6 reason, were not found in the initial retest, 7 not because it was 2002, or not because they 8 were 23 percent, but just that, you know, we 9 still have people coming forward.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. There are other ways that people were missed 12 as well.</p> <p>13 DR. LAING:</p> <p>14 A. Yes.</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. And that's been explored here and will 17 continue to be explored.</p> <p>18 THE COMMISSIONER:</p> <p>19 Q. I'm just making sure I understand the current 20 search, is that just for those patients who 21 might have been between the 10 and 30 and 22 might have been missed because of the cutoff, 23 or are there other patients?</p> <p>24 DR. LAING:</p> <p>25 A. No, I think it's just the former. However,</p>
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<p>1 A. Yes.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. Before that decision was made, it was decided 4 to consult Dr. Trudeau to see whether or not 5 it would be beneficial to those patients 6 having been identified to then offer them 7 hormonal therapy? Is that an accurate summary 8 of what happened here?</p> <p>9 DR. LAING:</p> <p>10 A. Yeah, yeah.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. Okay, and what was Dr. Trudeau's opinion? The 13 search is under way, so do I take it that --</p> <p>14 DR. LAING:</p> <p>15 A. So at the end of the conference call there was 16 actually a consensus amongst all those 17 involved that--you know, that it would be 18 worthwhile to do. One of the things that-- 19 you know, when we had had these discussions as 20 a group within Eastern Health, you know, one 21 of the things was how--just really putting our 22 heads together to think of how are we going to 23 find these patients, number one; number two, 24 do we think that there's anybody else who's 25 out there that could potentially fall in this</p>	<p>1 one of the things--one of the reasons to sort 2 of get all this finally put into a database 3 was really to sort of see that if, you know, 4 we may find people that were outside those 5 parameters. So the decision at the end of the 6 day was to take all of the breast cancer 7 patients and put them all in a database.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. But, Doctor, if you're going to go through 10 that effort and review--have all the charts 11 reviewed and pulled, wouldn't you identify 12 everyone as opposed to just the 10 and the 30 13 percent, so it may have been in that gap?</p> <p>14 DR. LAING:</p> <p>15 A. So those are the people that you kind of have 16 your eyes and ears open to find, but if you're 17 really at the end of the day going to have a 18 comprehensive understanding of this whole 19 thing, then everybody needs to be put in 20 there.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. What's the search criteria right now, though? 23 Have people been asked to review their files 24 just looking for this 10 to 30 percent 25 potential gap?</p>

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1 DR. LAING:
 2 A. I'm not sure where they are with who they're
 3 putting in, but --
 4 THE COMMISSIONER:
 5 Q. And who's doing it?
 6 DR. LAING:
 7 A. Mr. Wayne Miller is the lead on it, working
 8 with the Centre for Health Information, who
 9 have the information that we have thus far on
 10 the patients who have been retested in a
 11 database.
 12 CHAYTOR, Q.C.:
 13 Q. And have the clinician been asked to review
 14 your chart--review your charts?
 15 DR. LAING:
 16 A. No, not --
 17 CHAYTOR, Q.C.:
 18 Q. You're not doing any review --
 19 DR. LAING:
 20 A. Not yet. Actually, I'd have to find out from
 21 them where the process is.
 22 CHAYTOR, Q.C.:
 23 Q. But it is contemplated that each oncologist
 24 would review their charts?
 25 DR. LAING:

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

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

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

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<p>1 Q. Okay.</p> <p>2 DR. LAING:</p> <p>3 A. But I could find the exact date.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. Okay, thank you, and who besides yourself was</p> <p>6 on that call?</p> <p>7 DR. LAING:</p> <p>8 A. Mrs. Pilgrim would have been on the call, and</p> <p>9 Mr. Miller, and Dr. Trudeau, and I. Those are</p> <p>10 the ones I can remember for sure. I know at</p> <p>11 some of the discussions we had, Mr. Gulliver</p> <p>12 was there, and they also asked for some</p> <p>13 opinions from some of the epidemiologists at</p> <p>14 the hospitals. I recall Dr. Brendan Barrett</p> <p>15 being at one of the meetings prior to the</p> <p>16 conference call, but I can't remember exactly</p> <p>17 if he was on that particular conference call.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And was there anyone from pathology?</p> <p>20 DR. LAING:</p> <p>21 A. I'm not sure if there was a pathologist or</p> <p>22 not. There certainly would have been at the</p> <p>23 meetings that we had had in Eastern Health. I</p> <p>24 know Dr. Denic was there, but I can't recall</p> <p>25 if on the conference call--I was in my office,</p>	<p>1 were taught that that was not common. I</p> <p>2 wouldn't have put it as low as 5 percent, but</p> <p>3 I can't remember a number. You know, maybe</p> <p>4 somewhere around 10/15 percent.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. So it was just as rare as having a lobular --</p> <p>7 DR. LAING:</p> <p>8 A. Not as rare as that.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. Not quite as rare as that?</p> <p>11 DR. LAING:</p> <p>12 A. Not as rare as that for sure.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. I thought it was 85 to 90 percent --</p> <p>15 DR. LAING:</p> <p>16 A. Right.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. From what you've said.</p> <p>19 DR. LAING:</p> <p>20 A. Yeah, the time that I became most aware of it</p> <p>21 was through the tumour panel. Again looking</p> <p>22 back at that time, can I recall through my</p> <p>23 practice in the first few years --</p> <p>24 CHAYTOR, Q.C.:</p> <p>25 Q. That's the Review Panel, right, we're talking</p>
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<p>1 so that's why it's harder for me to remember</p> <p>2 who was around the table.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. Yes, you can't picture the people around the</p> <p>5 table.</p> <p>6 DR. LAING:</p> <p>7 A. Yes.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. Fair enough. The other point I wanted to</p> <p>10 clarify from the line of questioning I was</p> <p>11 asking you is to go back to that issue about</p> <p>12 the ER and PR positivity and the correlation</p> <p>13 between the two.</p> <p>14 DR. LAING:</p> <p>15 A. Uh-hm.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. And I just want to be clear because I know you</p> <p>18 said to me--you've said as of late, you've</p> <p>19 become aware of it and recently. So I just</p> <p>20 want to be clear that in asking you, were you</p> <p>21 aware that it was rare for a tumour to be ER</p> <p>22 negative, PR positive, you're aware of that</p> <p>23 now. When did you become aware of that?</p> <p>24 DR. LAING:</p> <p>25 A. So in--I would say that in my training, we</p>	<p>1 about?</p> <p>2 DR. LAING:</p> <p>3 A. Yes.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. "The" panel.</p> <p>6 DR. LAING:</p> <p>7 A. "The" panel.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. Okay.</p> <p>10 DR. LAING:</p> <p>11 A. When I look back to my practice, you know,</p> <p>12 from 1999 on, can I say that it ever entered</p> <p>13 my mind, "Um, you know, we seem to have a lot</p> <p>14 of tumours here that are ER negative/PR</p> <p>15 positive", no, it didn't. When I first</p> <p>16 noticed it was when we did the panel.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. Yes, but the knowledge that that is a fairly</p> <p>19 rare thing --</p> <p>20 DR. LAING:</p> <p>21 A. Sure, the knowledge was there.</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. You knew since your training days?</p> <p>24 DR. LAING:</p> <p>25 A. Right, but there wasn't--I wasn't picking up</p>

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1 that I was seeing those consistently in the
 2 clinic to the point where it raised any sort
 3 of concern.
 4 CHAYTOR, Q.C.:
 5 Q. And nobody was tracking that?
 6 DR. LAING:
 7 A. Nobody was tracking it. Again it comes back
 8 to the fact that you have a whole bunch of
 9 different people involved, and, you know,
 10 there wasn't any--I cannot recall at that
 11 time. When I do recall it was as part of the
 12 panel because what would happen is that the
 13 decision was made to retest based on ER only,
 14 and that, you know, we would get these charts
 15 and we would open them up and we would look at
 16 what it was initially and what it was on
 17 repeat, and then we would look and we would
 18 see, oh, look, good, the first one was ER
 19 negative, PR 60 percent positive, we'd read
 20 down through the notes, they were started on
 21 appropriate adjuvant hormonal therapy, good,
 22 you know, and we'd say, no change in
 23 treatment, review of the chart shows the
 24 patient was on Tamoxifen and on we would go.
 25 And, you know, over time, we would see so many

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1 of these --
 2 CHAYTOR, Q.C.:
 3 Q. Again and again that you started to --
 4 DR. LAING:
 5 A. Again and again in the panel, and we called
 6 them the saved by the PR's and, you know, it
 7 was interesting to look--and as I said
 8 earlier, some of those patients, it almost
 9 seemed that they flipped, so that they were ER
 10 negative/PR positive and became PR positive/ER
 11 negative, and for some of them, they went from
 12 negative positive to positive for both.
 13 CHAYTOR, Q.C.:
 14 Q. Uh-hm.
 15 DR. LAING:
 16 A. And when we had the final numbers, there were
 17 130 some odd of those people. We'll talk
 18 about that I know, but just--you know, that's
 19 when it struck home in those early days of the
 20 panel and we all--I can remember us all
 21 looking around and saying, my goodness, now
 22 that we sit down and look at this, we had more
 23 of these than we should have, but as time was
 24 going on, I didn't recognize it, and I don't
 25 remember any discussions or even --

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1 CHAYTOR, Q.C.:
 2 Q. None of your colleagues brought it to your
 3 attention in the years prior either?
 4 DR. LAING:
 5 A. No.
 6 CHAYTOR, Q.C.:
 7 Q. Nobody queried that as being something passing
 8 strange?
 9 DR. LAING:
 10 A. No.
 11 CHAYTOR, Q.C.:
 12 Q. That was never brought up?
 13 DR. LAING:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. Is there any correlation between gender and
 17 hormone receptivity?
 18 DR. LAING:
 19 A. Oh, in terms of male breast cancer patients?
 20 CHAYTOR, Q.C.:
 21 Q. Yes.
 22 DR. LAING:
 23 A. Again, you know, if you look at men with
 24 breast cancer, they're uncommon, but they're
 25 still about one percent of all the breast

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1 cancers that we see. It's generally thought
 2 that again the majority of men with breast
 3 cancer end up having hormone receptor positive
 4 disease. There is very little data, close to
 5 none, on actually how they respond to hormonal
 6 therapy aside from anecdotal information and--
 7 because if you look at all of the breast
 8 cancer trials, they're done in women. There
 9 are actually no breast cancer trials that--
 10 large breast cancer trials done that include
 11 men. If you look, though, at the experience
 12 in the clinic, they do respond to hormonal
 13 therapy and they can respond to Tamoxifen, and
 14 they can also interestingly respond to
 15 aromatase inhibitors because there is some
 16 estrogen made even in males.
 17 CHAYTOR, Q.C.:
 18 Q. And so the thinking--generally the knowledge
 19 was that they tend to be hormone receptor
 20 positive. Would that have been known in--we
 21 had Mr. White testify here, and he was
 22 diagnosed in 1999. Would that have been known
 23 in 1999?
 24 DR. LAING:
 25 A. I mean, I knew it as a resident, so I would

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1 have to say from my point of view, yes, but
 2 again it wasn't an all or none phenomena.
 3 CHAYTOR, Q.C.:
 4 Q. An absolute.
 5 DR. LAING:
 6 A. It wasn't an absolute, it was just--I mean,
 7 when I look back to my training, I would have
 8 certainly--I've seen male breast cancer
 9 patients and I've cared for some in my own
 10 practice, and, you know, the thing that I
 11 remember being taught was that men who present
 12 with breast cancer, they all get a mastectomy,
 13 they all get radiation because of this whole
 14 idea of having a smaller amount of breast
 15 tissue, and that you would otherwise treat
 16 them the same way that you would treat a
 17 female. So you would look at the same
 18 prognostic factors, you would determine
 19 whether or not they needed chemotherapy in the
 20 same way, and that, you know, if they were
 21 hormone receptor positive, which many of them
 22 would be, then you would treat them with
 23 hormones. More recently, and I mean more
 24 recently as in the last few years, there have
 25 been some--I've had some conversations with

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1 people regarding aromatase inhibitors for
 2 males with breast cancer, and there is some at
 3 least experience in clinics that these
 4 patients seem to respond, and I do have a
 5 patient of my own who's responding well to an
 6 aromatase inhibitor who has metastatic male
 7 breast cancer.
 8 CHAYTOR, Q.C.:
 9 Q. And I take it any males that came up in the
 10 review then were treated no differently in
 11 terms of considerations as to whether or not
 12 they would now be offered Tamoxifen or some
 13 other treatment?
 14 DR. LAING:
 15 A. That's correct.
 16 CHAYTOR, Q.C.:
 17 Q. They were treated the same as the females?
 18 DR. LAING:
 19 A. Yes.
 20 THE COMMISSIONER:
 21 Q. Ms. Chaytor, we're getting near the luncheon
 22 break, so wherever you can find a convenient
 23 spot.
 24 CHAYTOR, Q.C.:
 25 Q. Thank you. Doctor, along life's way, I guess,

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1 from the time of your training up until, say,
 2 2005, when all of this starts to unfold, had
 3 you ever been aware of any concerns regarding
 4 the reliability of ER and PR testing on a
 5 global or wider--global or national basis in
 6 terms of any limitations with the tests,
 7 anything like that ever brought to your
 8 attention?
 9 DR. LAING:
 10 A. As part of our training, we would have been
 11 told that this is a test that there were
 12 certainly false negatives. The--you know,
 13 you're looking for something--you're looking
 14 to see if these receptors are present, and,
 15 you know, my training and my understanding at
 16 that time was that, you know, there was a
 17 possibility that you could get a result that
 18 was negative, but really the receptors were
 19 there. I don't remember at that time knowing
 20 what that accepted percentage was or those
 21 sorts of things, and, of course, subsequently
 22 through this process, you know, I now know all
 23 about the importance of getting the sample,
 24 getting it to the lab, fixation, and all those
 25 other issues, but really as an oncologist and

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1 my oncology training, that wouldn't have been
 2 things that had been discussed or taught to us
 3 or anything like that.
 4 CHAYTOR, Q.C.:
 5 Q. But you were aware that there is such a thing
 6 as there could be false negatives, and would
 7 that cause you then to be more vigilant in
 8 terms of questioning any results that you
 9 would get from an ER/PR test? For example, if
 10 the result that you received didn't really
 11 meet your expectations or what you would
 12 expect for the vast majority of patients in a
 13 particular category, whether it's type of
 14 disease, PR positivity --
 15 DR. LAING:
 16 A. Sure, yeah. I mean, I think in general in
 17 medicine, you know, we know that there's
 18 limitations in many of the things that we do.
 19 When I look back over the early days of my
 20 practice, I can probably think about one or
 21 two times when I may have asked for an ER test
 22 to be repeated because it was an elderly
 23 patient who had a well differentiated tumour
 24 and it was more just trying to see, you know,
 25 if--because I wasn't--I didn't feel that that

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1 person could tolerate chemotherapy, I may have
 2 asked for, you know, could you please review
 3 this to make sure that this is negative, but
 4 it was--the two instances that I can think
 5 back to where in people that were older, and
 6 again, you know, getting back to the general
 7 idea that the older you are, the more likely
 8 you are to be positive, but--and then, of
 9 course, the other instances were the ones that
 10 we're going to talk about specifically where
 11 we had differing reports on two different
 12 patients.
 13 CHAYTOR, Q.C.:
 14 Q. So you never asked to have a test repeated
 15 because it was a lobular, invasive lobular,
 16 until the --
 17 DR. LAING:
 18 A. That's right, yeah.
 19 CHAYTOR, Q.C.:
 20 Q. Until the index?
 21 DR. LAING:
 22 A. Yes, and again, as I said earlier, when I look
 23 back, you know, and again looking back
 24 retrospectively is always different, but, you
 25 know, when I looked back at these patients

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1 charts, when I read through my notes, there
 2 wasn't anything obviously at the time that
 3 made me think, oh, my goodness, this person is
 4 lobular, should I question this, and I think
 5 it was because of the way that they presented
 6 with the poorly differentiated and the
 7 advanced disease in that instance.
 8 CHAYTOR, Q.C.:
 9 Q. Thank you, Commissioner. This is a good time
 10 to break.
 11 THE COMMISSIONER:
 12 Q. All right then, we'll meet at five after two.
 13 (BREAK)
 14 THE COMMISSIONER:
 15 Q. Ms. Chaytor.
 16 CHAYTOR, Q.C.:
 17 Q. Thank you, Commissioner. Good afternoon, Dr.
 18 Laing.
 19 DR. LAING:
 20 A. Good afternoon.
 21 CHAYTOR, Q.C.:
 22 Q. Dr. Laing, we know that Dr. Siddiqui sat on
 23 the surgical pathology review committee. I
 24 think you mentioned this morning in your
 25 evidence that Dr. Gardiner chose him for that

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1 position. I think Dr. Siddiqui was of the
 2 understanding that you, in fact, invited him
 3 to participate or sit on that committee?
 4 DR. LAING:
 5 A. I do recall that at that time Dr. Gardiner was
 6 the Medical Director of the Newfoundland
 7 Cancer Treatment and Research Foundation, so
 8 we would have had regular weekly meetings with
 9 him. So that would have been Dr. Ganguly who
 10 was the Director of Radiation Oncologists, and
 11 as well myself as Director of Medical
 12 Oncology, and when the issue of having some
 13 representation from the NCTRF on that
 14 committee came up, Dr. Gardiner had suggested
 15 that perhaps it would be somebody other than
 16 the directors, that we would ask another one
 17 of the oncologists to sit on that committee.
 18 Perhaps I had recommended Dr. Siddiqui, I
 19 don't recall that, but I think that the actual
 20 decision to appoint someone would have come
 21 from the medical director.
 22 CHAYTOR, Q.C.:
 23 Q. Okay, and what did you understand Dr.
 24 Siddiqui's role would be on the committee?
 25 DR. LAING:

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1 A. That they wished to have someone who was a
 2 clinician who was involved in the cancer
 3 clinic itself with the care of patients, I
 4 guess to be able to act in an advisory role if
 5 there were issues that came up to the
 6 connection between pathology and oncology.
 7 CHAYTOR, Q.C.:
 8 Q. And did you expect him to fill any sort of
 9 liaison between information from the medical
 10 oncologists to the committee and vice versa?
 11 DR. LAING:
 12 A. Usually that would happen at our senior
 13 management committees. So those people who
 14 were representatives on various committees,
 15 that would filter back through Dr. Gardiner
 16 for information to our senior management
 17 meeting. So I would have expected that that
 18 committee would have followed the same
 19 structure that we were used to.
 20 CHAYTOR, Q.C.:
 21 Q. So Dr. Siddiqui, in sitting on that committee,
 22 his reporting role from that committee would
 23 not have been to you, but directly to Dr.
 24 Gardiner?
 25 DR. LAING:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And why would that be?
 4 DR. LAING:
 5 A. Because Dr. Gardiner was the medical director
 6 at that time, and that this was--Dr. Siddiqui
 7 wasn't simply representing medical
 8 oncologists, but he was an oncologist who was
 9 chosen to sit on that committee. There was
 10 not a radiation oncologist who was represented
 11 on that committee.
 12 CHAYTOR, Q.C.:
 13 Q. And did you ever receive any information or
 14 feedback from Dr. Siddiqui with respect to
 15 anything that was being discussed or any
 16 issues that came before that committee?
 17 DR. LAING:
 18 A. No.
 19 CHAYTOR, Q.C.:
 20 Q. And do you know whether or not anyone else
 21 did, whether or not Dr. Gardiner or any other
 22 oncologist received such information?
 23 DR. LAING:
 24 A. No, I don't know.
 25 CHAYTOR, Q.C.:

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

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1 CHAYTOR, Q.C.:
 2 Q. And when was that?
 3 DR. LAING:
 4 A. It would have been well into 2005, if not into
 5 2006 before I ever saw this memo.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and if we could have, please, P-0113,
 8 and these, Doctor, are a series of memos that
 9 we're familiar with here at the Commission,
 10 and they're written by Dr. Ejeckam.
 11 DR. LAING:
 12 A. Uh-hm.
 13 CHAYTOR, Q.C.:
 14 Q. And the first is dated April 4th, 2003, the
 15 second is May 2nd, 2003. Both of these are
 16 addressed to pathologists.
 17 DR. LAING:
 18 A. Yes.
 19 CHAYTOR, Q.C.:
 20 Q. And copied to others, but not oncologists.
 21 DR. LAING:
 22 A. That's correct.
 23 CHAYTOR, Q.C.:
 24 Q. And June 19, 2003, addressed to Mr. Gulliver
 25 and that one is copied to Drs. Robb, Cook,

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

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<p>1 the memos, for example, the April 4th memo 2 where it refers to stains including, "The 3 ER/PR stains have remained unreliable, 4 erratic, and, therefore, unhelpful for 5 diagnostic purposes", what about the message 6 that's being portrayed there, did that come to 7 your attention at the time? 8 DR. LAING: 9 A. Absolutely not, and I had no idea that this 10 was something that was of concern to the 11 pathologists. That had never been brought to 12 my attention. 13 CHAYTOR, Q.C.: 14 Q. Okay, and again the fact that this issue had 15 happened in 2003, I understand you to say that 16 you didn't see the memo until perhaps into 17 2006, well into the retesting process. 18 DR. LAING: 19 A. Yes. 20 CHAYTOR, Q.C.: 21 Q. But the fact that there had been a suspension 22 of ER/PR testing in 2003, or that some 23 problems had been detected in 2003, when did 24 you first learn that? 25 DR. LAING:</p>	<p>1 struck home with me, that this was not 2 something that I had seen. When we had some 3 discussions through the process of the review, 4 the pathologist did mention to us, and I 5 believe that was well into when we were, you 6 know, meeting with the tumour panel and 7 panelling patients that there was a period of 8 time that there had been some difficulty. 9 First of all, it was around 2002, but these 10 were not things that I had seen, and the other 11 issue--because again, you know, I sort of 12 thought about this. I do not recall a time 13 period during this time that we had a delay in 14 receiving back test results. When we would 15 see patients in the clinic, it is sometimes, 16 but not usual and not often that we would not 17 have the ER/PR results back yet whilst we were 18 seeing those patients, and I do not recall at 19 any time period that there was a prolonged 20 delay in receiving this information back. So 21 if a referral was sent to the Cancer Centre, 22 the new patient referral clerks would gather 23 all the information and there's a checklist. 24 So for a new breast cancer referral, one of 25 the items on the checklist is the ER/PR</p>
<p>Page 198</p> <p>1 A. When I first saw the memos. In fact, I'm not 2 certain if this was the memo or if it was one 3 of them that the Premier had, and had made 4 reference to, and that, I believe, was well 5 into 2006. 6 CHAYTOR, Q.C.: 7 Q. That was in 2007, in fact. 8 DR. LAING: 9 A. In fact, it might have been around May of 10 2007. 11 CHAYTOR, Q.C.: 12 Q. You're talking about the Premier publicly 13 having the memo? 14 DR. LAING: 15 A. Yes. 16 THE COMMISSIONER: 17 Q. I'm sorry, are you saying you didn't know 18 about it until then? 19 DR. LAING: 20 A. I did not ever see a copy of--I'm not sure 21 which of these memos were--I think it was this 22 one because I do recall that when I first 23 actually read that first statement that said 24 that they were "unreliable, erratic, and, 25 therefore, unhelpful", you know, that really</p>	<p>Page 200</p> <p>1 results, and so sometimes going to the clinic 2 to see a new patient, I may not have had those 3 results back because of some delay in getting 4 those, but never during this time in 2002 or 5 2003 do I remember there being a long delay in 6 any patients, or that there were a lot of 7 patients delayed. So I guess what I'm trying 8 to say is I didn't see these memos, nor did I 9 notice at that time any change in practice 10 that would have made me question, well, why 11 are we not getting these back, you know, is 12 there a problem, what's the delay. 13 THE COMMISSIONER: 14 Q. Excuse me, Dr. Laing, I just want to make sure 15 that I have your evidence clear. 16 DR. LAING: 17 A. Okay. 18 THE COMMISSIONER: 19 Q. Is your reference to the pathologist having 20 mentioned this shutdown period during 21 panelling your first information regarding Dr. 22 Ejeckam's action? 23 DR. LAING: 24 A. Yes, it is. 25 THE COMMISSIONER:</p>

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<p>1 Q. And presumably you would not have actually 2 seen the memos at that time, you just heard 3 about it? 4 DR. LAING: 5 A. Heard about them. 6 THE COMMISSIONER: 7 Q. And can you be more precise about when you 8 actually first saw the memos or any one of 9 them? 10 DR. LAING: 11 A. I would have first seen this one when the 12 Premier made it public knowledge. 13 THE COMMISSIONER: 14 Q. So 2007? 15 DR. LAING: 16 A. So that would have been in the spring of 2007, 17 and though it was--I remember reading it and 18 the impact that it had, seeing that there, and 19 not having known it at the time, but also not 20 having seen it through the process of these 21 discussions. I guess there hadn't been an 22 opportunity for someone to say, here, these 23 are the minutes or the memos from Dr. Ejeckam. 24 THE COMMISSIONER: 25 Q. And there are, in fact, three memos.</p>	<p>1 written to Terry Gulliver, and that's June 2 19th, 2003. 3 DR. LAING: 4 A. This is the one that I saw--this is the one 5 that the Premier had, the third one. 6 Subsequently I've seen all three of them, but 7 this I recall, Commissioner, was the first 8 one, the one that was from Dr. Ejeckam to Dr. 9 Gulliver. That was the first time that I had 10 seen this in writing, and subsequent to that, 11 I would have seen all three of those memos. 12 CHAYTOR, Q.C.: 13 Q. And what did you do upon learning that this 14 memo existed, the June 19, 2003--you're saying 15 you learned about that when the Premier used 16 it publicly? 17 DR. LAING: 18 A. Yes. 19 CHAYTOR, Q.C.: 20 Q. So what did you do? 21 DR. LAING: 22 A. What did I do? 23 CHAYTOR, Q.C.: 24 Q. Yes, what did you do upon learning that this 25 memo existed? Did you make inquiries of</p>
<p>1 DR. LAING: 2 A. Okay. 3 THE COMMISSIONER: 4 Q. Did you see the three of them or only one of 5 them? 6 CHAYTOR, Q.C.: 7 Q. This is the first, this is the second, it's at 8 page two. 9 DR. LAING: 10 A. Yeah. 11 CHAYTOR, Q.C.: 12 Q. And this one talks about May 2, 2003, "I'm 13 glad to inform you that we have rectified the 14 difficulties". 15 DR. LAING: 16 A. Yes. 17 CHAYTOR, Q.C.: 18 Q. And then sets out a number of--some 19 information for the pathologists. 20 DR. LAING: 21 A. Uh-hm. 22 CHAYTOR, Q.C.: 23 Q. Issues of fixation, pointing out types of 24 tumours that would be expected to be ER 25 positive. Then the third memo is the one</p>	<p>1 anyone, did you ask what is this, where can I 2 get a copy? 3 DR. LAING: 4 A. Yes. So then I would have--we were provided 5 then with a copy of this to read, as well as 6 the other ones pertaining to it, and I believe 7 perhaps that it was either--by this time, it 8 was either Dr. Howell or perhaps Dr. Denic who 9 had provided us with a copy of it. I simply 10 felt it was something that I recognized that I 11 hadn't seen or known about during that time 12 period, but I felt that perhaps it would have 13 been something that through this whole process 14 and the review that we would have been seeing 15 and had looked at as the oncologists prior to 16 seeing this come out the way that it did. 17 CHAYTOR, Q.C.: 18 Q. So sometime in April of 2007, or thereafter, 19 you were provided copies. Who gave you the 20 copies? 21 DR. LAING: 22 A. As I said, I believe it was either Dr. Howell 23 or Dr. Denic, but I can't recall. 24 CHAYTOR, Q.C.: 25 Q. And did you ask them why wasn't this brought</p>

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<p>1 to our attention beforehand as the oncologist 2 looking into this matter? I take it you felt 3 it would have been helpful for you to have 4 known about this?</p> <p>5 DR. LAING: 6 A. I think it would have been helpful--well, I 7 guess there's two points when it would have 8 been helpful. It would have been helpful, 9 obviously, to know back at the time in 2003, 10 and I also felt that if there had have been, 11 you know, such a discussion that--you know, I 12 suspect that the pathologists were looking at 13 this when they were thinking about sort of 14 things from their side with the retesting, and 15 perhaps didn't--because it was a lab issue and 16 things, didn't feel that they, you know, 17 needed to bring it forth to our attention and 18 to show it to us. I guess it wasn't until I 19 saw it and sort of read how it was laid out, 20 that it really made it clear that this was 21 something that we should have known in 2003. 22 I don't believe that the pathologists or Dr. 23 Cook or Dr. Williams, and subsequently Dr. 24 Howell or Dr. Denic didn't show it to us on 25 purpose, I just think that it was something</p>	<p>1 that we might want to see and read.</p> <p>2 CHAYTOR, Q.C.: 3 Q. So was that the explanation as to why it 4 wasn't given to you in 2003?</p> <p>5 DR. LAING: 6 A. No.</p> <p>7 CHAYTOR, Q.C.: 8 Q. That's the explanation as to why it wasn't 9 given to you in 2005?</p> <p>10 DR. LAING: 11 A. Right, when we were--when we were sitting 12 around and having--working together with these 13 people in a panel process. I'm not sure why 14 it wasn't given in 2003. I was not part of 15 those discussions.</p> <p>16 CHAYTOR, Q.C.: 17 Q. And --</p> <p>18 DR. LAING: 19 A. I actually wasn't there at this particular 20 point. I was on leave again.</p> <p>21 CHAYTOR, Q.C.: 22 Q. In June of 2003?</p> <p>23 DR. LAING: 24 A. Yes.</p> <p>25 CHAYTOR, Q.C.:</p>
<p>Page 206</p> <p>1 that they were dealing with on the laboratory 2 side. It was just that, you know, once it was 3 out there and it was something that, you know, 4 the people said, well, didn't you see that or 5 didn't you know it, and I say, no, but then 6 obviously we sat down and we looked at it, and 7 we did address some of the limitations that we 8 know with the test and some of the possible 9 things, but, of course, these were also 10 factors that we had heard about through the 11 peer review process, if you will. So, I mean, 12 by that time, this was things that I would 13 have heard about through different venues, but 14 I think it was just that I felt that at some 15 point in the beginning of this process, it 16 would have been helpful for us to have sat 17 down and looked at this.</p> <p>18 CHAYTOR, Q.C.: 19 Q. And what explanation was given to you as to 20 why it hadn't been provided to you beforehand?</p> <p>21 DR. LAING: 22 A. I think it was just that it was something that 23 was, you know, part of the laboratory, part of 24 the pathology department, and it was more of a 25 --not a thought that it would be something</p>	<p>Page 208</p> <p>1 Q. And when were you gone in 2003, what time 2 period?</p> <p>3 DR. LAING: 4 A. From June 17th, the early arrival of my second 5 child, until January of 2004.</p> <p>6 CHAYTOR, Q.C.: 7 Q. Until January '04?</p> <p>8 DR. LAING: 9 A. Yes.</p> <p>10 CHAYTOR, Q.C.: 11 Q. So you were there in April when the shutdown 12 occurred?</p> <p>13 DR. LAING: 14 A. Oh, certainly. I was there in April, and 15 perhaps that's why --</p> <p>16 CHAYTOR, Q.C.: 17 Q. And you were there in May when it started up 18 again?</p> <p>19 DR. LAING: 20 A. Yes, so I actually--I left right when I had 21 the baby.</p> <p>22 CHAYTOR, Q.C.: 23 Q. So the only time you wouldn't--you were gone 24 then was the third memo.</p> <p>25 DR. LAING:</p>

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<p>1 A. Yes, but I didn't see either of them at that 2 time. 3 CHAYTOR, Q.C.: 4 Q. And I take it from what you're saying, as 5 Director of Medical Oncology at the time, and 6 as an oncologist practising within the same 7 institution, this should have been brought to 8 your attention? 9 DR. LAING: 10 A. Yes. 11 CHAYTOR, Q.C.: 12 Q. Okay, and had it been, Doctor--for example, if 13 we look at the first memo and it's worded to 14 say that ER and PR have remained unreliable, 15 erratic, and, therefore, unhelpful for 16 diagnostic purposes, had this been brought to 17 your attention, what would you have done in 18 2003? 19 DR. LAING: 20 A. I would have contacted Dr. Ejeckam and would 21 have wanted to know for what period of time 22 had this been an issue in the lab, was this 23 something that had been happening for this 24 last month, was this something that had been 25 going on perhaps for a longer period of time,</p>	<p>1 A. Yes. 2 CHAYTOR, Q.C.: 3 Q. And it also refers to this consensus statement 4 under paragraph five, reporting or ER/PR, and 5 several formulae are in the literature for 6 positive results, ER plus greater or equal to 7 5 percent nuclear staining, ER plus 10 percent 8 of tumour staining, ER positive, 1 percent 9 shown to benefit from endocrine treatment and 10 the reference to the consensus statement. 11 DR. LAING: 12 A. Uh-hm. 13 CHAYTOR, Q.C.: 14 Q. And that's in 2000, National Institute of 15 Health, and we spoke about that earlier. 16 DR. LAING: 17 A. Right. 18 CHAYTOR, Q.C.: 19 Q. That's the consensus statement that we spoke 20 about. 21 DR. LAING: 22 A. Yes. 23 CHAYTOR, Q.C.: 24 Q. Okay, and this is where it says, "Being any 25 positive nuclear ER immunostaining is</p>
<p>Page 210</p> <p>1 and then, you know, would have had to say, 2 well, what are we going to about this now, 3 we've had some test results come out that 4 we've acted upon, treated patients in the 5 clinic based upon those results, and would 6 have wanted to go back and look at those 7 again. 8 CHAYTOR, Q.C.: 9 Q. So what was initiated in May of 2005 -- 10 DR. LAING: 11 A. Would have done back then. 12 CHAYTOR, Q.C.: 13 Q. Would have been done back then had it been 14 brought to your attention? 15 DR. LAING: 16 A. Yes. 17 CHAYTOR, Q.C.: 18 Q. The second memo, May 2nd, 2003 -- 19 DR. LAING: 20 A. Uh-hm. 21 CHAYTOR, Q.C.: 22 Q. And this refers to results of the immunostains 23 may be affected by, and there's different 24 issues regarding fixation mentioned. 25 DR. LAING:</p>	<p>Page 212</p> <p>1 considered to be a positive result". 2 DR. LAING: 3 Q. Do you know if that was taken directly from 4 the consensus statement? 5 CHAYTOR, Q.C.: 6 Q. We haven't compared the quote, but it is 7 consistent with what you were saying in terms 8 of any positive nuclear ER immunostaining, so 9 I just wanted to bring that to your attention 10 that this is the statement that you were 11 referring to. 12 DR. LAING: 13 A. Right. 14 CHAYTOR, Q.C.: 15 Q. Have you compared it, do you know the answer? 16 DR. LAING: 17 A. It doesn't say exactly that, it's similar, but 18 it does not say exactly that. 19 CHAYTOR, Q.C.: 20 Q. Okay, but your point earlier was that the one 21 percent -- 22 DR. LAING: 23 A. It just says hormone receptor. 24 CHAYTOR, Q.C.: 25 Q. It appears wasn't referred to.</p>

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<p>1 DR. LAING: 2 A. Right, it doesn't--it actually--it doesn't use 3 any cutoffs in the consensus statement. It 4 says that--it starts out by saying that, 5 "Irregardless of age, menopausal status, a 6 patient should be considered", and then it 7 says, "While there's some evidence that the 8 greater the staining, the greater the 9 benefit", something around that--it says any 10 staining or any positive results, it doesn't 11 use thresholds or cutoff, "may be considered 12 for hormonal therapy". 13 CHAYTOR, Q.C.: 14 Q. Okay. I'm just looking at a portion of it 15 here now and it says, "While the likelihood of 16 benefit correlates with the amount of hormone 17 receptor protein, tumour cell patients with 18 any extent of hormone receptor in their tumour 19 cells may still benefit from the hormonal 20 therapy". 21 DR. LAING: 22 A. Yes. 23 CHAYTOR, Q.C.: 24 Q. So does that sound consistent with your 25 recollection of the paper?</p>	<p>1 note that went prior to our meeting with 2 Minister Ottenheimer, I believe, in 2005. 3 CHAYTOR, Q.C.: 4 Q. Yes. 5 DR. LAING: 6 A. So--I'm not sure if I saw it before that 7 meeting or after the meeting, but, you know, 8 I'd be very aware of the content -- 9 CHAYTOR, Q.C.: 10 Q. You'd be aware of--so sometime around July, 11 August, of 2005? 12 DR. LAING: 13 A. Yes. 14 CHAYTOR, Q.C.: 15 Q. You were aware of this. Doctor, on page three 16 of that exhibit, that briefing note, it's 17 written, "Eastern Health, Vice President of 18 Quality Diagnostic and Medical Services, Dr. 19 Robert Williams, has also asked that an 20 investigation be conducted into the five week 21 stoppage of immunoperoxidase staining for 22 ER/PR receptors in 2003 by Dr. Ejeckam". So, 23 Doctor, would you not have been aware from 24 this memo then in July or August, 2005, that 25 there had been an issue in 2003?</p>
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<p>1 DR. LAING: 2 A. Yes. 3 CHAYTOR, Q.C.: 4 Q. Okay. Doctor, regardless of not having seen 5 the memos until into 2007, and not knowing the 6 specific content of the memos, were you 7 otherwise aware in this time period, 2002, 8 2003, any of that time period prior to 2005, 9 were you aware of any problems in the lab or 10 concerns with ER/PR staining? 11 DR. LAING: 12 A. No, I was not. 13 CHAYTOR, Q.C.: 14 Q. If we could look, please, at P-0075. This is 15 a briefing note. 16 DR. LAING: 17 A. Yes. 18 CHAYTOR, Q.C.: 19 Q. You've seen this, I take it, have you, Doctor? 20 DR. LAING: 21 A. I have, yes. 22 CHAYTOR, Q.C.: 23 Q. And when did you first see this briefing note? 24 DR. LAING: 25 A. This was--this would have been the briefing</p>	<p>1 DR. LAING: 2 A. The--when we first started to meet with the 3 pathologists as part of the panel and have 4 some discussions, my understanding was that 5 the problem was in--that there may have been a 6 problem that went back to 2002. You'll recall 7 that as we went through the process with the 8 index case, there would have been some--you 9 know, we had picked some patients in the 10 clinic and they had retested and then there 11 was a small sample taken from 2002. So it was 12 my understanding that the period of concern 13 according to the pathologists had been in 14 2002. I'm not sure if the note from Dr. 15 Ejeckam is based on concerns that he had at 16 that exact time, in the spring of 2003, or if 17 they stem back to issues in 2002. 18 CHAYTOR, Q.C.: 19 Q. Okay. My question, though, was whether or 20 not, by having read this memo in 2005, July, 21 August, 2005, you would have been aware that 22 there was reference to an issue arising in 23 2003 which was identified by Dr. Ejeckam? 24 DR. LAING: 25 A. To me that, when I read that, I just thought,</p>

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1 okay, this is what the pathologists have been
2 talking to us about about the problem in 2002.
3 CHAYTOR, Q.C.:
4 Q. So you thought that should be 2002, not 2003.
5 And so then you would have been aware that
6 there had been a five-week stoppage of
7 staining for ER/PR receptors and you were
8 thinking it happened in 2002?
9 DR. LAING:
10 A. My recollection was that the problem, when I
11 first talked to Dr. Cook after the index case,
12 they had been concerned about the period of
13 time from 2002, which is why they picked
14 patients from that time period as to the
15 retesting. So I wasn't certain if this meant
16 that Dr. Ejeckam was concerned about what had
17 happened in 2002 and decided that he was going
18 to halt testing until he sorted things out.
19 So how long back, as I mentioned to you, that
20 would have been my first question to them was
21 how long has this been a concern, has this
22 been something going on in the lab for the
23 last three months or the last, you know,
24 couple of years, when did this exactly happen.
25 And to be quite honest with you, when I would

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1 read something like this, most of what I would
2 be focusing on would be the chronology of
3 events related to the index patient and, you
4 know, what Dr. McCarthy and I had done
5 surrounding that.
6 CHAYTOR, Q.C.:
7 Q. So regardless if it's 2002 or 2003, upon
8 reading this memo in July or August, 2005, you
9 would have become aware?
10 DR. LAING:
11 A. Yeah.
12 CHAYTOR, Q.C.:
13 Q. If you weren't before, you would have become
14 aware that there was some issue -
15 DR. LAING:
16 A. Right.
17 CHAYTOR, Q.C.:
18 Q. - raised by Dr. Ejeckam which caused a
19 shutdown or a stoppage of the staining for a
20 period of time?
21 DR. LAING:
22 A. For a brief period of time.
23 CHAYTOR, Q.C.:
24 Q. Okay. So you were aware of that then in July
25 or August of 2005?

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1 DR. LAING:
2 A. If I picked it up on that by reading that
3 memo, certainly. But as I said, my first
4 recollections of a concern were from my
5 conversations with Dr. Cook regarding the 2002
6 time period.
7 CHAYTOR, Q.C.:
8 Q. Okay. And what did Dr. Cook tell you about
9 the 2002 time period, why were they concerned
10 about that time period?
11 DR. LAING:
12 A. That when they--well, let me just stop and
13 think. During 2002 when they went back and
14 looked at the percent of positivity, I'm not
15 sure if that was one of the years, because Dr.
16 Cook and Dr. Williams had some summary numbers
17 of the percent of overall tumours that were
18 ER/PR by year and I know that in one of--
19 sometime during that time there were instead
20 of being around 75 percent, which is what's
21 suggested in the literature, that there was a
22 lower number. But I don't, you know, I don't
23 recall him telling me specifically that there
24 was a problem with fixation or that there was
25 a problem with something else. You know, at

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1 that time my main focus was on, you know, the
2 patients in the clinic and really, you know,
3 the issues related to the pathology lab and
4 all that were being handled directly by Dr.
5 Cook at that time.
6 CHAYTOR, Q.C.:
7 Q. So, Doctor, prior to 2005 you said you weren't
8 aware of any issues or concerns regarding the
9 results -
10 DR. LAING:
11 A. That's right.
12 CHAYTOR, Q.C.:
13 Q. - coming from the lab. Did you ever have
14 reason or cause to have an ER/PR test
15 repeated?
16 DR. LAING:
17 A. Yes.
18 CHAYTOR, Q.C.:
19 Q. Okay. And under what circumstances did you
20 ask to have that done and did you have a
21 changed result?
22 DR. LAING:
23 A. Right.
24 CHAYTOR, Q.C.:
25 Q. And this is again, of course, prior to what

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<p>1 happens in 2005.</p> <p>2 DR. LAING:</p> <p>3 A. Right. So I can recall three instances. Two</p> <p>4 of them were patients that I had who were</p> <p>5 elderly patients with breast cancer who had</p> <p>6 ER/PR tumours and who I was not prepared to</p> <p>7 offer them chemotherapy because of their</p> <p>8 comorbidities and things. And so I asked if</p> <p>9 they would recheck the ER/PR because they came</p> <p>10 back as negative and the test results were</p> <p>11 still negative; there was no change. And</p> <p>12 that's, you know, kind of sitting back and</p> <p>13 sort of searching through and remembering</p> <p>14 calling Dr. Chittal at one time to ask him</p> <p>15 that. The second instance was I had a</p> <p>16 patient, and I'm not sure what year it was,</p> <p>17 but I think it was 2002, 2003.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. I believe it would be July, 2002.</p> <p>20 DR. LAING:</p> <p>21 A. Okay, so it was in 2002. Who was referred to</p> <p>22 me from Dr. Kwan. And this lady had had her</p> <p>23 initial biopsy which showed that she had a</p> <p>24 breast cancer done in Clarendville.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 and the second one was done through the lab in</p> <p>2 St. John's. The result from the Clarendville</p> <p>3 testing was positive and the result from the</p> <p>4 lab in St. John's was negative. So because of</p> <p>5 this I asked if they would repeat the testing</p> <p>6 on the mastectomy specimen, which they did -</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. Who did you ask to do that?</p> <p>9 DR. LAING:</p> <p>10 A. I had asked the pathologist.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. So, Doctor, I take it it made--it didn't make</p> <p>13 any sense to you that the biopsy of the same</p> <p>14 tumour has positive and the residual of the</p> <p>15 tumour had a negative?</p> <p>16 DR. LAING:</p> <p>17 A. Right. So, you know, this was one of these</p> <p>18 situations we talked about this morning where</p> <p>19 you kind of said, hum, that's a bit strange,</p> <p>20 you know, we have these two differing results.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. And it caused you to question it and you asked</p> <p>23 for a repeat?</p> <p>24 DR. LAING:</p> <p>25 A. Right. So I asked for it to be repeated and</p>
<p>Page 222</p> <p>1 Q. And I just want to caution you that we're not</p> <p>2 using this particular patient's name.</p> <p>3 DR. LAING:</p> <p>4 A. Oh, of course.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. Okay.</p> <p>7 DR. LAING:</p> <p>8 A. Yeah, that's fine. And so then--so she had</p> <p>9 the biopsy done at an outside hospital.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. In Clarendville?</p> <p>12 DR. LAING:</p> <p>13 A. In Clarendville.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. Thank you. Sorry, I threw you off there.</p> <p>16 DR. LAING:</p> <p>17 A. Okay. And then she elected to come and have</p> <p>18 her mastectomy done in St. John's. And</p> <p>19 subsequently she was referred to me for</p> <p>20 adjuvant therapy. At the time of--so she had</p> <p>21 a biopsy and then at the time of her</p> <p>22 mastectomy there was residual disease and so</p> <p>23 both of those breast cancer specimens had</p> <p>24 ER/PR testing done. The first sample was done</p> <p>25 and reported through the lab in Clarendville</p>	<p>Page 224</p> <p>1 it came back as still being negative. And we</p> <p>2 talked about it, we being the pathologist and</p> <p>3 I.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. And who was that pathologist?</p> <p>6 DR. LAING:</p> <p>7 A. I'm not 100 percent certain. Was it Dr.</p> <p>8 Chittal? I'm not--perhaps you know, but -</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. Dr. Chittal is the name on the pathology</p> <p>11 report.</p> <p>12 DR. LAING:</p> <p>13 A. Yeah, so that's who it was.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. Is that who you would have had your</p> <p>16 conversation with?</p> <p>17 DR. LAING:</p> <p>18 A. Yes, it is, yeah.</p> <p>19 CHAYTOR, Q.C.:</p> <p>20 Q. Okay.</p> <p>21 DR. LAING:</p> <p>22 A. So I remember having a discussion then with</p> <p>23 the patient and explaining to her that we had</p> <p>24 two different results, that one was from the</p> <p>25 excisional biopsy, so it wasn't simply a</p>

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<p>1 needle core, it was actually, you know, a fair 2 piece of tissue, that there was some residual 3 tumour left at the time of the mastectomy, 4 that one was positive and the other one was 5 negative, that we had retested the negative 6 one and it had remained negative, that perhaps 7 there had been a clone of cells along the edge 8 that was different, but in any case, because 9 the biopsy was positive, that I would treat 10 her following the completion of our adjuvant 11 chemotherapy with adjuvant Tamoxifen, which I 12 did do.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. Okay. And did you inquire of the pathologist 15 as to how this could be, and, if so, what 16 explanation was given to you as to how there 17 could be two different results?</p> <p>18 DR. LAING:</p> <p>19 A. Well, when I explained the reason for the 20 retesting, because I had the two different 21 results, the pathologist did repeat the test. 22 And then when I spoke to him subsequently to 23 say, you know, it still came back as negative, 24 then the discussion to that could this just be 25 because of, you know, this was the rim, if you</p>	<p>1 positive but from the bit that was left, that 2 the mastectomy specimen was negative, but we 3 went ahead and treated her with adjuvant 4 Tamoxifen.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. Yes. And without Dr. McCarthy obviously not 7 being able to explain why that, in fact, might 8 be, why there might be these conflicting 9 results?</p> <p>10 DR. LAING:</p> <p>11 A. Yeah.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. And, Doctor, the test on the mastectomy 14 specimen and the retest were both done in St. 15 John's?</p> <p>16 DR. LAING:</p> <p>17 A. Yes, yes.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And you chose to go with the result from the 20 biopsy?</p> <p>21 DR. LAING:</p> <p>22 A. Yes.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And were you aware, this would have been 25 according to the record, the pathology record</p>
<p>Page 226</p> <p>1 will, of the tumour and it might have been 2 some sort of a sampling or a clone of the 3 cells that were ER/PR negative. You know, at 4 the time I didn't--I suspect because the two 5 results came back as being the same that I 6 didn't sort of think that there was a problem 7 with the test that had been done in St. John's 8 at all. And you know, when I explained it to 9 the patient, I said given the fact that we do 10 have one that's positive and that that was the 11 actual, you know, larger piece of the primary 12 tumour, then that's the one that I'm going to 13 base my treatment recommendations on and 14 that's what we did. The other thing that's 15 interesting about this case when we did review 16 it was subsequently this patient was left and 17 we had to transfer her care to another 18 oncologist. That was when I was on my second 19 maternity leave and Dr. McCarthy had assumed 20 this patient's care in my absence. And she 21 wrote a referral letter to the oncologist 22 where this patient was moving, to a different 23 province and had made a comment in the 24 referral letter, interestingly, this lady's, 25 you know, ER/PR status from her biopsy was</p>	<p>Page 228</p> <p>1 for this patient is July 26th, 2002. Does 2 that sound about the right time period?</p> <p>3 DR. LAING:</p> <p>4 A. Yes. You said that she came to see me as a 5 new patient in July of 2002, so the pathology 6 would have been just prior to that.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. Yes, okay. And I think the biopsy specimen 9 was done July 26th, 2002 and the mastectomy 10 was August 1st, 2002, the ER/PR first test.</p> <p>11 DR. LAING:</p> <p>12 A. So would have I had seen her then in August of 13 2002?</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. Sometime around that time period, I believe.</p> <p>16 DR. LAING:</p> <p>17 A. Okay, yeah.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And my question is when you had this 20 conversation with the pathologist, who you 21 believe would be perhaps Dr. Chittal, was 22 there any conversation as to where the biopsy 23 test, the ER/PR test on the biopsy had 24 actually taken place?</p> <p>25 DR. LAING:</p>

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<p>1 A. None whatsoever. I was under the assumption 2 that the staining had taken place at the 3 hospital in St. John's. The slides would come 4 in from the outside labs, they would have 5 staining done and then they would be sent back 6 for reporting to the pathologist in 7 Clarenville or whatever other region. So in 8 my conversations with Dr. Chittal, the 9 pathologist, I had not been given any idea 10 that the testing was actually done at a 11 different institute, nor did it indicate on 12 the pathology report that this was actually 13 sent out for testing. It wasn't until later 14 on, much later on, through the review process, 15 that we indeed discovered that Clarenville 16 Hospital was sending their specimens to Mount 17 Sinai Hospital for testing.</p> <p>18 CHAYTOR, Q.C.: 19 Q. And had you known in 2002 that the original 20 test had been conducted at Mount Sinai 21 Hospital, the original positive test, would 22 you have asked anything further or made any 23 other inquiries?</p> <p>24 DR. LAING: 25 A. You know, in retrospect knowing that the</p>	<p>1 DR. LAING: 2 A. Yes, it was.</p> <p>3 CHAYTOR, Q.C.: 4 Q. And what was the outcome of that?</p> <p>5 DR. LAING: 6 A. It was positive.</p> <p>7 CHAYTOR, Q.C.: 8 Q. It was positive?</p> <p>9 DR. LAING: 10 A. Yeah. I don't have the numbers in front of me 11 or know if it was ER/PR, what it was, but I do 12 know that she, this patient did come up in the 13 review panel and, of course, we remembered her 14 case, both Dr. McCarthy and I, because we had 15 both seen her at one time and that's when we 16 were aware that, in fact, the specimen had 17 gone to Mount Sinai for testing.</p> <p>18 CHAYTOR, Q.C.: 19 Q. So she fell into the category of somebody 20 whose test result had changed but she didn't 21 require change in treatment because you had 22 started her on hormonal therapy based on the 23 result of the biopsy test?</p> <p>24 DR. LAING: 25 A. Yes.</p>
<p>Page 230</p> <p>1 testing was done at a different hospital, I 2 may have, you know, asked that specifically to 3 Dr. Chittal, to say, well, this is the 4 Clarenville specimen and it was done at Mount 5 Sinai, you know, do you think that that might 6 be the reason why the test results are 7 different. I mean, if you get a test result 8 that's from a different province, then it may 9 raise a question. But, you know, at that time 10 I thought that the staining for both specimens 11 was done in St. John's, although the 12 reporting, the actual interpretation of it may 13 have been done by two separate pathologists. 14 And I cannot recall if Dr. Chittal did or did 15 not review, you know, the slide of the biopsy 16 from Clarenville. I don't remember that being 17 part of the conversation at all.</p> <p>18 CHAYTOR, Q.C.: 19 Q. Okay. And, Doctor, do you know was this 20 patient's negative ER test repeated through 21 the -</p> <p>22 DR. LAING: 23 A. Yes, it certainly was.</p> <p>24 CHAYTOR, Q.C.: 25 Q. - review process?</p>	<p>Page 232</p> <p>1 CHAYTOR, Q.C.: 2 Q. The test on the biopsy sample?</p> <p>3 DR. LAING: 4 A. Yes.</p> <p>5 CHAYTOR, Q.C.: 6 Q. Okay. Doctor, did--through the review process 7 were there any other of those types of cases 8 noted, where the biopsy or a test done on the 9 biopsy specimen, in fact, was different from 10 the results of a test on the mastectomy 11 specimen?</p> <p>12 DR. LAING: 13 A. Not that I can recall between the biopsy and 14 the mastectomy specimen. There may have been 15 another case where there was a difference 16 between the lymph nodes and the primary. And 17 there were some other cases we had had where 18 we had had a biopsy from the primary disease 19 and we had primary disease and we had a biopsy 20 from the chest wall recurrence. We had cases 21 where there was bilateral breast cancer and we 22 had biopsies from the left side and the right 23 side, and they would have -</p> <p>24 CHAYTOR, Q.C.: 25 Q. Which were different?</p>

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

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

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

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

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<p>1 something that's potentially curable. And one 2 of them was the instance that I mentioned to 3 you about a patient who presents with an 4 axillary lymph nodes, always think about 5 breast cancer. Someone who presents with 6 lymph nodes in the neck, head and neck, always 7 think about a head and neck primary. And 8 someone who presents with a tumour that's got 9 small round blue cells, always think about a 10 lymphoma. And that's where that comes from. 11 CHAYTOR, Q.C.: 12 Q. Okay, thank you. And if we could have, 13 please, C-0226? This is a request form, IHC 14 request form. And then attached at page 2 of 15 the exhibit we have a pathology report which 16 has been redacted. And this particular 17 pathology report there's an addendum No. 2 18 entered March 26th, 2003. 19 DR. LAING: 20 A. Um-hm. 21 CHAYTOR, Q.C.: 22 Q. And it's written, "I have received a request 23 from Dr. Kara Laing to review this case to 24 clarify lymph node status and ER/PR status. 25 In review this patient's original biopsy,</p>	<p>1 28th, 2003. And you'll see the addendum, 2 first addendum had indicated that 3 immunohistochemical staining for estrogen and 4 progesterone receptors is negative and that 5 had been entered on March 4th, 2003. Doctor, 6 do you recall the circumstances of this case 7 and why you would have asked Dr. Laing (sic.) 8 to review the case to clarify the lymph node 9 status and ER/PR status? 10 DR. LAING: 11 A. No. 12 CHAYTOR, Q.C.: 13 Q. Okay. 14 DR. LAING: 15 A. If I perhaps had the patient's file, I might 16 be able to, but not just by looking at this. 17 CHAYTOR, Q.C.: 18 Q. Okay. 19 DR. LAING: 20 A. Perhaps I could speak to why I had asked for 21 the lymph node status to be reviewed. 22 CHAYTOR, Q.C.: 23 Q. And I guess, Doctor, the main point being that 24 at this point in time, for whatever reason, 25 there would have been something to cause you</p>
<p>1 which was an axillary node biopsy, does show 2 extra extracapsular extension and lymph node 3 status is therefore" and we have here, I guess 4 this is - 5 DR. LAING: 6 A. That means extranodal. 7 CHAYTOR, Q.C.: 8 Q. Okay, thank you, Doctor. "Further, estrogen 9 and progesterone receptors have been reviewed 10 in both cases. In both case," and there's two 11 numbers given there. "In the earlier case ER 12 and PR are both weakly positive. In the later 13 case ER and PR are both negative. It is worth 14 noting that the areas of DCIS in" and then the 15 number again, "are positive for estrogen 16 receptors. Overall, given that the metastatic 17 lesion is weakly ER/PR positive, this is 18 interpreted as a tumour having ER/PR receptor 19 positivity. The discrepancy on the later case 20 is possibly on the basis of weak presence of 21 estrogen and progesterone receptors overall in 22 the tumour, with the possible existence of 23 hormone receptor negative clones within the 24 slide tested on the latter case." And it's 25 signature on file by Dr. Ford Elms on March</p>	<p>1 to ask to have and I don't want - 2 DR. LAING: 3 A. Does this sound like something in which there 4 was both lymph nodes and that done at a 5 separate time period? 6 CHAYTOR, Q.C.: 7 Q. And I don't know that - 8 DR. LAING: 9 A. I'm not sure. 10 CHAYTOR, Q.C.: 11 Q. - I'm not sure if that's from just the 12 pathology report. 13 DR. LAING: 14 A. No, I'm not sure. No, neither am I just by 15 looking at that. 16 CHAYTOR, Q.C.: 17 Q. But for whatever reason something caught your 18 attention and you asked to have both the lymph 19 nodes and the ER/PR status reviewed. And - 20 DR. LAING: 21 A. The lymph nodes would have been because if 22 there was extranodal extension, that would 23 have been an indication to consider adjuvant 24 radiation. So if it wasn't clear to me if 25 there was extranodal extension or not, I would</p>
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1 review that. And if there was extranodal
 2 extension, I would arrange for that patient to
 3 have an opinion from a radiation oncologist.
 4 CHAYTOR, Q.C.:
 5 Q. And, Doctor, if you hadn't done that and the
 6 addendum 1 were to go forward, this patient
 7 would have been treated as though he or she
 8 were hormone receptor negative, but upon
 9 review -
 10 DR. LAING:
 11 A. It just makes me curious because it does say
 12 that there's two separate specimens here and
 13 it looks like they're both from St. Clare's,
 14 they're both St. Clare's specimens, they're
 15 both from 2003, and but they're different
 16 surgical numbers. So I can only assume that
 17 perhaps because I did have those two separate
 18 things that, I had asked for it to be, but I
 19 just, I'm sorry, I can't tell you any more
 20 than that just by looking at that.
 21 CHAYTOR, Q.C.:
 22 Q. And at the end of the day, Dr. Elms has
 23 indicated that the second addendum is that the
 24 tumour is seen to be ER/PR positive?
 25 DR. LAING:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And if we could have--well, actually, Doctor,
 4 if I could ask you first then, do you know if
 5 anyone else or any other of your colleagues
 6 who had occasion to ask to have an ER/PR test
 7 repeated prior to 2005?
 8 DR. LAING:
 9 A. Not that I can recall right now off the top of
 10 my head, no.
 11 CHAYTOR, Q.C.:
 12 Q. And if one of your colleagues had had a test
 13 repeated and had a different result, would you
 14 expect to have known about that?
 15 DR. LAING:
 16 A. Not necessarily, no.
 17 CHAYTOR, Q.C.:
 18 Q. Okay. And why not?
 19 DR. LAING:
 20 A. Because they may not have seen to tell me
 21 about it.
 22 CHAYTOR, Q.C.:
 23 Q. So if something like this, something like this
 24 happens or what happens, we'll get to Peggy
 25 Deane's case, would it be required that an

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1 incident report of any type be filed?
 2 DR. LAING:
 3 A. We do have a process for incident reports at
 4 the Cancer Centre. It mostly, in our realm,
 5 deals with issues related to treatment, but
 6 certainly there are other--you know, pretty
 7 much anything that happens that a staff member
 8 identifies as, you know, a potential important
 9 event can be put forward on an incident
 10 report. But, you know, in medicine, there's
 11 often times where we get one report. We may,
 12 you know, look at something ourselves or we
 13 may get another report back on something that
 14 it doesn't necessarily always mean that you
 15 would fill out an incident report related to
 16 that. Perhaps radiology reports would be a
 17 good example. Unless there was something
 18 about that that, you know, the process of how
 19 the different result came was a cause of
 20 concern. I'm thinking of perhaps a laboratory
 21 test that you got back on a patient that just
 22 looked completely like nothing that you ever
 23 expected, and if you looked into that and
 24 found out it was because the specimen was
 25 mislabelled, then certainly that would be

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1 something that I would expect somebody to
 2 bring forward, because that could be something
 3 that could happen again, but with these sorts
 4 of instances, then, you know, it wouldn't be
 5 something that I would necessarily think that
 6 people would fill out an incident form about,
 7 no.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and if we could have, please, C-0175?
 10 And Doctor, this is a pathology report, again,
 11 and we've redacted anything that could--the
 12 patient's identifying information.
 13 DR. LAING:
 14 A. Okay.
 15 CHAYTOR, Q.C.:
 16 Q. And addendum one of this report is, and I
 17 believe that to be May 6th, 2003. "Stains
 18 have been delayed due to unavailability in the
 19 lab," and then it says "when compared to
 20 controls, the specimen is negative for
 21 HER2/neu, ER and PR."
 22 DR. LAING:
 23 A. Um-hm.
 24 CHAYTOR, Q.C.:
 25 Q. And then three days later, there's an addendum

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<p>1 two, May 9th, 2003. "The ER and PR were 2 repeated due to quality assurance issues. The 3 repeated stains show the following, ER 4 positive in 80 percent of the cells, PR 5 positive in ten percent of the cells. This 6 replaces the previous report," and then in 7 brackets "phoned to Cancer Clinic voice mail 8 on May 9th, 2003" and signed by Dr. Morris- 9 Larkin. Does this ring any bells to you? I'm 10 not suggesting that you were the medical 11 oncologist involved, but -</p> <p>12 DR. LAING: 13 A. Okay. 14 CHAYTOR, Q.C.: 15 Q. - you don't recall getting a phone message on 16 this particular matter? 17 DR. LAING: 18 A. No, I don't. 19 CHAYTOR, Q.C.: 20 Q. And you don't recall any of your colleagues 21 bringing it to your attention that this had 22 happened? 23 DR. LAING: 24 A. No. No, this isn't--I've not ever seen this 25 before. This is not something that rings any</p>	<p>1 I bring it to your attention, it's--I'm just 2 wondering if you recall any discussion around, 3 again, in May of 2003, around the same time 4 period, of a request to have an ER/PR 5 repeated? 6 DR. LAING: 7 A. No. 8 CHAYTOR, Q.C.: 9 Q. And having a change in the result? 10 DR. LAING: 11 A. None of this is anything that I'm familiar 12 with. 13 CHAYTOR, Q.C.: 14 Q. Familiar to you. 15 DR. LAING: 16 A. No. 17 CHAYTOR, Q.C.: 18 Q. Okay, and if I could have then, please, C- 19 0174? And Doctor, this is a case that we know 20 is Dr. Zaidi's case. 21 DR. LAING: 22 A. Okay. 23 CHAYTOR, Q.C.: 24 Q. And if I could just bring you to the fourth 25 page of this exhibit. Again, it's a pathology</p>
<p>1 bells with me, no. 2 CHAYTOR, Q.C.: 3 Q. Okay, and C-0228, please? And this is just 4 the requisition form, and on page two of the 5 exhibit, again we have a pathology report, and 6 if we go to page four, we have an addendum 7 one, which is entered March 17th, 2003, 8 "estrogen and progesterone, ER occasional 9 positive cells, less than one percent. PR 15 10 percent positivity, no controls available." 11 DR. LAING: 12 A. Um-hm. 13 CHAYTOR, Q.C.: 14 Q. And addendum two, "as requested, repeat. 15 Estrogen and progesterone receptors by 16 immunoperoxidase staining. Estrogen receptors 17 40 percent positivity. Progesterone receptors 18 73 positivity" and that's done on May 28th, 19 2003 and entered as the addendum, and in this 20 particular case, there was a request obviously 21 for a repeat. 22 DR. LAING: 23 A. Um-hm. 24 CHAYTOR, Q.C.: 25 Q. And this would have been--and the only reason</p>	<p>1 report and the first addendum is actually July 2 31st, 2002, "immunohistochemical staining is 3 negative for metastatic deposits." 4 DR. LAING: 5 A. Um-hm, on the sentinel node. 6 CHAYTOR, Q.C.: 7 Q. Yes, thank you, and addendum two, then August 8 29th, 2002, "immunohistochemical staining for 9 progesterone receptors is positive in 10 approximately 15 percent of lesional cells and 11 staining for estrogen receptors is negative," 12 and signed by Dr. Elms on August 29th. And 13 then on June 11th, 2003, "at the request of 14 Dr. Zaidi, immunohistochemical staining for 15 estrogen and progesterone receptors has been 16 repeated. Estrogen receptor show faint 17 positivity in approximately 10 to 15 percent 18 of lesional cells. Progesterone receptors are 19 unequivocally positive in approximately 75 20 percent of lesional cells." Do you recall-- 21 and I realize that you went on your maternity 22 leave shortly after this, but in June of 2003, 23 do you recall did Dr. Zaidi discuss with you 24 the fact that he'd had an ER/PR test repeated 25 and some changes in the results?</p>
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<p>1 DR. LAING: 2 A. No. No, and this was a little bit different 3 than the other one because this was a whole 4 year later. 5 CHAYTOR, Q.C.: 6 Q. Yes. 7 DR. LAING: 8 A. If I remember the other one, it was just sort 9 of as a quality assurance review. No, I don't 10 have any recollection. 11 CHAYTOR, Q.C.: 12 Q. And yes, as you point out, it's almost a year 13 between the two. 14 DR. LAING: 15 A. Yeah. 16 CHAYTOR, Q.C.: 17 Q. Which makes it seem a little unusual. You 18 don't recall that being brought to your 19 attention? 20 DR. LAING: 21 A. No. You don't know if this patient had 22 metastatic disease develop in that interim, do 23 you? 24 CHAYTOR, Q.C.: 25 Q. No, we don't know on what we have here, but we</p>	<p>1 A. No. 2 CHAYTOR, Q.C.: 3 Q. And this wasn't brought to your attention as 4 director of medical oncology at the time? 5 DR. LAING: 6 A. No. 7 CHAYTOR, Q.C.: 8 Q. Looking back on it, Doctor, do you think 9 perhaps it should have been? 10 DR. LAING: 11 A. It's hard to know because these are--although 12 they're tests in which the results changed, 13 the clinical circumstances surrounding them 14 are slightly different. The first case, you 15 know, without having known that it was sent to 16 an outside lab for testing, makes it 17 different. The other ones seem to be - 18 CHAYTOR, Q.C.: 19 Q. No, the first case that I'm referring to is 20 March 26th, 2003, the review of the lymph node 21 and the ER - 22 DR. LAING: 23 A. Oh, the one that I - 24 CHAYTOR, Q.C.: 25 Q. Yes, the other one was back in '02.</p>
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<p>1 could certainly check that. 2 DR. LAING: 3 A. I'm wondering if maybe that that was why. 4 CHAYTOR, Q.C.: 5 Q. Okay. We could certainly check that. And 6 again, I take it that would have been then 7 unusual to get a chance in the result? 8 DR. LAING: 9 A. I could only say that he--there must have been 10 some reason why he would have requested for it 11 to be repeated, but I don't know why that 12 would have been, without looking at the 13 patient's chart or seeing what he may have 14 documented at that time. 15 CHAYTOR, Q.C.: 16 Q. And Doctor, what I've taken you through there 17 indicates that there were four cases in 2003, 18 in less than a three-month period, the first 19 being yours in late March of 2003, March 26th, 20 and two in May 2003, and another then on June 21 11th, 2003 which resulted--were repeats of 22 ER/PR tests which resulted in different 23 results, and this wasn't the subject of 24 discussion amongst oncologists at the time? 25 DR. LAING:</p>	<p>1 DR. LAING: 2 A. Oh, okay. Okay, all right, sorry. 3 CHAYTOR, Q.C.: 4 Q. The one with the outside lab was separate 5 again. 6 DR. LAING: 7 A. Okay, okay, sorry. I didn't realize you were 8 thinking about--it's difficult for me to say 9 for sure, without kind of knowing what the 10 circumstances were around the retesting, and 11 you know, I guess it comes back to the 12 question too, you know, when do you decide 13 that something is happening frequently enough 14 that it sort of tweaks your attention. Again, 15 I think this speaks to the fact that yes, if 16 there had been some sort of follow up and some 17 sort of database to capture these, that this 18 may have probably first been tweaked the 19 attention of the pathologists that they were 20 having these changes, but you know, in 21 retrospect it's fine for me to say yeah, 22 knowing what I know today, yes, but in 2003, 23 if we had had three or four people who 24 changed, I'd suspect that we would have had 25 some discussions, just like we did with the</p>

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<p>1 index case in 2005. I can't imagine that I 2 would not have had a discussion at that time 3 with the pathologists, but you know, it's hard 4 to say that looking back, for sure that I 5 definitely would have. Knowing what I know 6 now, yes, but you know, it would be a lot more 7 helpful if I had some more information 8 surrounding the request, why the repeats were 9 requested and those sorts of things.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And regardless though of why they would have 12 been requested, if it results in a change?</p> <p>13 DR. LAING:</p> <p>14 A. The results changed?</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. Yes.</p> <p>17 DR. LAING:</p> <p>18 A. This results is different. The one that you 19 showed me just prior to this says it was--was 20 it negative? Yes, it was negative or was it 21 unavailable to test?</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. The one before that went from being less than 24 one percent ER, 15 percent PR. The repeat 25 resulted in 40 percent ER -</p>	<p>1 Q. And as director of medical oncology, if there 2 is to be a incident report filed, would you be 3 made aware of it?</p> <p>4 DR. LAING:</p> <p>5 A. Yes. So how we looked at the incident reports 6 that were, that many of them would come 7 through to senior administration and we have a 8 provincial pharmacy and therapeutics committee 9 and we would look at incident reports during 10 that time and we look at incident reports--and 11 they would be ones specifically pertaining to 12 treatments, and then we would also look at 13 incident reports as part of senior management.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. And I would take it then, Doctor, if incidents 16 reports had been filed on those and brought to 17 your attention, then you would have noticed 18 that we have four of those now within -</p> <p>19 DR. LAING:</p> <p>20 A. A short period of time.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. - short period of time?</p> <p>23 DR. LAING:</p> <p>24 A. Yes.</p> <p>25 CHAYTOR, Q.C.:</p>
<p style="text-align: right;">Page 254</p> <p>1 DR. LAING:</p> <p>2 A. Oh, and 73</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. - and 73 percent PR.</p> <p>5 DR. LAING:</p> <p>6 A. Yeah, and then the one before that, it says 7 that it wasn't available for testing or -</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. No, the one before that was negative, and -</p> <p>10 DR. LAING:</p> <p>11 A. And then came back positive.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. - came back positive, yes. So all of those 14 resulted in changed results.</p> <p>15 DR. LAING:</p> <p>16 A. Yeah, they were--I would agree that they would 17 have been a significant change, yeah.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And it wasn't any discussion though amongst 20 the oncologists, and I take it no incident 21 report filed for any of those that you're 22 aware of?</p> <p>23 DR. LAING:</p> <p>24 A. Not that I'm aware of, no.</p> <p>25 CHAYTOR, Q.C.:</p>	<p style="text-align: right;">Page 256</p> <p>1 Q. Doctor, I'd like to turn now then and--before 2 I do though, the two that you requested the 3 repeat for on your elderly patients, and you 4 asked for a repeat, why did you think there 5 might be a chance in result?</p> <p>6 DR. LAING:</p> <p>7 A. Really the main reason for asking for them to 8 be repeated was that because they were elderly 9 patients and because the incidents is higher 10 in patients as they get older, that was the 11 one reason and the second one was they had 12 well differentiated tumours and, you know, as 13 I said before, I wasn't prepared to offer them 14 chemotherapy, and often when you see elderly 15 patients with breast cancer, it's more common 16 for them to be positive. So because I didn't 17 have another treatment option that I was 18 prepared to give them, then I did ask for that 19 to be repeated, and as I said, the results 20 didn't change.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. Did you have any reason to doubt the original 23 results?</p> <p>24 DR. LAING:</p> <p>25 A. No, I think I was just sort of looking, if you</p>

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1 will, for, you know, sort of grasping at
 2 straws, if you will, for another treatment
 3 that I may offer these patients. It's
 4 interesting, as part of the tumour review, we
 5 looked back to 19--back as far as 1997, and
 6 there were a couple of patients that we found
 7 who were ER/PR negative who were offered
 8 hormonal therapy simply based on their age,
 9 without looking at their ER/PR status, and
 10 that would have been a practice that would
 11 have been common for European physicians to
 12 not rely on ER/PR testing, and so one of our
 13 more senior oncologists, on a couple of
 14 occasions, had prescribed Tamoxifen to hormone
 15 receptor negative patients, just simply based
 16 on their age and the fact that they had high
 17 risk disease for which there wasn't any other
 18 option available.
 19 CHAYTOR, Q.C.:
 20 Q. Thank you. I'd like to turn now then, Doctor,
 21 and talk about what's been referred to as the
 22 index case.
 23 DR. LAING:
 24 A. Okay.
 25 CHAYTOR, Q.C.:

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1 Q. Peggy Deane's case.
 2 DR. LAING:
 3 A. Yes.
 4 CHAYTOR, Q.C.:
 5 Q. And from your perspective and involvement,
 6 perhaps you could tell the Commissioner how it
 7 all began?
 8 DR. LAING:
 9 A. Sure. So Peggy Deane was a patient under my
 10 care. She first came to see me in July of
 11 2002, at which time she was diagnosed with
 12 breast cancer. She had had--prior to this,
 13 had had a breast lump for some time that had
 14 been investigated back in 2000, and then
 15 noticed that the lump was increasing in size
 16 and this led to mammograms and ultrasounds and
 17 subsequently to a biopsy. She then had
 18 surgery prior to me seeing her, and had had a
 19 metastatic work up, and the metastatic work
 20 up, unfortunately revealed that she had
 21 evidence of liver metastases. There was a
 22 lesion in the liver that was evident on her
 23 staging CAT scan, and in fact this was
 24 biopsied just to make sure that it wasn't
 25 something else, although characteristically on

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1 imaging, it did look like a metastatic deposit
 2 and in fact, it was confirmed to be metastatic
 3 disease.
 4 So when I saw her for the first time in
 5 the clinic, she had stage four disease. She
 6 had a tumour that was fairly large. It was
 7 three centimetres or so. I can't remember
 8 exactly, but somewhere around three or four
 9 centimetres, and she did also have lymph node
 10 involvement at that time. The report that we
 11 received regarding the ER/PR on the primary
 12 tumour was what we would consider negative.
 13 So one was, I think, zero percent and the
 14 other one was certainly less than ten percent.
 15 CHAYTOR, Q.C.:
 16 Q. Less than ten.
 17 DR. LAING:
 18 A. And you know, I recall sitting there with her
 19 and her husband and explaining that, you know,
 20 we were now faced with metastatic disease and
 21 what that meant, that this was an incurable
 22 situation, that given the fact that she had
 23 less than ten percent staining, in fact I said
 24 ER/PR negative disease, that I didn't feel
 25 that she would derive benefit from hormonal

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1 therapy and that I felt that we should treat
 2 her metastatic disease with chemotherapy.
 3 She was very young, younger than our
 4 usual breast cancer patient, so someone that I
 5 would group in my group of young patients.
 6 Obviously, you know, an aggressive disease.
 7 It's not very often that our patients who
 8 present, present with metastatic disease at
 9 initial diagnosis. That's very uncommon. In
 10 fact, most people that I would see like her
 11 would be coming to me for a discussion
 12 regarding adjuvant therapy, but knowing that
 13 she had, I think, four or five lymph nodes
 14 involved and knowing that, you know, she
 15 certainly would have been in a high risk
 16 category, and she would have had chemotherapy.
 17 So after that discussion, I commenced her
 18 on treatment with chemotherapy. She would
 19 have initially received anthracycline based
 20 chemotherapy, which would be standard,
 21 particularly certainly standard then and now.
 22 The anthracyclines and the taxanes are our
 23 most active medications against metastatic
 24 breast cancer. So she had that, and she
 25 responded, was off treatment for a few months,

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

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

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

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

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

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

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

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

23 We talked about whether or not there

1 CHAYTOR, Q.C.:

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

5 DR. LAING:

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

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1 approach to, you know, care, because sometimes
 2 our American counterparts are seen by us as
 3 being sort of more aggressive and that sort of
 4 thing. But, so I knew him well enough, so I
 5 sent him an e-mail, and because I was doing
 6 this as a consultation, I took out Peggy's
 7 chart and sort of sat down and sent this as if
 8 I would send, you know, a consult.
 9 So I included in it, you know, her
 10 initial diagnosis, her pathology, her hormone
 11 receptor results, and all that information,
 12 the treatment that she had received to date.
 13 I explained that I didn't feel that she was
 14 well enough to travel, but if he had any ideas
 15 of what might help to let me know. So within
 16 a day or two, I got an e-mail back from him
 17 saying that, you know, picked up on the fact
 18 that she was lobular and I had said that she
 19 was ER/PR negative, and he said, you know,
 20 "very rare indeed" kind of thing, and I
 21 explained that, you know, that she had this
 22 less than ten percent staining and he said
 23 that he'd try a hormonal therapy. That he
 24 hadn't seen a negative lobular cancer.
 25 So subsequent to receiving this e-mail, I

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1 spoke to both the patient and her husband and
 2 as well as to Dr. McCarthy. At this point,
 3 Peggy had been cared for myself, then Dr.
 4 McCarthy and so we kind of both considered
 5 ourselves to be, you know, her oncologists,
 6 her medical oncologists. And so I called Dr.
 7 Ford Elms, because he was the pathologist who
 8 had signed out the original ER/PR. I
 9 explained the correspondence that I had had
 10 with Dr. Hudis and I said, you know, would you
 11 retest her tumour.
 12 CHAYTOR, Q.C.:
 13 Q. And Doctor, prior to doing that and making the
 14 contact with Dr. Elms, did you discuss the
 15 issue with the patient?
 16 DR. LAING:
 17 A. Yes, I did.
 18 CHAYTOR, Q.C.:
 19 Q. So she was aware that she was going to be
 20 retested?
 21 DR. LAING:
 22 A. She was aware that this is--right, yeah.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, sorry, go ahead.
 25 DR. LAING:

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1 A. So I recall that when Dr. Elms went and he got
 2 the slides and subsequently we spoke again and
 3 he said he was going to do the testing, and he
 4 said that the--although it was a lobular
 5 cancer, that it may have had some ductal
 6 features, which sometimes lobular tumours will
 7 have, and that, you know, he would run the
 8 test. At this time, they had the Ventana
 9 system and that he would get back to us, you
 10 know, in the next little while with the test
 11 results.
 12 At this point, Peggy was an in-patient in
 13 the hospital, and you know, we had explained
 14 this, and so she was waiting for the test
 15 results, just as we were, and -
 16 CHAYTOR, Q.C.:
 17 Q. And what was her reaction? What was her
 18 reaction when you told her that she was going
 19 to be retested?
 20 DR. LAING:
 21 A. She was very hopeful. She was hopeful that
 22 this was going to come back as being positive
 23 and it meant that, you know, we could try
 24 hormonal therapy for her.
 25 CHAYTOR, Q.C.:

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1 Q. It's another form of treatment for her?
 2 DR. LAING:
 3 A. Yeah, so yes.
 4 CHAYTOR, Q.C.:
 5 Q. And what reason did you give her for having
 6 the retest done? What was she told as to why
 7 she was going to be retested?
 8 DR. LAING:
 9 A. Oh, exactly what Dr. Hudis had said to me, was
 10 that, you know, she had lobular pathology and
 11 she was aware of the fact that she had lobular
 12 pathology. Interestingly, for another reason,
 13 because she went at one point and had a PET
 14 scan done and there was some discussion about
 15 PET scans in lobular breast cancer and things,
 16 but the--so I explained that I had spoken with
 17 Dr. Hudis, that he felt that we should repeat
 18 it, given the fact that it was lobular, and
 19 that you know, he felt that that was an
 20 indication to retest it at that point to see
 21 if it was positive, and if it was, to try her
 22 with hormonal therapy.
 23 We were then waiting for the test results
 24 to come back, and when they did, she was an
 25 in-patient and one of our other medical

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

9 CHAYTOR, Q.C.:

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

13 DR. LAING:

14 A. Yes.

15 CHAYTOR, Q.C.:

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

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

5 DR. LAING:

6 A. Peritoneal disease.

7 CHAYTOR, Q.C.:

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

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1 for their benefit."

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

12 DR. LAING:

13 A. Yeah.

14 CHAYTOR, Q.C.:

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

17 DR. LAING:

18 A. Yes.

19 CHAYTOR, Q.C.:

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

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

5 DR. LAING:

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

11 CHAYTOR, Q.C.:

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

15 DR. LAING:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. Okay, and who did that for you?

19 DR. LAING:

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

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1 back, when he got the slide out, he said "you
 2 know, I remember this had some ductal
 3 features," but he didn't change--you know,
 4 when he looked at it and I believe that he
 5 told me that he looked at it with some of the
 6 other pathologists, that they still called it
 7 lobular.
 8 CHAYTOR, Q.C.:
 9 Q. That it was still lobular?
 10 DR. LAING:
 11 A. Yeah, they didn't change that it was lobular
 12 at that time.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, and in 2002, based on Ms. Deane's
 15 profile at that time, did it occur to you that
 16 it was unusual that she was ER negative?
 17 DR. LAING:
 18 A. No.
 19 CHAYTOR, Q.C.:
 20 Q. And the fact that in 2005, Dr. Hudis was
 21 saying that he had never seen an ER/PR
 22 negative invasive lobular, I take it that
 23 hadn't been your experience. You'd seen
 24 negatives?
 25 DR. LAING:

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1 A. That's right. That's right, yeah, and so you
 2 know, really getting back to what we've
 3 already discussed, that we accepted that there
 4 was a high percentage that were ER/PR
 5 positive, but this is the first time that I
 6 had ever had anybody tell me, in my training
 7 or in discussions, that it was all of the
 8 lobular patients were ER/PR positive.
 9 CHAYTOR, Q.C.:
 10 Q. So what was -
 11 DR. LAING:
 12 A. At the same time, as well, you know, this was
 13 a lady who presented to me with metastatic
 14 disease right from the beginning, clearly an
 15 aggressive cancer, and so it didn't really,
 16 you know, sort of stand out that it should be
 17 positive, just based on the fact that it was
 18 lobular. And then, of course, the other
 19 issue is, you know, looking back, if I had
 20 have known that she was hormone receptor
 21 positive, this was someone who had metastatic
 22 disease at that time, was a young patient with
 23 clearly an aggressive cancer, who had liver
 24 metastases. So it is likely that I would have
 25 treated her with chemotherapy still as the

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

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1 even known to be hormone receptor positive on
 2 their primary cancer, will not respond to that
 3 sort of treatment.
 4 CHAYTOR, Q.C.:
 5 Q. Doctor, what was your reaction upon reading
 6 what Dr. Hudis had to say?
 7 DR. LAING:
 8 A. I remember looking at it and saying, "oh,
 9 okay." That's, you know, a pretty definitive
 10 statement, and not my sort of what I would
 11 consider. I actually subsequently had an
 12 opportunity to have a further discussion with
 13 him regarding this point.
 14 CHAYTOR, Q.C.:
 15 Q. And I take it Dr. Hudis is known--is he known
 16 to be a breast oncologist?
 17 DR. LAING:
 18 A. Yes, he is.
 19 CHAYTOR, Q.C.:
 20 Q. Okay, and he's well known?
 21 DR. LAING:
 22 A. Oh yeah. Yes, he is.
 23 CHAYTOR, Q.C.:
 24 Q. And perhaps then, tell us what was your
 25 subsequent discussion with him, and was it

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<p>1 around the same time period?</p> <p>2 DR. LAING:</p> <p>3 A. It was after this, and certainly to the point</p> <p>4 after this that I, you know, we were well</p> <p>5 underway with the review, sort of getting</p> <p>6 ready to do the tumour panel, that I would</p> <p>7 have seen him again.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. So by then, Ms. Deane would have already -</p> <p>10 DR. LAING:</p> <p>11 A. So sometime in the fall, October of 2005.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. - and Ms. Deane would have already passed on?</p> <p>14 DR. LAING:</p> <p>15 A. Yes. Yes, she would have, and I saw him at a</p> <p>16 meeting and spoke to him and said "remember I</p> <p>17 had talked to you about that lady?" and you</p> <p>18 know, explained to him that we did retest her,</p> <p>19 that her results came back as positive. That</p> <p>20 we treated her with hormonal therapy, but she</p> <p>21 didn't really have any significant response,</p> <p>22 and that, you know, it led to us deciding to</p> <p>23 this review, and then he subsequently said to</p> <p>24 me that they had done a review where they had</p> <p>25 looked back at lobular samples, so tumour</p>	<p>1 DR. LAING:</p> <p>2 A. They would have been, because they would have</p> <p>3 come from, obviously they would have come from</p> <p>4 patients, and so what they did was that they--</p> <p>5 using their current antibodies and things,</p> <p>6 they had rerun the lobular samples that they</p> <p>7 had had in their tumour bank from over the</p> <p>8 years and all of them, he told me, came back</p> <p>9 as being hormone receptor positive.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And did he indicate how that compared to what</p> <p>12 the original test on those samples had been?</p> <p>13 DR. LAING:</p> <p>14 A. No, because these were again samples that they</p> <p>15 had had, that they had gathered, but they</p> <p>16 didn't necessarily--they weren't necessarily</p> <p>17 tied back and they wouldn't have necessarily</p> <p>18 always had the patient data related to them.</p> <p>19 So I'm not sure that he would be able to tell</p> <p>20 me had these been people that had been--you</p> <p>21 know, what had their original result been.</p> <p>22 This was sort of done in a laboratory setting</p> <p>23 with these blocks of lobular specimens, and I</p> <p>24 was quite interested, because I thought well,</p> <p>25 was this something that you would--you know,</p>
<p>Page 278</p> <p>1 samples of lobular breast cancer, and they had</p> <p>2 retested them in the lab and that, you know,</p> <p>3 using the new antibodies, that they had</p> <p>4 actually, all of the lobular cancers had</p> <p>5 tested positive.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. And they being, this is Sloan Kettering?</p> <p>8 DR. LAING:</p> <p>9 A. Yeah. Now, so of course, I was quite</p> <p>10 interested in that, because I said "well, what</p> <p>11 did you do? Was this related to patients?"</p> <p>12 and he said no, many of these large cancer</p> <p>13 centres have tumour banks where they have</p> <p>14 anonymous tumour samples from different sorts</p> <p>15 of cancers, including breast cancers, that</p> <p>16 they do research studies on in the lab, and it</p> <p>17 was on these tumour samples that they reran</p> <p>18 the immunohistochemistry testing for the</p> <p>19 lobular samples. So this wasn't a patient</p> <p>20 based or a patient centred review. This was</p> <p>21 something that was done only in the laboratory</p> <p>22 on tissue samples.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And were these tissue samples that had</p> <p>25 previously been tested and had ER/PR results?</p>	<p>Page 280</p> <p>1 that you then had to communicate back to</p> <p>2 patients, and he said "no, this was not a</p> <p>3 patient centred review." And that was really</p> <p>4 the last time that we've spoken about this.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. You've never had a discussion with him on this</p> <p>7 issue since?</p> <p>8 DR. LAING:</p> <p>9 A. No.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Okay, and that discussion took place in the</p> <p>12 fall, sometime after October 2005 or around</p> <p>13 October?</p> <p>14 DR. LAING:</p> <p>15 A. Around that time.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. Around that time period.</p> <p>18 DR. LAING:</p> <p>19 A. Yeah, I was at a meeting in--a European</p> <p>20 conference and I believe that that's when it</p> <p>21 would have been.</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. And Doctor, after receiving Dr. Hudis' e-mail</p> <p>24 and being somewhat surprised by the content</p> <p>25 yourself, did you discuss it with any other</p>

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<p>1 oncologists?</p> <p>2 DR. LAING:</p> <p>3 A. Yes, I discussed it with Dr. McCarthy.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. Okay, and what was discussed between you and</p> <p>6 Dr. McCarthy?</p> <p>7 DR. LAING:</p> <p>8 A. Well, I initiated the discussion with Dr.</p> <p>9 McCarthy because, as I said, we were both</p> <p>10 really thinking about what we were going to do</p> <p>11 next with this patient, Peggy Deane. When we</p> <p>12 got the result come back and it changed, the</p> <p>13 result that we got was--Dr. Elms had called</p> <p>14 us. He said that they're both positive and we</p> <p>15 started the patient on the Tamoxifen. Then we</p> <p>16 said, well, you know, this is really the case,</p> <p>17 then you know, should we be thinking about</p> <p>18 looking at our lobular patients? You know,</p> <p>19 what should we do about this? And we just had</p> <p>20 a--we had a discussion at that time, and she</p> <p>21 said to me "well, I'll give Dr. Cook a call"</p> <p>22 and so she called Dr. Don Cook and that, you</p> <p>23 know, was sort of the start of that whole</p> <p>24 process. And then, of course, there were some</p> <p>25 other events that had happened, in terms of</p>	<p>1 tests had previously been retested and</p> <p>2 experienced a change result?</p> <p>3 DR. LAING:</p> <p>4 A. Not at that time, no.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. At any point in time has Dr. Elms had that</p> <p>7 discussion with you?</p> <p>8 DR. LAING:</p> <p>9 A. Not--no, no.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Has anyone brought that, in the way of a</p> <p>12 pathologist, brought that to your attention?</p> <p>13 DR. LAING:</p> <p>14 A. You mean prior to --</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. That there were prior tests before Peggy</p> <p>17 Deane's ER/PR test that had been repeated and</p> <p>18 resulted in a change result?</p> <p>19 DR. LAING:</p> <p>20 A. No, I don't remember having those</p> <p>21 conversations with--prior to this incident,</p> <p>22 no.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. So, for example, the examples that I've shown</p> <p>25 you today, other than your own --</p>
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<p>1 some other patients with lobular who we asked</p> <p>2 to be retested.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. Yes, and I'll take you to those. I just want</p> <p>5 to stick with Ms. Deane's case for a moment.</p> <p>6 So you discussed the matter after getting this</p> <p>7 e-mail. You discussed it with Dr. McCarthy.</p> <p>8 Was she equally surprised by what Dr. Hudis</p> <p>9 had to say?</p> <p>10 DR. LAING:</p> <p>11 A. Yes.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. Okay, and when you talked to Dr. Elms and you</p> <p>14 explained to him that you were looking for a</p> <p>15 retest, and I take it you told him it was</p> <p>16 because --</p> <p>17 DR. LAING:</p> <p>18 A. Yes.</p> <p>19 CHAYTOR, Q.C.:</p> <p>20 Q. Of what Dr. Hudis had told you?</p> <p>21 DR. LAING:</p> <p>22 A. That's correct.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. All right, and did Dr. Elms indicate to you</p> <p>25 whether he was aware that other patients ER/PR</p>	<p>1 DR. LAING:</p> <p>2 A. So the examples you showed me about Dr.</p> <p>3 Zaidi's patients.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. Yes, and there are others, yes.</p> <p>6 DR. LAING:</p> <p>7 A. And the other ones --</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. But those that I've shown you, there's been no</p> <p>10 discussion since with you about, well, perhaps</p> <p>11 we had a similar situation back in 2002 or</p> <p>12 2003?</p> <p>13 DR. LAING:</p> <p>14 A. No, that discussion came out after this, in</p> <p>15 the early discussions we had with Dr. Cook, as</p> <p>16 I indicated, that they said there may have</p> <p>17 been a problem in the lab in 2002.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And when did you have that discussion with Dr.</p> <p>20 Cook? When was it brought to your attention</p> <p>21 that perhaps Peggy Deane was not the first?</p> <p>22 DR. LAING:</p> <p>23 A. Oh, that would have been in--now getting into</p> <p>24 July of 2005.</p> <p>25 CHAYTOR, Q.C.:</p>

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1 Q. Okay.

2 THE COMMISSIONER:

3 Q. Ms. Chaytor, wherever you can find a

4 convenient spot, we'll take the afternoon

5 break.

6 CHAYTOR, Q.C.:

7 Q. Okay. Doctor, upon Peggy Deane's case coming

8 to light and the retest, and this time period

9 with receiving Dr. Hudis' e-mail, did you do

10 any research? Did you look into the issue

11 yourself and look back through the literature?

12 DR. LAING:

13 A. Not a whole lot. You know, at this point,

14 really we were looking at this particular

15 case, we had some discussion about--some early

16 discussion with Dr. Cook about where we went

17 from here. We had identified in the clinic a

18 couple of more patients who we retested. You

19 know, I remember sort of going and sort of

20 doing a literature search looking at, you

21 know, sort of lobular disease to see if I

22 could find some reference to saying that it

23 was 100 percent. I remember taking out my big

24 oncology textbook and seeing if I could look

25 in there and see, and I couldn't find a

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1 reference anywhere that gave actually 100

2 percent. You know, there were statements

3 like, you know, the majority or most, but

4 certainly I didn't find anything that said

5 "all".

6 CHAYTOR, Q.C.:

7 Q. So this would have been a textbook that you

8 had from the time that you were in med school

9 or in your residency?

10 DR. LAING:

11 A. Yes. It's a textbook that still exists and

12 gets updated, The DeVita. So that's our --

13 CHAYTOR, Q.C.:

14 Q. And why would you have looked back to that as

15 opposed to currently literature?

16 DR. LAING:

17 A. Oh, no, it's a current book. It's updated

18 regularly.

19 CHAYTOR, Q.C.:

20 Q. It's updated.

21 DR. LAING:

22 A. Oh, yes, yes.

23 CHAYTOR, Q.C.:

24 Q. So you would have an updated version of it?

25 DR. LAING:

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1 A. Oh, yes, yes, certainly.

2 CHAYTOR, Q.C.:

3 Q. That makes more sense.

4 DR. LAING:

5 A. Yes.

6 CHAYTOR, Q.C.:

7 Q. Okay.

8 DR. LAING:

9 A. Like, edition who know what, probably 12 now.

10 These textbooks are updated.

11 CHAYTOR, Q.C.:

12 Q. Pretty close to a 2005 edition?

13 DR. LAING:

14 A. Yes.

15 CHAYTOR, Q.C.:

16 Q. And there was no reference to it being 100

17 percent?

18 DR. LAING:

19 A. 100 percent, right.

20 CHAYTOR, Q.C.:

21 Q. What did it say on that issue?

22 DR. LAING:

23 A. Oh, they didn't even give a percentage. Most

24 of what I looked at was again what we had

25 said, you know, most--there wasn't anything

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1 that said 100 percent or that had said "all"

2 lobular tumours.

3 CHAYTOR, Q.C.:

4 Q. Other than discussing this with Dr. McCarthy,

5 the information that has been forwarded on to

6 you by Dr. Hudis, did you discuss it with any

7 of the rest of the oncologists?

8 DR. LAING:

9 A. Yes.

10 CHAYTOR, Q.C.:

11 Q. Who else did you discuss it with?

12 DR. LAING:

13 A. We would have had a discussion as an entire

14 group of medical oncologists. We actually are

15 together once a week. On Tuesday mornings, we

16 do our in-patient ward rounds together, and

17 afterwards we always have an informal meeting

18 and we talk about lots of different issues.

19 So, I mean, even down to Dr. Rorke, who

20 doesn't treat breast cancer, you know, knew

21 all about what was going on because, of

22 course, he had been the attending looking

23 after Peggy while she was in the hospital.

24 So, you know, this was something that we

25 really talked about really initially as an

<p style="text-align: right;">Page 289</p> <p>1 isolated case, and then went on to think about 2 this--I think in the early days our mindset 3 was really around that this was going to be 4 something related to lobular tumours, and it 5 wasn't until the events unfolded over the next 6 little while that we realized that this was 7 something that was beyond just this being 8 something that we were seeing in lobular 9 patients. 10 CHAYTOR, Q.C.: 11 Q. So, Doctor, in your Tuesday morning then get 12 together, you chatted about this particular 13 case? 14 DR. LAING: 15 A. That's right. 16 CHAYTOR, Q.C.: 17 Q. In your Tuesday morning oncology get 18 together, had it previously ever come up, for 19 example, the cases I showed you in 2003? 20 DR. LAING: 21 A. No. 22 CHAYTOR, Q.C.: 23 Q. That issue had never come up? 24 DR. LAING: 25 A. No.</p>	<p style="text-align: right;">Page 291</p> <p>1 Q. So into July or August, 2005 period? 2 DR. LAING: 3 A. Yes. 4 CHAYTOR, Q.C.: 5 Q. After it became the subject, the discussion -- 6 DR. LAING: 7 A. Sure, yeah. 8 CHAYTOR, Q.C.: 9 Q. And when you had your first Tuesday morning 10 meeting of oncologists after Dr. Hudis' 11 communication to you, at that point in time 12 did any other oncologist mention any issues 13 that had happened in the past, any issues of 14 changes in ER/PR results? 15 DR. LAING: 16 A. Not that I recall, no. It was--you know, it 17 probably wasn't the very next Tuesday, but it 18 would have been within the weeks after this 19 once we had the results come back from Peggy's 20 retesting, and then subsequently once we go 21 the next results back. 22 CHAYTOR, Q.C.: 23 Q. Thank you. Commissioner, this would be a 24 convenient point. 25 THE COMMISSIONER:</p>
<p style="text-align: right;">Page 290</p> <p>1 CHAYTOR, Q.C.: 2 Q. And the issues back in 2002, 2003, or any 3 change results back in that time period, had 4 they ever come up in the tumour board rounds 5 with the pathologists? 6 DR. LAING: 7 A. Not that I was present for, and not that I 8 have any knowledge of, no. 9 CHAYTOR, Q.C.: 10 Q. And you've subsequently heard that that has 11 happened. Has anyone ever told you that there 12 may have been a discussion back in that time 13 period at the tumour board rounds? 14 DR. LAING: 15 A. Yes, there was some reference made--I'm not 16 sure if it was by Dr. Greenland or someone 17 back in 2002 or 2003, that someone could 18 recall somebody saying about it, but that was 19 the only thing that I have ever heard 20 subsequently. 21 CHAYTOR, Q.C.: 22 Q. And when did you learn about that? 23 DR. LAING: 24 A. Oh, after this had all developed. 25 CHAYTOR, Q.C.:</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. All right then, take the afternoon break. 2 (BREAK) 3 THE COMMISSIONER: 4 Q. Ms. Chaytor. 5 CHAYTOR, Q.C.: 6 Q. Thank you, Commissioner. If I could have, 7 please, C-0167. Doctor, this is a discharge 8 summary related to Mrs. Deane, and the 9 admission date is April 12th, 2005, discharged 10 April 20th, 2005, "Repeat testing of her ER/PR 11 receptor status changed its status to ER/PR 12 positive, and thus she was started on 13 treatment with Tamoxifen, and also given 14 Zoladex injections after laboratory parameters 15 showed that she was pre-menopausal". I take 16 it her change in treatment by this point in 17 time before she was discharged on April 20th, 18 she had already been started on Tamoxifen? 19 DR. LAING: 20 A. Yes. 21 CHAYTOR, Q.C.: 22 Q. And her test had already been repeated? 23 DR. LAING: 24 A. Yes. 25 CHAYTOR, Q.C.:</p>

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

6 DR. LAING:
7 A. Yes.

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

21 DR. LAING:
22 A. Oh, that's Estradiol. So she was still pre-
23 menopausal.

24 CHAYTOR, Q.C.:
25 Q. Okay, and you spoke about that before.

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1 DR. LAING:
2 A. Yes.

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

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

21 CHAYTOR, Q.C.:
22 Q. Yes, but didn't the original pathology also
23 indicate that it was lobular with ductal
24 features?

25 DR. LAING:

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

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1 CHAYTOR, Q.C.:
2 Q. And was there any indication on the addendum
3 that came back to you that there was ever even
4 any review of the original diagnosis?

5 DR. LAING:
6 A. No, the--the only addendum that came said that
7 the ER/PR were both positive.

8 CHAYTOR, Q.C.:
9 Q. Yes, and have you subsequently in your
10 discussion with Dr. Elms, discussed whether or
11 not he, in fact, did review the original
12 diagnosis?

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

20 CHAYTOR, Q.C.:
21 Q. Okay. So what you're saying is this note is
22 dictated and at the time that you dictated it,
23 you had asked for her pathology to be
24 reviewed, so not just her ER/PR, you had asked
25 for the --

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<p>1 DR. LAING: 2 A. I didn't ask for a pathology review, no. 3 CHAYTOR, Q.C.: 4 Q. Okay. 5 DR. LAING: 6 A. What had happened was when I had initially 7 called Dr. Elms and said, you know, we've got 8 this e-mail, it indicates that because this 9 lady's pathology is lobular, that, you know, 10 Dr. Hudis felt that she should be ER/PR 11 positive, and he had said to me--you know, I 12 remember that this--he looked at the slides. 13 He said, yes, it was lobular, but it had 14 ductal features, and I had misunderstood that 15 to mean that he was thinking that it was, in 16 fact, a ductal cancer, but what he had said 17 was that it had ductal features, he was going 18 to look at it again, and when he signed out 19 the final report, he did not change his 20 histological type of this tumour. It remained 21 a lobular cancer. 22 CHAYTOR, Q.C.: 23 Q. Okay, and when a pathologist tells you, 24 because I'm assuming that's something that you 25 would read on a pathology report from time to</p>	<p>1 DR. LAING: 2 A. Oh, yes, and even then when--so subsequent to 3 this dictation note, which was the first time 4 that I had seen Peggy in the clinic after her 5 discharge from the hospital, I did get the 6 addendum after and it eventually came through 7 the mail and made it to me, and put on her 8 chart, that, no, there was no change in her 9 histological diagnosis, she remained a 10 lobular. 11 CHAYTOR, Q.C.: 12 Q. And -- 13 DR. LAING: 14 A. And that's important because that formed the 15 basis of some of the other patients that we 16 decided to retest. 17 CHAYTOR, Q.C.: 18 Q. Okay, and if we could see, please, C-0156. 19 This is the addendum? 20 DR. LAING: 21 A. Yes. 22 CHAYTOR, Q.C.: 23 Q. And it's not entered until May 31st, 2005. 24 DR. LAING: 25 A. Yes.</p>
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<p>1 time, when you're told that it's lobular with 2 ductal features -- 3 DR. LAING: 4 A. Yes. 5 CHAYTOR, Q.C.: 6 Q. You still understand that it would be a 7 lobular cancer? 8 DR. LAING: 9 A. Yes, and there are some cancers that actually 10 come back as mixed ductal and lobular because 11 you see both types of patterns of histology 12 present. 13 CHAYTOR, Q.C.: 14 Q. So this here, "Interestingly, it came back 15 saying that it was a ductal cancer", Dr. Elms 16 never called you back and said I've reviewed 17 it and it, in fact, is a ductal cancer? 18 DR. LAING: 19 A. No, no, no. 20 CHAYTOR, Q.C.: 21 Q. And in your discussions subsequently with Dr. 22 Elms more recently, did he, in fact, confirm 23 that he had reviewed her original diagnosis in 24 terms of this issue of was it ductal, was it 25 lobular?</p>	<p>1 CHAYTOR, Q.C.: 2 Q. But it--I've taken you to the discharge 3 summary which indicates that the retest was 4 actually done sometime in April. 5 DR. LAING: 6 A. Yes. 7 CHAYTOR, Q.C.: 8 Q. And immunohistochemical staining for ER and PR 9 has been repeated on this tissue using Ventana 10 automated systems. Stains for both receptors 11 are positive", and that's the only addendum in 12 2005. Do you know was Mrs. Deane's case ever 13 repeated by Mount Sinai as part of the review? 14 DR. LAING: 15 A. Not that I know of. 16 CHAYTOR, Q.C.: 17 Q. Okay. 18 DR. LAING: 19 A. I have no idea. I've never seen a result come 20 back from Mount Sinai that I can recall. 21 CHAYTOR, Q.C.: 22 Q. And why would her case not have been--her 23 original ER negative specimen not have been 24 retested by Mount Sinai? 25 DR. LAING:</p>

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<p>1 A. I'm not certain.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. Doctor, did Mrs. Deane respond to the</p> <p>4 Tamoxifen treatment?</p> <p>5 DR. LAING:</p> <p>6 A. I don't really think so. You know, when we</p> <p>7 first started it, she had had ascites. So she</p> <p>8 had fluid within her entero-abdominal cavity.</p> <p>9 We drained that as we often do for a comfort</p> <p>10 measure for patients, and when she first</p> <p>11 started on the Tamoxifen, it seemed that there</p> <p>12 was maybe a little bit of a longer time</p> <p>13 between when she needed to be--like, the</p> <p>14 interval was a little bit longer, and we</p> <p>15 thought maybe that was a sign of her first</p> <p>16 starting to respond, but really her condition</p> <p>17 continued to deteriorate over the next couple</p> <p>18 of months, and she had other palliative</p> <p>19 radiations and other admissions, and</p> <p>20 palliative procedures done, and then she</p> <p>21 ultimately died of her disease in early August</p> <p>22 of that year.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And, Doctor, the addendum here just says that</p> <p>25 both receptors are positive?</p>	<p>1 treatment. Perhaps at some point he did tell</p> <p>2 me what the numbers are, but I wouldn't be</p> <p>3 able to remember now what they were.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. If you had received this result in 2002 at the</p> <p>6 time of her original diagnosis, would Mrs.</p> <p>7 Deane have been placed on hormonal therapy at</p> <p>8 that time?</p> <p>9 DR. LAING:</p> <p>10 A. Looking back, and looking at my practice at</p> <p>11 that time, I suspect I would have given her</p> <p>12 upfront chemotherapy, and then following that</p> <p>13 I would have given her hormonal therapy for</p> <p>14 her metastatic disease.</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. If we could have P-0046, please. This is a</p> <p>17 report, October 17th, 2005, from BC Cancer</p> <p>18 Agency from Dr. Banerjee, and this is just his</p> <p>19 cover letter.</p> <p>20 DR. LAING:</p> <p>21 A. Uh-hm.</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. And there's a report, and, Doctor, when did</p> <p>24 you first--when did you first see this report?</p> <p>25 DR. LAING:</p>
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<p>1 DR. LAING:</p> <p>2 A. Yes.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. And this is in 2005?</p> <p>5 DR. LAING:</p> <p>6 A. Yes.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. There's no indication of percentages, and at</p> <p>9 this point in time, I take it, it was usual</p> <p>10 that percentages would be given?</p> <p>11 DR. LAING:</p> <p>12 A. It would have been.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. Did you have any discussion with Dr. Elms as</p> <p>15 to whether or not--how positive is she? She</p> <p>16 was already less than 10 percent on the</p> <p>17 original test, less than 10 percent PR</p> <p>18 positive.</p> <p>19 DR. LAING:</p> <p>20 A. Yes. No, I don't know what her actual numbers</p> <p>21 would have been, and I can't recall if he</p> <p>22 would have said when we spoke to him, because,</p> <p>23 of course, the first verbal report of the</p> <p>24 change in receptor status was communicated</p> <p>25 through to Dr. Rorke who started her on the</p>	<p>1 A. I've never read this report in its entirety.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. You've never read it in its entirety?</p> <p>4 DR. LAING:</p> <p>5 A. No.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. When did you see any portion of this report</p> <p>8 for the first time?</p> <p>9 DR. LAING:</p> <p>10 A. It would have been--as I said, I've never sat</p> <p>11 down and read this report. This was</p> <p>12 something, as you know, that was done as part</p> <p>13 of a peer review process and then that whole</p> <p>14 issue was subsequently changed. So when Dr.</p> <p>15 Banerjee attended and did the review, I did</p> <p>16 not have an opportunity to meet with him,</p> <p>17 nobody had requested that I spend some time</p> <p>18 with him, and this was really a review of the</p> <p>19 pathology in the laboratory. You know, I</p> <p>20 don't--I haven't read through this report.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. Did you know Dr. Banerjee?</p> <p>23 DR. LAING:</p> <p>24 A. No.</p> <p>25 CHAYTOR, Q.C.:</p>

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<p>1 Q. You've never met him?</p> <p>2 DR. LAING:</p> <p>3 A. I searched back in my mind to try and think if</p> <p>4 I can remember him when I was in my BC days,</p> <p>5 but--perhaps if I saw a picture of him, I</p> <p>6 would remember, but he's not one of the</p> <p>7 pathologists that I recall interacting with a</p> <p>8 lot when I was a resident there. In fact, I'd</p> <p>9 have to go back and look at his CV to see if</p> <p>10 he was, in fact, there when I was a resident.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. My original question then, when did you see,</p> <p>13 read, any portion of his report of October</p> <p>14 17th, 2005?</p> <p>15 DR. LAING:</p> <p>16 A. I've never read this in its entirety.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. No, any portion of it?</p> <p>19 DR. LAING:</p> <p>20 A. I may have had some discussions with Dr. Cook</p> <p>21 and Dr. Denic subsequently as to the content</p> <p>22 of this report, but this would not be</p> <p>23 something that I have sat down and seen or</p> <p>24 read.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. Uh-hm, and Dr. Banerjee says at page three, I</p> <p>3 believe it is, of his report, he talks about</p> <p>4 the index case and four other patients</p> <p>5 previously tested as negative in 2002.</p> <p>6 DR. LAING:</p> <p>7 A. Yes.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. Uh-hm. There's a portion here I wanted to</p> <p>10 take you to. Right here under the "Incident</p> <p>11 problem case".</p> <p>12 DR. LAING:</p> <p>13 A. Oh, okay.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. The case is that a patient with invasive</p> <p>16 lobular carcinoma whose tumour was tested in</p> <p>17 2002 on the DAKO immunostainer and reported as</p> <p>18 negative for ER and PR, and when retested in</p> <p>19 2005 on the Ventana Benchmark was strongly</p> <p>20 positive for both receptor proteins. So he's</p> <p>21 indicating that she was, in fact, strongly</p> <p>22 positive?</p> <p>23 DR. LAING:</p> <p>24 A. Yes.</p> <p>25 CHAYTOR, Q.C.:</p>
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<p>1 Q. So, Doctor, is it correct to say that you have</p> <p>2 never read or seen any portion of this report?</p> <p>3 DR. LAING:</p> <p>4 A. Not that I can recall, no.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. Doctor, of course, this report is a public</p> <p>7 exhibit here at the inquiry, and have you--</p> <p>8 even since its become a public document,</p> <p>9 you've never read it or reviewed it, any</p> <p>10 portion of it?</p> <p>11 DR. LAING:</p> <p>12 A. No. We discussed it last week in preparation</p> <p>13 for my being here this week, and--but it</p> <p>14 wasn't something that I had--there was a lot</p> <p>15 of other material that I had reviewed, and</p> <p>16 I've not read it.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. And it's not long, it's four pages really--</p> <p>19 well, maybe five pages because the first page</p> <p>20 is the cover page, or page two is the cover</p> <p>21 page. So upon it becoming a public document</p> <p>22 even, you didn't read it?</p> <p>23 DR. LAING:</p> <p>24 A. I've never gone to the website and read any of</p> <p>25 the documents related to the inquiry.</p>	<p>1 Q. "It should be noted that invasive lobular</p> <p>2 carcinomas are frequently ER positive", and he</p> <p>3 puts in brackets, 92 percent.</p> <p>4 DR. LAING:</p> <p>5 A. Right.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. "Thus the initial negative result should have</p> <p>8 been questioned".</p> <p>9 DR. LAING:</p> <p>10 A. I'd like to just mention that this is the only</p> <p>11 part of this report--not that I see where this</p> <p>12 is coming, I have seen this page, not the full</p> <p>13 report, but I did look at this last week, and</p> <p>14 I'm sorry I didn't realize that this was</p> <p>15 something that was in the body of his report.</p> <p>16 Certainly Dr. Banerjee is speaking as a</p> <p>17 pathologist and, you know, as a medical</p> <p>18 oncologist, as I said, unless there was</p> <p>19 something else about an ER/PR negative</p> <p>20 invasive lobular cancer, I--you know, I</p> <p>21 wouldn't think that I would question each one</p> <p>22 of those results, knowing that there's</p> <p>23 certainly--the percentage he gives 92 percent</p> <p>24 and a reference, I'm not sure what that</p> <p>25 reference is to, but it's probably appended to</p>

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<p>1 his report. 2 CHAYTOR, Q.C.: 3 Q. Yes, it is. 4 DR. LAING: 5 A. So, you know, that's really -- 6 CHAYTOR, Q.C.: 7 Q. And he was asked about that. I can fill you 8 in on that. 9 DR. LAING: 10 A. Okay. 11 CHAYTOR, Q.C.: 12 Q. He was asked about that in his evidence 13 because the reference that he gave was to a 14 2005 journal article. 15 DR. LAING: 16 A. Okay. 17 CHAYTOR, Q.C.: 18 Q. And that he was asked, well, what about in 19 2002 because he's saying that it should have 20 been noted. 21 DR. LAING: 22 A. Sure. 23 CHAYTOR, Q.C.: 24 Q. And his response to that was that it was well 25 known in 2002 that invasive lobular carcinomas</p>	<p>1 acknowledge the fact that it was ER/PR 2 negative and it wasn't questioned then. This 3 is certainly something that, as you can 4 imagine, I have discussed with my colleagues 5 to say that, you know, what was your 6 understanding. And, you know, people said we 7 understood that there was a high proportion 8 but not that it was 100 percent. 9 THE COMMISSIONER: 10 Q. Not that it was 100 percent or not that it was 11 92 percent? 12 DR. LAING: 13 A. That it was not 100 percent and that it was, 14 you know, my teaching, as I said, had been 15 that it was somewhere around 85, 90 percent. 16 THE COMMISSIONER: 17 Q. So are you saying that what the other 18 oncologists have said to you were consistent 19 with your training or did they have another 20 number entirely? 21 DR. LAING: 22 A. No, it was consistent with that. It would 23 usually be around 90 percent would be what the 24 people that I spoke with certainly said. 25 THE COMMISSIONER:</p>
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<p>1 are virtually 100 percent ER positive, and 2 when he was also asked who should have noted 3 this, he responded the pathologist and the 4 oncologist, and that's Dr. Banerjee's 5 evidence, so I wanted to offer you an 6 opportunity then to respond to that? 7 DR. LAING: 8 A. Well, certainly, as I said, that's his opinion 9 as a pathologist. My training and what I had 10 been taught was that it was 85 to 90 percent. 11 I've certainly had this discussion with other 12 colleagues of mine who have certainly 13 indicated a similar amount. Perhaps this is 14 time we should refer to, we talked a lot about 15 the index case. In fact, as part of Peggy's 16 course they asked for to be seen by Maureen 17 Trudeau, who we've spoken about. Dr. Trudeau 18 is a medical oncologist at Sunnybrook. There 19 was a letter, a referral letter sent by Dr. 20 McCarthy as that was when I was on my 21 maternity leave. I have subsequently read the 22 consultation note back from Dr. Trudeau which 23 was dictated by one of her fellows and very 24 clearly in that do they acknowledge the fact 25 that this was a lobular tumour and do they</p>	<p>1 Q. Thank you. 2 CHAYTOR, Q.C.: 3 Q. And you're saying that Dr. Trudeau would have 4 been clear in any communications to her that 5 the ER/PR status on the original tumour was ER 6 negative? 7 DR. LAING: 8 A. Yes. 9 CHAYTOR, Q.C.: 10 Q. And PR positive, less than ten percent? 11 DR. LAING: 12 A. Yes, in the consultation note back, they 13 indicate that it was ER/PR negative. 14 CHAYTOR, Q.C.: 15 Q. And have you subsequently discussed that with 16 Dr. Trudeau? 17 DR. LAING: 18 A. No, I have not. 19 CHAYTOR, Q.C.: 20 Q. Okay. Doctor, the decision then to go further 21 in the aftermath of Peggy Deane's case and to 22 test further, well, first of all, within the 23 first days or couple of weeks following Peggy 24 Deane's situation and so back in, I guess that 25 would take us into late April, early May, was</p>

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1 this a subject of much discussion amongst the
2 oncology department?

3 DR. LAING:

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

17 CHAYTOR, Q.C.:

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

21 DR. LAING:

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

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

4 CHAYTOR, Q.C.:

5 Q. Okay.

6 DR. LAING:

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

22 CHAYTOR, Q.C.:

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

25 DR. LAING:

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1 A. Yeah.

2 CHAYTOR, Q.C.:

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

5 DR. LAING:

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

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

8 CHAYTOR, Q.C.:

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

12 DR. LAING:

13 A. Okay.

14 CHAYTOR, Q.C.:

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

22 DR. LAING:

23 A. Yes.

24 CHAYTOR, Q.C.:

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

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<p>1 note, most of this clinic note has been 2 redacted. And under "Clinical diagnosis" is 3 "Poorly differentiated lobular carcinoma." 4 DR. LAING: 5 A. Um-hm. 6 CHAYTOR, Q.C.: 7 Q. And you see her on May 6th, 2005. I'll just 8 scroll down so you can see that, that's your 9 signature. And ER/PR negative with staining 10 only in one to two percent? 11 DR. LAING: 12 A. Right. 13 CHAYTOR, Q.C.: 14 Q. "I had a look at her pathology today. It is 15 interesting that it was said to be lobular, 16 but there was evidence of DCIS and the ER/PR 17 was essentially negative with only one to two 18 percent staining. Reviews have suggested that 19 most lobulars should be ER/PR positive. I'm 20 going to have the pathology review this for 21 me. I will see her back in six months." So, 22 Doctor, you've written here, "Reviews have 23 suggested that most lobulars should be ER/PR 24 positive." And what are you referring to 25 there?</p>	<p>1 clinic and that I decided, well, maybe I'll 2 ask to have this reviewed and see if that 3 changes or not. 4 CHAYTOR, Q.C.: 5 Q. Um-hm. And the idea, though, of any review, 6 when we look at Dr. Hudis' e-mail, there's 7 certainly no indication of any review at that 8 point in time? 9 DR. LAING: 10 A. No. 11 CHAYTOR, Q.C.: 12 Q. Okay. And so "Reviews have suggested that 13 most lobulars should be ER/PR" where does that 14 come from out of what Dr. Hudis had told you 15 up to this point in time? 16 DR. LAING: 17 A. I can only say that, you know, looking at what 18 I've written there and knowing what I knew at 19 the time, it was based on what he had told me. 20 CHAYTOR, Q.C.: 21 Q. Doctor, you, in your own training, have told 22 us that you were aware that most lobulars 23 should be ER/PR positive? 24 DR. LAING: 25 A. That's correct.</p>
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<p>1 DR. LAING: 2 A. I'm referring to the communication that I 3 received from Dr. Hudis. 4 CHAYTOR, Q.C.: 5 Q. Okay. And that communication would have been 6 a review that Sloan Kettering did which 7 indicated on tumour bank--anonymous tumour 8 bank - 9 DR. LAING: 10 A. I wouldn't have had any of that information at 11 this time. 12 CHAYTOR, Q.C.: 13 Q. You didn't have that at that time? 14 DR. LAING: 15 A. No, no, no. 16 CHAYTOR, Q.C.: 17 Q. Oh, okay. 18 DR. LAING: 19 A. This was just only after, you know, I get this 20 e-mail from Dr. Hudis suggesting that, you 21 know, as I--you know, as we read that the 22 number shouldn't be what I had always thought, 23 that perhaps it even should be 100 percent, 24 which is why I thought, okay, you know, here's 25 a case that just happens to be coming into the</p>	<p>1 CHAYTOR, Q.C.: 2 Q. So this wasn't recent knowledge, that was 3 something that you knew, that most lobulars 4 should be ER/PR positive? 5 DR. LAING: 6 A. Right. It was his statement that he had never 7 seen an invasive that was negative. So never 8 seen invasive lobular that was negative would 9 translate to me to be that they were 100 10 percent positive. And as I said, that was the 11 first time I had had any indication was when 12 he sent me that e-mail that all lobulars, ie, 13 100 percent, were potentially positive. So, 14 you know, this was in the early days so I had 15 said, you know, this is a lobular, I had this 16 information and that was the rationale I had 17 placed in the chart at that time for asking 18 for the review. 19 CHAYTOR, Q.C.: 20 Q. Yes. And Dr. Hudis had indicated that he had 21 never seen - 22 DR. LAING: 23 A. That's correct. 24 CHAYTOR, Q.C.: 25 Q. - is exactly what he said?</p>

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<p>1 DR. LAING: 2 A. That was his exact words. 3 CHAYTOR, Q.C.: 4 Q. He had never seen it? 5 DR. LAING: 6 A. Yeah. 7 CHAYTOR, Q.C.: 8 Q. The idea that you're going to have her 9 pathology reviewed and you're going to see her 10 back in six months. 11 DR. LAING: 12 A. So she would have been on a six-month follow- 13 up. 14 CHAYTOR, Q.C.: 15 Q. Okay. And I take it if you're going to have 16 her pathology reviewed and there were any 17 change, you'd see her back sooner than six 18 months? 19 DR. LAING: 20 A. Yes. 21 CHAYTOR, Q.C.: 22 Q. And, Doctor, did you, in fact, do that, did 23 you have then her pathology reviewed and, if 24 so, what happened? 25 DR. LAING:</p>	<p>1 DR. LAING: 2 A. Most often - 3 CHAYTOR, Q.C.: 4 Q. So you don't know if you spoke to him or just 5 sent along a requisition? 6 DR. LAING: 7 A. Yeah. 8 CHAYTOR, Q.C.: 9 Q. Okay. And having her retested and then having 10 a change in her result, you then had her back? 11 DR. LAING: 12 A. Yes. 13 CHAYTOR, Q.C.: 14 Q. On June 10th. And think, as I said, it was 15 May 20th that the addendum was placed on her 16 chart. You indicate here that "She returns to 17 clinic today for review. I saw a month ago. 18 At that time on reviewing her chart I noted 19 that she had a lobular cancer which was said 20 to be ER/PR negative. I had this reviewed and 21 in fact it did come back as being ER/PR 22 positive with staining that was strongly 23 positive. I called her and told her this news 24 and asked her to come in and speak to me 25 today."</p>
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<p>1 A. I had it reviewed, yes, and the results 2 changed and I brought her back. 3 CHAYTOR, Q.C.: 4 Q. And, Doctor, it indicates from our review 5 that, I believe, May 20th, 2005, Dr. Cook did 6 an addendum to her pathology report indicating 7 that she was both ER/PR strongly positive? 8 DR. LAING: 9 A. Right. 10 CHAYTOR, Q.C.: 11 Q. Did you--after having her in on May 4th, I'm 12 sorry, May 6th, after having her in on May 13 6th, after having her in on May 6th I take it 14 you made contact with Dr. Cook? 15 DR. LAING: 16 A. Yes. 17 CHAYTOR, Q.C.: 18 Q. And what exactly did you explain to Dr. Cook 19 as to why you wanted this patient redone? 20 DR. LAING: 21 A. I'd have to look at her chart to know if I 22 sent a consult or if I spoke to him directly. 23 I can't recall at this point which one it was. 24 CHAYTOR, Q.C.: 25 Q. Okay.</p>	<p>1 DR. LAING: 2 A. Yes. 3 CHAYTOR, Q.C.: 4 Q. So I take it patient number two, you contacted 5 her on the phone and told her this? 6 DR. LAING: 7 A. Yes, I told her that I had change in her 8 result and would she come in and we would sit 9 down and talk about it. 10 CHAYTOR, Q.C.: 11 Q. Okay. And "We now know that her tumour was 12 ER/PR positive." 13 DR. LAING: 14 A. That's right. 15 CHAYTOR, Q.C.: 16 Q. "Had we known that at her initial diagnosis I 17 would have placed her either on Tamoxifen or 18 Arimidex at that time. However, because we 19 believed her to be ER/PR negative, that was 20 not done. These has been some literature 21 which does support late starting of Tamoxifen. 22 I have talked to some of my colleagues across 23 the country about this situation and they felt 24 it was reasonable at this time now that she is 25 just over two years from when we would have</p>

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<p>1 started her Tamoxifen to offer her this." 2 DR. LAING: 3 A. Right. 4 CHAYTOR, Q.C.: 5 Q. So I take it that refers to your discussion 6 you mentioned earlier today with Dr. Kathy 7 Pritchard? 8 DR. LAING: 9 A. With Doctor--that's right, yeah. 10 CHAYTOR, Q.C.: 11 Q. Okay. And did you speak with anyone else 12 other than Dr. Kathy Pritchard about that 13 situation? 14 DR. LAING: 15 A. No. Actually, when I did have that 16 conversation with Dr. Pritchard, I was at a 17 meeting with, you know, probably half a dozen 18 medical oncologists that deal with breast 19 cancer from across the country and I brought 20 up the issue and Dr. Pritchard said, oh, yes, 21 you know, there's a paper and it was--she then 22 asked to have it sent to me, she asked her 23 assistant to e-mail it to me, which is--or e- 24 mail me the reference, so that's how I first 25 got that particular paper.</p>	<p>1 started on Tamoxifen. 2 CHAYTOR, Q.C.: 3 Q. Yes. 4 DR. LAING: 5 A. That's right. 6 CHAYTOR, Q.C.: 7 Q. And she's reviewed in December, December 18th, 8 2005, there's a panel letter - 9 DR. LAING: 10 A. Okay, so then she would have had - 11 CHAYTOR, Q.C.: 12 Q. - for her. 13 DR. LAING: 14 A. Yeah. 15 CHAYTOR, Q.C.: 16 Q. And it indicates she is already on Tamoxifen 17 so no need of any--no impact, I believe, is 18 what it says. The letter says "There's no 19 impact on the patient's treatment and no 20 treatment follow-up required." 21 DR. LAING: 22 A. Because I had already disclosed it and started 23 her on the appropriate therapy. 24 CHAYTOR, Q.C.: 25 Q. Okay. So in terms of indicating at the end of</p>
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<p>1 CHAYTOR, Q.C.: 2 Q. And, Doctor, do you know whether or not this 3 patient was also--this is early on days now, 4 this is May 20th that her retest was done and 5 noted on her chart. Do you know whether or 6 not she was also sent or her sample was sent 7 Mount Sinai for further retesting? 8 DR. LAING: 9 A. I am not certain. 10 CHAYTOR, Q.C.: 11 Q. And I can indicate that her review of her 12 chart would indicate that there was a repeat 13 at Mount Sinai and she was found to be 80 to 14 20 percent positive, 80 percent ER - 15 DR. LAING: 16 A. 80 for ER - 17 CHAYTOR, Q.C.: 18 Q. - and 20 percent PR. 19 DR. LAING: 20 A. Okay, fair enough, yeah. 21 CHAYTOR, Q.C.: 22 Q. And she in fact was reviewed by your panel. 23 DR. LAING: 24 A. Yes. And I believe the panel letter says that 25 she had already been contacted and already</p>	<p>1 the day the number of people who would have 2 required a change in treatment, people such as 3 patient number two who had been started 4 because of your review back in the early days, 5 May and June of 2005, who had a treatment 6 change at that point, were they counted in the 7 numbers who at the end of the day were 8 disclosed as having a change in treatment? 9 DR. LAING: 10 A. I would have to say yes. That would be if you 11 were to ask me which category I would place 12 this lady in, it certainly would be the ones 13 in which the new information had an impact and 14 resulted in a treatment change, she would 15 belong in that category. 16 CHAYTOR, Q.C.: 17 Q. Okay. She would belong to that category? 18 DR. LAING: 19 A. Yes. 20 CHAYTOR, Q.C.: 21 Q. Regardless if her panel letter said that she 22 required a change in treatment or not? 23 DR. LAING: 24 A. The number that came from those treatment 25 changes would have been based on the panel</p>

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1 letters. That would have been a tabulation
 2 that was not done by me, but I would think,
 3 and the only way I could know would be if I
 4 had a list of the patients that were included
 5 in that 104, but she would belong in that 104
 6 and which subsequently became 117. But she
 7 certainly would have been someone who it just
 8 so happened that because of where she was,
 9 that she was one that was very early on in the
 10 process. She was started on Tamoxifen. You
 11 know what, I couldn't even tell you to be
 12 sure. She was started on one or the other and
 13 remains on that medication to date.
 14 CHAYTOR, Q.C.:
 15 Q. So based on your understanding of -
 16 DR. LAING:
 17 A. Based on my understanding.
 18 CHAYTOR, Q.C.:
 19 Q. You would expect her to be included in the 117
 20 because she was certainly a patient that
 21 required a change in treatment as a result of
 22 this review?
 23 DR. LAING:
 24 A. That's correct.
 25 CHAYTOR, Q.C.:

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1 Q. Okay.
 2 THE COMMISSIONER:
 3 Q. My understanding is as follows, in your view
 4 number two belongs in any list of persons who
 5 required treatment change, you don't know
 6 whether, in fact, she is in the list?
 7 DR. LAING:
 8 A. No, but I would assume that she is, but I'd
 9 have to see that list.
 10 THE COMMISSIONER:
 11 Q. I understood you didn't compile the list?
 12 DR. LAING:
 13 A. No.
 14 CHAYTOR, Q.C.:
 15 Q. And you'd be surprised if her name wasn't on
 16 the list?
 17 DR. LAING:
 18 A. I would.
 19 CHAYTOR, Q.C.:
 20 Q. And you would suggest that she be added?
 21 DR. LAING:
 22 A. Yes.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. And did you have any input into
 25 comprising who was placed on the list of 117

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1 patients?
 2 DR. LAING:
 3 A. The input that I had would be that we felt
 4 that the patients who had a treatment change
 5 should be the ones who were on that list. That
 6 was our definition, if you will. And the
 7 reason for that was that as we alluded to this
 8 morning, there were several patients who were
 9 already treated way back from the time of
 10 their initial diagnosis with adjuvant hormonal
 11 therapy because of their progesterone receptor
 12 status.
 13 CHAYTOR, Q.C.:
 14 Q. Okay. And, Doctor, were you, at this point in
 15 time in May and into June of 2005, were other
 16 oncologists doing the same thing that you're
 17 obviously doing here, people are appearing
 18 before you and you're questioning whether or
 19 not you should have a look at the ER/PR
 20 status, were your colleagues doing the same?
 21 DR. LAING:
 22 A. Yes, so that the other colleague of mine that
 23 I know did this was Dr. McCarthy. And when we
 24 were asked recently if we could recall which
 25 patients may have been in those very, very

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1 early patients, this is the five patients that
 2 we're reviewing now that we could remember
 3 back then. And some of them were her patients
 4 and some of them were my patients. Some of
 5 them were patients that through our maternity
 6 leaves that we had both been involved at some
 7 point in their care. And three of those
 8 patients had lobular histology, which is what
 9 tweaked us, if you will, for asking for the
 10 repeat. One of those patients, a patient of
 11 Dr. McCarthy's had metastatic breast cancer.
 12 She had extensive disease, particularly
 13 involving her chest wall, which had stopped
 14 responding to chemotherapy and the reason to
 15 retest her was to see if there might be a
 16 therapy, because she had run out of
 17 chemotherapy options, to might see if there
 18 was a therapy that she could be offered for
 19 her metastatic disease. But, in fact, her
 20 initial pathology was ductal.
 21 THE COMMISSIONER:
 22 Q. I'm sorry, her initial pathology was?
 23 DR. LAING:
 24 A. Was ductal. Yeah, she wasn't a lobular
 25 patient. But, you know, Dr. McCarthy had

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1 someone sitting in the clinic who had run out
2 of chemotherapy options and thought, well,
3 maybe I'll ask for it to be reviewed to see if
4 there's any change in her status that would at
5 least allow her to offer this lady hormonal
6 therapy for her metastatic disease.
7 CHAYTOR, Q.C.:
8 Q. Okay. And I believe that might be patient
9 number three?
10 DR. LAING:
11 A. I think it's patient one, but.
12 CHAYTOR, Q.C.:
13 Q. Patient one, okay. Well, let's look at
14 patient number one, if we could?
15 DR. LAING:
16 A. Oh, wait now.
17 CHAYTOR, Q.C.:
18 Q. That's fine.
19 DR. LAING:
20 A. Okay.
21 CHAYTOR, Q.C.:
22 Q. Patient number one I think is a lobular.
23 DR. LAING:
24 A. It's hard for me to know -
25 CHAYTOR, Q.C.:

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1 Q. Yes, she's a lobular, yes, she's a lobular.
2 If we could look, please, at -
3 DR. LAING:
4 A. So is patient one a lobular then?
5 CHAYTOR, Q.C.:
6 Q. Patient one is a lobular.
7 DR. LAING:
8 A. Okay.
9 CHAYTOR, Q.C.:
10 Q. According to my notes.
11 DR. LAING:
12 A. Then this lady would be patient number three.
13 And we put these patients in order by looking
14 at what we could determine to be their retest
15 date.
16 THE COMMISSIONER:
17 Q. So when you say this lady would be number
18 three, are you talking about the one we have
19 been talking about as number two or the next
20 one?
21 DR. LAING:
22 A. No, we're talking about another one. Number
23 is definitely number two.
24 THE COMMISSIONER:
25 Q. All right. I'm fine if number two is number

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1 two. You can work out -
2 CHAYTOR, Q.C.:
3 Q. Number two is number two, all right.
4 DR. LAING:
5 A. I know that much.
6 CHAYTOR, Q.C.:
7 Q. We'll look at number one, yeah, because
8 patient number two is your patient.
9 DR. LAING:
10 A. Yeah, patient number two is my patient, that's
11 what I know.
12 CHAYTOR, Q.C.:
13 Q. Patient number one is Dr. McCarthy's. C-0243.
14 DR. LAING:
15 A. Okay. Let me see if I can figure it out from
16 this.
17 CHAYTOR, Q.C.:
18 Q. Okay. And this is a poorly differentiated
19 infiltrating carcinoma, lobular carcinoma.
20 DR. LAING:
21 A. Okay.
22 CHAYTOR, Q.C.:
23 Q. Okay.
24 THE COMMISSIONER:
25 Q. And we are calling this one patient number?

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1 CHAYTOR, Q.C.:
2 Q. This is patient number one.
3 DR. LAING:
4 A. This is patient number one.
5 THE COMMISSIONER:
6 Q. Thank you.
7 CHAYTOR, Q.C.:
8 Q. And she's seen in clinic by Dr. McCarthy. And
9 we'll get a chance, Commissioner, I'm sure, to
10 hear from Dr. McCarthy on this. But she's
11 seen May 4th, 2005. And I've redacted--
12 there's no reference that I could see to
13 anything about the review on that date. But
14 then on May 11th.
15 DR. LAING:
16 A. Okay.
17 CHAYTOR, Q.C.:
18 Q. Now if we bear in mind that it was May 6th
19 that you saw patient number two. So on May
20 11th, 2005 this patient is back in, patient
21 No. 1 is back in to see Dr. McCarthy on that
22 date. And she writes on that date, "I do note
23 that her previous cancer was lobular and even
24 though it said that she was ER/PR negative, I
25 think we should repeat this because in 2002

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<p>1 there were some problems with the assay. We</p> <p>2 have had a previous case of lobular carcinoma</p> <p>3 that was read as being negative which was</p> <p>4 actually positive on review, thus, I will</p> <p>5 consult pathology urgently today. I will see</p> <p>6 her again once her CAT scan is done and we</p> <p>7 will stop chemotherapy for now." And, Doctor,</p> <p>8 the reference Dr. McCarthy makes here because,</p> <p>9 ask for a repeat because in 2002 there were</p> <p>10 some problems with the assay, do you know what</p> <p>11 she's referring to there, was that discussed</p> <p>12 between yourself and her?</p> <p>13 DR. LAING:</p> <p>14 A. I'm not certain, but I suspect that the 2002</p> <p>15 may be there because that was the year of</p> <p>16 Peggy Deane's diagnosis, so I think that</p> <p>17 that's the reason for 2002.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. Okay. And according to this patient's chart</p> <p>20 on May 13th Dr. Cook did do the retest.</p> <p>21 DR. LAING:</p> <p>22 A. And I think that's the reason why she got to</p> <p>23 be patient number one.</p> <p>24 CHAYTOR, Q.C.:</p> <p>25 Q. Yes. She was actually -</p>	<p>1 Q. So this is the patient you were referring to?</p> <p>2 DR. LAING:</p> <p>3 A. That's correct.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. Yes, okay, and "was originally felt to be</p> <p>6 ER/PR negative, but recently retested in the</p> <p>7 past couple of weeks and she is actually</p> <p>8 strongly positive for both ER and PR," and</p> <p>9 this again is June 22nd, 2005.</p> <p>10 DR. LAING:</p> <p>11 A. That's right.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. And Dr. McCarthy also writes, under her plan,</p> <p>14 "I have previously presented her case in</p> <p>15 tumour board because I do not know how to use</p> <p>16 the ER/PR positivity information at this time.</p> <p>17 The group agreed that I would give her Femera</p> <p>18 with the Herceptin as long as she is</p> <p>19 responding." And Doctor, do you recall Dr.</p> <p>20 McCarthy bringing the case of patient number</p> <p>21 three and the change in her result to the</p> <p>22 tumour board rounds at that time?</p> <p>23 DR. LAING:</p> <p>24 A. Yes.</p> <p>25 CHAYTOR, Q.C.:</p>
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<p>1 DR. LAING:</p> <p>2 A. We went by the testing date.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. Yes, testing date, that's right. So your</p> <p>5 patient was actually tested on May 20th,</p> <p>6 whereas this patient was tested May 13th, a</p> <p>7 week prior, and of course, she did convert,</p> <p>8 okay.</p> <p>9 DR. LAING:</p> <p>10 A. Yes, and she was lobular, that's correct.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. And she was lobular, that's right. Now</p> <p>13 patient three, so she would be C-0245, please,</p> <p>14 and Doctor, we're running a bit short on time,</p> <p>15 so I won't take you through all five, but I'll</p> <p>16 take you through number three.</p> <p>17 DR. LAING:</p> <p>18 A. Right, so this is the real number three.</p> <p>19 CHAYTOR, Q.C.:</p> <p>20 Q. This is the real number three, and she is a</p> <p>21 moderately differentiated ductal carcinoma.</p> <p>22 DR. LAING:</p> <p>23 A. Right, so this is the one that I was talking</p> <p>24 about.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 Q. Okay, and so you--and do you recall that there</p> <p>2 would have been other oncologists and</p> <p>3 pathologists present at that tumour board</p> <p>4 round?</p> <p>5 DR. LAING:</p> <p>6 A. There usually is a group of pathologists and</p> <p>7 oncologists.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. Okay, so and this would have taken place</p> <p>10 obviously sometime before June 22nd, 2005,</p> <p>11 because she's stating "I had previously done</p> <p>12 this." So I take it by the middle of June or</p> <p>13 certainly by June 22nd, 2005, it was very well</p> <p>14 known that these issues had arisen and there</p> <p>15 were changes in results?</p> <p>16 DR. LAING:</p> <p>17 A. So there would have been some discussion. I'm</p> <p>18 not certain that I was actually at this</p> <p>19 specific tumour board round, but this is a</p> <p>20 lady that I mentioned that I was involved with</p> <p>21 her care when Dr. McCarthy was on maternity</p> <p>22 leave, so I know who this lady is and I know</p> <p>23 her case, and she really had quite extensive</p> <p>24 chest wall disease that really had stopped</p> <p>25 responding to treatment and we were really</p>

<p style="text-align: right;">Page 341</p> <p>1 looking for something else to be able to give 2 her, which was--because, if you'll note, this 3 is the first retest now that we've done on a 4 ductal cancer. 5 CHAYTOR, Q.C.: 6 Q. Yes, and that was, I understood your evidence 7 to be that's because she was basically--you 8 were looking--Dr. McCarthy was looking for 9 anything to potentially help this woman? 10 DR. LAING: 11 A. That's right, yeah. That was the reason to 12 retest her. At this particular--I know that I 13 was away on June 22nd, but if this was 14 presented perhaps the week or two weeks before 15 at tumour board round, I may have been present 16 for that discussion, but I do know that Dr. 17 McCarthy and I did discuss this particular 18 lady's care and we did start her on Femara, 19 which I'll remind you is letrozole, which is 20 one of the aromatase inhibitors, and we picked 21 that one because of its higher response rate 22 than Tamoxifen in the metastatic setting. 23 CHAYTOR, Q.C.: 24 Q. Doctor, take us forward then from there. How 25 did you then continue to identify other</p>	<p style="text-align: right;">Page 343</p> <p>1 DR. LAING: 2 A. Yeah, and - 3 CHAYTOR, Q.C.: 4 Q. And did you sit in on that telephone 5 conversation? 6 DR. LAING: 7 A. I'm not sure if it was the initial one, but 8 there was another time when she did call Dr. 9 Cook and I was in the office with Dr. 10 McCarthy, and she was talking to Dr. Cook at 11 St. Clare's, but I think it might have been a 12 subsequent to that initial phone conversation, 13 because by this time, we both now, in the 14 middle of May, have had patients with new 15 results. But my first patient, patient number 16 two, I wouldn't have been aware of her results 17 until after the 20th of May. So it would have 18 been subsequent to that. 19 CHAYTOR, Q.C.: 20 Q. I'm sorry, yes, so he--you would be--as 21 patients are coming before you, you're 22 identifying them or checking the chart at that 23 point? 24 DR. LAING: 25 A. Right, so yes.</p>
<p style="text-align: right;">Page 342</p> <p>1 patients that should be retested? You now 2 have a ductal carcinoma that has also 3 converted. 4 DR. LAING: 5 A. Yes. 6 CHAYTOR, Q.C.: 7 Q. So what happens after that? 8 DR. LAING: 9 A. So by this time, you know, we've had the 10 preliminary discussions with Dr. Cook. 11 CHAYTOR, Q.C.: 12 Q. And what do you mean by that? Other than 13 requesting retests from him, have you had any 14 other discussion with him? 15 DR. LAING: 16 A. Well, there was the phone call between him and 17 Dr. McCarthy, which was earlier than June, and 18 in fact, the - 19 CHAYTOR, Q.C.: 20 Q. According to Dr. Cook's note, it was May 11th, 21 according to his letter anyhow. 22 DR. LAING: 23 A. Okay, sure. 24 CHAYTOR, Q.C.: 25 Q. And I'll take you to that.</p>	<p style="text-align: right;">Page 344</p> <p>1 CHAYTOR, Q.C.: 2 Q. Yes, and so is, Dr. McCarthy is doing that? 3 DR. LAING: 4 A. Yeah, yeah. 5 CHAYTOR, Q.C.: 6 Q. And Doctor, what was it in May, May 6th is the 7 first reference we have with patient number 8 two, that you do that? What is it on May 6th 9 that causes you to start to do that and start 10 to question and look for retests on ER/PR 11 status? 12 DR. LAING: 13 A. Oh, it was the index case. It was Peggy's 14 case. It was the discussions with Dr. Hudis, 15 and so really our first clue, if you will, or 16 what was that, I mean, that's what started 17 this whole process. The second one was, of 18 course, we now have two more cases, albeit 19 lobular, that change, and now our first ductal 20 case. I have another lobular who's another 21 one of these patients, and these are the 22 people that we can remember from those early 23 days as being the ones that we either retested 24 by virtue of them having lobular disease that 25 was negative or because they were patients</p>

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1 really, you know, with metastatic disease who
 2 really had no other treatment options.
 3 CHAYTOR, Q.C.:
 4 Q. Doctor, Mrs. Deane's case was retested back in
 5 mid April and the first, next retest happens,
 6 it appears, May 13th.
 7 DR. LAING:
 8 A. Right.
 9 CHAYTOR, Q.C.:
 10 Q. So what was it--it's not like you went back to
 11 your office within, you know, two or three
 12 days and sat down and started -
 13 DR. LAING:
 14 A. Oh, you mean why was there that delay between
 15 -
 16 CHAYTOR, Q.C.:
 17 Q. Yes, there's a period of two or three, maybe
 18 even four weeks.
 19 DR. LAING:
 20 A. I would suspect that it was because during
 21 that time period, I didn't come across any
 22 patients through my work that raised it. I
 23 mean, the next patient that really raised it
 24 for me was that lobular chart that I picked up
 25 that said, you know, that this was negative,

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1 and that was the reason -
 2 CHAYTOR, Q.C.:
 3 Q. So it was the next lobular in through the
 4 door?
 5 DR. LAING:
 6 A. Yeah. Now certainly, between now and then, in
 7 that time, I'm sure there were other charts
 8 that I looked at that were lobulars that were
 9 positive that were--you know, we still had
 10 lots of patients who were -
 11 CHAYTOR, Q.C.:
 12 Q. So were you doing that? Were you pulling your
 13 charts in the meantime?
 14 DR. LAING:
 15 A. No, no, I wasn't pulling my charts. These
 16 were people that we were seeing as part of our
 17 day-to-day clinical practice, and you know, in
 18 the run of a day, in a busy clinic, I'll see
 19 15-18 patients, and that would have been three
 20 or four days a week. So there would have been
 21 a large volume of people that we would have
 22 been seeing during that time period. This was
 23 in 2005, and every year, in the end of April,
 24 I'm gone to usually a week long of national
 25 meetings. So I'm certain that at the last

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1 week in April of 2005, I would have been at
 2 these meetings. So really between when we had
 3 the index case and when we started sort of--it
 4 was pretty much right away that we were
 5 looking at things as we were seeing them
 6 coming through the door in the clinic.
 7 CHAYTOR, Q.C.:
 8 Q. Now, Dr. McCarthy would have had the patient
 9 number one.
 10 DR. LAING:
 11 A. Yes.
 12 CHAYTOR, Q.C.:
 13 Q. Who was also a lobular, infiltrating lobular.
 14 DR. LAING:
 15 A. Yes.
 16 CHAYTOR, Q.C.:
 17 Q. She saw her on May 4th, and there was no
 18 indication at that time of any review
 19 happening or looking at her chart and
 20 questioning her pathology on May 4th. On May
 21 6th, that happens for you with patient number
 22 two. But Dr. McCarthy saw patient number one
 23 on May 4th and it's May 11th, the next time
 24 that patient is in, that Dr. McCarthy also

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1 initiates a retest for her.
 2 DR. LAING:
 3 A. Okay.
 4 CHAYTOR, Q.C.:
 5 Q. So I'm just wondering is there something that
 6 happened to trigger this in those--between May
 7 4th, May 6th?
 8 DR. LAING:
 9 A. No.
 10 CHAYTOR, Q.C.:
 11 Q. And it was May 6th when your patient walked in
 12 that you -
 13 DR. LAING:
 14 A. Sure.
 15 CHAYTOR, Q.C.:
 16 Q. - you picked up on this and thought "isn't
 17 this unusual? I now have another lobular
 18 who's negative."
 19 DR. LAING:
 20 A. Right, so that was my thinking.
 21 CHAYTOR, Q.C.:
 22 Q. And then did you relay that to Dr. McCarthy,
 23 and is that what caused her to go back and
 24 look at patient number one?
 25 DR. LAING:

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1 A. I'm not sure, not that I can recall. I mean,
 2 I think that these discussions had been
 3 happening right from the index case, right
 4 from Peggy Deane's case, so you know, I don't
 5 think that there was any sort of a sentinel
 6 event on May 6th that, you know, made Dr.
 7 McCarthy do what she did on May 11th. It
 8 probably had to do with when the patient was
 9 coming to the clinic.

10 CHAYTOR, Q.C.:

11 Q. No, she was there on May 4th, that's why I was
 12 wondering.

13 DR. LAING:

14 A. Yeah, it--you know, the only way you could
 15 really know is to sort of read through what
 16 exactly was in the clinic note to say if--you
 17 know, there are often patients, particularly
 18 patients with metastatic disease, that are
 19 seen in the clinic on a weekly basis. That
 20 would not be an uncommon thing for people on
 21 active treatment.

22 CHAYTOR, Q.C.:

23 Q. It seemed to be a regular clinic visit, and we
 24 did read through the clinic note, but I'll ask
 25 Dr. -

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1 DR. LAING:

2 A. No, the regular clinic visit that you had for
 3 that first patient was all blacked out, so -

4 CHAYTOR, Q.C.:

5 Q. Yes, yes.

6 DR. LAING:

7 A. - I don't know. Oh, you read through it.

8 CHAYTOR, Q.C.:

9 Q. Yes, I've read it.

10 DR. LAING:

11 A. Sorry, you read through it at the time, okay.

12 CHAYTOR, Q.C.:

13 Q. We've read it.

14 DR. LAING:

15 A. Okay, fair enough.

16 CHAYTOR, Q.C.:

17 Q. But well, obviously, you and Dr. McCarthy, if
 18 you wish. That's why I'd given the names of
 19 the patients. I thought perhaps it would have
 20 been reviewed beforehand, but that's all
 21 right.

22 DR. LAING:

23 A. No, we actually came up with these, when we
 24 had the request last week.

25 CHAYTOR, Q.C.:

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1 Q. Yes, and I indicated that I'd be asking
 2 questions about them, so I--but that's okay.

3 DR. LAING:

4 A. We did look at them, but you know, I can't
 5 remember any reason why--what we did is
 6 remembered their names. We pulled them up on
 7 our patient computer system, on our OPUS
 8 system, and I asked them to print out--asked
 9 the secretaries in Health Records, to print
 10 out the first clinic note that had any mention
 11 of ER/PR retesting and the note that
 12 corresponded to the disclosure to the
 13 patients, and then we got the pathology
 14 reports and printed those off. So, but you
 15 know, as to what had happened before or after,
 16 or you know, why Dr. McCarthy didn't indicate
 17 it on the May 4th as opposed to just one week
 18 later.

19 CHAYTOR, Q.C.:

20 Q. You haven't reviewed that, that's fine. I'll
 21 ask Dr. McCarthy.

22 THE COMMISSIONER:

23 Q. Doctor, while we're looking at it, so I can
 24 understand the proper context of this.

25 DR. LAING:

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1 A. Yeah.

2 THE COMMISSIONER:

3 Q. Peggy Deane's case occurs, it's a big surprise
 4 and you and your colleagues talk about it.

5 DR. LAING:

6 A. Yes.

7 THE COMMISSIONER:

8 Q. Is it a case of because Peggy Deane is in your
 9 mind, the next person who walks through the
 10 door who is a lobular and who has a negative
 11 ER, you remember, or did you start out with
 12 the idea "I am going to check every lobular
 13 that now walks through my door to see if
 14 they're negative or positive"? How did it
 15 occur in that sense?

16 DR. LAING:

17 A. So what I would tell you -

18 THE COMMISSIONER:

19 Q. I'm trying to figure out what Peggy Deane's
 20 case meant to you.

21 DR. LAING:

22 A. So what Peggy Deane's case meant to me, back
 23 in those days, was that this was a change in a
 24 lobular histology. That it was because it was
 25 lobular that it was different. So it

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1 certainly meant that I was going to be looking
 2 at the results for my patients, in terms of
 3 their ER/PR testing, if they had been lobular,
 4 yes, and so the first person that I came in
 5 contact with in my day-to-day clinical
 6 practice was patient number two.
 7 THE COMMISSIONER:
 8 Q. Okay.
 9 DR. LAING:
 10 A. And so, you know, as I said that's written at
 11 the top of the chart, so I was making a
 12 conscious effort to look at and to see if
 13 there were people there who were lobular who
 14 had said to be ER/PR negative.
 15 THE COMMISSIONER:
 16 Q. And do you have any knowledge of whether or
 17 not other oncologists who were all of--all of
 18 the oncologists in the province would be
 19 operating out of the same institution that you
 20 were operating out of. Would you have any
 21 knowledge as to whether or not all of the
 22 oncologists in your shop, as it were, would
 23 set out to look at their charts in the same
 24 way?
 25 DR. LAING:

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1 A. Certainly after--maybe not right then, but
 2 certainly within the next few weeks, after we
 3 started to have more and more people, then
 4 yes, other people were looking at lobulars.
 5 Because as I said, this was now a discussion
 6 that was had within the larger group of
 7 oncologists, outside for just Dr. McCarthy and
 8 I.
 9 CHAYTOR, Q.C.:
 10 Q. And was there a direction given to the
 11 oncologist that they, in fact, do that?
 12 DR. LAING:
 13 A. Was there a specific direction given?
 14 CHAYTOR, Q.C.:
 15 Q. Yes.
 16 DR. LAING:
 17 A. No, not at that time, other than to say that
 18 if there were patients that were being seen in
 19 the course of our clinical practice that they
 20 wanted to have the ER/PR testing repeated,
 21 that we would send a consult to pathology and
 22 that they would do those--that retesting for
 23 us. At this point, that retesting was being
 24 done on the Ventana System. So there were
 25 requests for retesting to be done and that

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1 was, you know, those--that was carried out,
 2 and that --
 3 THE COMMISSIONER:
 4 Q. I'm taking what you're saying to say that at
 5 some point you communicated to other
 6 oncologists that if they wanted repeat tests
 7 done, I presume in the context of lobulars
 8 that were negative --
 9 DR. LAING:
 10 A. Yes.
 11 THE COMMISSIONER:
 12 Q. To make the order and that would be done by
 13 pathology. At what point would that have been
 14 done?
 15 DR. LAING:
 16 A. I'm thinking that it was sometime towards
 17 June, but I can't tell you exactly when that
 18 was. I'm trying to think of when the first
 19 retesting summary results came back, and I
 20 believe that was sometime towards the end of
 21 June, 2005, that Dr. Cook would have written a
 22 summary note to Dr. McCarthy with the
 23 retesting that had been done so far. So it was
 24 in the days sort of leading up to and after
 25 that. In fact, that was a process that was

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1 allowed to continue all through the review,
 2 that if any time one of the oncologists, one
 3 of the treating oncologists had a patient who
 4 had not been retested as part of the review,
 5 and they felt that there was something about
 6 that case that they wanted to have it done,
 7 then we would send a specific consult to
 8 pathology and ask for that to be done at that
 9 time.
 10 THE COMMISSIONER:
 11 Q. I'm sure we'll get into this tomorrow, but to
 12 make sure that I have timing straight. Peggy
 13 Deane's case occurs. You and at least your
 14 colleague, Dr. McCarthy, are then--have a
 15 heightened awareness.
 16 DR. LAING:
 17 A. That's right.
 18 THE COMMISSIONER:
 19 Q. Of the question of lobular and negative ER
 20 results.
 21 DR. LAING:
 22 A. Yes.
 23 THE COMMISSIONER:
 24 Q. You, at least then as patients come through
 25 the door, check your charts whether it's a

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1 lobular, to see what the result was.
 2 DR. LAING:
 3 A. Uh-hm.
 4 THE COMMISSIONER:
 5 Q. And the first of these patients comes up here
 6 in our little group.
 7 DR. LAING:
 8 A. That's right.
 9 THE COMMISSIONER:
 10 Q. Dr. McCarthy has some similar kind of
 11 experience.
 12 DR. LAING:
 13 A. Yes.
 14 THE COMMISSIONER:
 15 Q. What I'm interested in now is when this hits a
 16 wider number of oncologists. When I asked you
 17 about when the other oncologists knew that
 18 they could similarly order retests, you seem
 19 to go back to after what I would describe as
 20 the first group of retests were done, and that
 21 grouping was one of three in their relatively
 22 early stages.
 23 DR. LAING:
 24 A. Right.
 25 THE COMMISSIONER:

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1 Q. But still much--still beyond this sort of
 2 first part of May.
 3 CHAYTOR, Q.C.:
 4 Q. It's June 29th that the first list is done and
 5 sent back to Dr. McCarthy.
 6 DR. LAING:
 7 A. Right. So on that list of patients, there
 8 would have been some that were my patients and
 9 some that were Dr. McCarthy's patients. I'd
 10 have to see that list to know if there might
 11 have been some--I don't think that list
 12 indicates who the attending oncologist was or
 13 who had requested the repeat.
 14 THE COMMISSIONER:
 15 Q. But are you suggesting that that list contains
 16 only patients who had been identified by you
 17 and Dr. McCarthy?
 18 DR. LAING:
 19 A. No, there may have been patients who had been
 20 identified by other oncologists at that time.
 21 THE COMMISSIONER:
 22 Q. And are you suggesting that those--the people
 23 on that list were people that were identified
 24 as they came through the door as opposed to as
 25 a result of a meeting between you and

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1 pathology, you and perhaps Dr. McCarthy and
 2 pathology?
 3 DR. LAING:
 4 A. The very first list, and I'm not sure if we
 5 have it there, has a--because I know when I
 6 looked at it prior to coming here last week,
 7 it contains the surgical numbers. So I can
 8 tell by looking at that that they are all
 9 different years. So they were various patients
 10 from various different time periods, and
 11 certainly the early discussions, Dr.
 12 McCarthy's initial phone call with Dr. Cook
 13 were kind of in the middle of May, and then
 14 subsequent to that, there are some further
 15 discussions with Dr. Cook, and there are these
 16 --this kind of retesting that's happening as
 17 the patients are being identified by the
 18 oncologists.
 19 THE COMMISSIONER:
 20 Q. Okay.
 21 DR. LAING:
 22 A. And then there is a decision, and I believe by
 23 that time we're into the middle of July, to do
 24 a wider retest of not just patients who we've
 25 sort of identified in the process in the

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1 clinic, but actually to include patients from
 2 2002, and so the subsequent list has quite a
 3 number of patients, if not all of the
 4 patients, have a surgical number of 2002.
 5 THE COMMISSIONER:
 6 Q. Okay, back to my original point which is sort
 7 of when the oncologists beyond you and Dr.
 8 McCarthy got involved in this process, and I'm
 9 still not sure when that is. Can you be a
 10 little more precise with me about when that
 11 might be?
 12 DR. LAING:
 13 A. It's hard for me to tell you that it was an
 14 exact date. I can tell you --
 15 THE COMMISSIONER:
 16 Q. Let's try a month.
 17 DR. LAING:
 18 A. Then I would say it was--I would say, if I was
 19 to pick a month to be the most accurate, I
 20 would say it was in June.
 21 THE COMMISSIONER:
 22 Q. Thank you.
 23 DR. LAING:
 24 A. You're welcome.
 25 CHAYTOR, Q.C.:

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<p>1 Q. Doctor, was there any way in your system of--</p> <p>2 in the system that you used for you to have</p> <p>3 been able to identify all your lobular</p> <p>4 patients?</p> <p>5 DR. LAING:</p> <p>6 A. No, none whatsoever.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. And is there currently any way in which those</p> <p>9 records are kept which would enable you to do</p> <p>10 that?</p> <p>11 DR. LAING:</p> <p>12 A. No.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. I just want to understand in terms of the</p> <p>15 oncologists, the other oncologists, there was</p> <p>16 no specific direction given to them to start</p> <p>17 to try and identify patients, but by some time</p> <p>18 in June they're aware that this is happening</p> <p>19 and they start to identify patients as well,</p> <p>20 is that right?</p> <p>21 DR. LAING:</p> <p>22 A. I mean, I can tell you that in terms of the</p> <p>23 index case, this was something that we talked</p> <p>24 about as a group. Everybody knew what had</p> <p>25 happened. As we started to find these early</p>	<p>1 A. No, we didn't talk about that at the time.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. Did you ask him how could this be, how could</p> <p>4 this happen?</p> <p>5 DR. LAING:</p> <p>6 A. No, I think at that time, you know, my main--</p> <p>7 we were so anxious to have those results back</p> <p>8 to offer this lady a therapy, that, you know,</p> <p>9 this was something that, you know, looking</p> <p>10 back to those early days, was something that</p> <p>11 we felt was related to her being lobular, and</p> <p>12 then we weren't sort of thinking about this as</p> <p>13 turning into something that was going to</p> <p>14 impact so many more patients. So, you know, I</p> <p>15 don't recall at the time having said to Dr.</p> <p>16 Elms, why do you think this was, you know,</p> <p>17 this was just--certainly as time went on,</p> <p>18 there were discussions had regarding these</p> <p>19 issues, as you're aware, but not at that time.</p> <p>20 I think at that time, you know, I can honestly</p> <p>21 tell you I didn't, and I don't think anybody</p> <p>22 else thought that this was something that was</p> <p>23 going to play out the way that it did. You</p> <p>24 know, thinking about--as I try and answer</p> <p>25 these questions, I'm trying to place myself in</p>
<p>Page 362</p> <p>1 retests from May, I know that people were</p> <p>2 aware of that, and certainly both Dr. McCarthy</p> <p>3 and I were telling our colleagues that, you</p> <p>4 know, we're retesting these people who are</p> <p>5 coming through the door, and that that's</p> <p>6 something that is possible and something that</p> <p>7 we can do. Whether that was something that</p> <p>8 happened towards the end of May or whether it</p> <p>9 wasn't until early June, it's difficult for me</p> <p>10 to recall, to put an exact date on it. I can</p> <p>11 only tell you what Dr. McCarthy and I were</p> <p>12 doing simply because I have pulled these files</p> <p>13 and we can see that activity from there, and</p> <p>14 also because, you know, right from the index</p> <p>15 case, this was something that Dr. McCarthy and</p> <p>16 I had talked about on a regular basis.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. And, Doctor, on Peggy Deane's case, when you</p> <p>19 spoke to Dr. Ford Elms --</p> <p>20 DR. LAING:</p> <p>21 A. Yes.</p> <p>22 CHAYTOR, Q.C.:</p> <p>23 Q. Did he ever offer you any explanation as to</p> <p>24 how her test could convert?</p> <p>25 DR. LAING:</p>	<p>Page 364</p> <p>1 my clinic in May and June of 2005. You know,</p> <p>2 we had the index case. To her--to us at that</p> <p>3 time, she wasn't an index case, she was one of</p> <p>4 the patients under our care. It wasn't until,</p> <p>5 you know, time went on and things evolved over</p> <p>6 the summer. So, you know, when I look back at</p> <p>7 that time, it's sometimes difficult to</p> <p>8 remember exactly what happened at exactly what</p> <p>9 time, but I think that your comments regarding</p> <p>10 the fact that we certainly had a heightened</p> <p>11 awareness, that, yes, you know, we were</p> <p>12 looking at the lobular people and reading it,</p> <p>13 and certainly there were a number of people</p> <p>14 that I would have read lobular that were</p> <p>15 positive, you know, and when I've gone back</p> <p>16 and thought about this, I can come up with</p> <p>17 three patients with lobular cancer that I can</p> <p>18 remember. There may be more within the panel</p> <p>19 review, but I can't remember their names, and</p> <p>20 these were the ones that we've talked--well,</p> <p>21 except for number five, the ones that we have</p> <p>22 addressed thus far.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And after speaking to Dr. Elms, did you--</p> <p>25 about Peggy Deane's case, did you think to</p>

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1 contact Dr. Cook and speak to him about this?
2 DR. LAING:
3 A. After --
4 CHAYTOR, Q.C.:
5 Q. About Peggy Deane's case. After speaking to
6 Dr. Elms, realizing her case has changed, did
7 you have any discussion with Dr. Cook about
8 Peggy Deane's case?
9 DR. LAING:
10 A. No, no.
11 THE COMMISSIONER:
12 Q. Ms. Chaytor, we'll break wherever you're
13 ready.
14 CHAYTOR, Q.C.:
15 Q. That's fine then, perhaps that'll be a good
16 place, Commissioner.
17 THE COMMISSIONER:
18 Q. All right then, 9:30 in the morning. Thank
19 you.

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1 CERTIFICATE
2 I, Judy Moss, hereby certify that the foregoing is
3 a true and correct transcript in the matter of the
4 Commission of Inquiry on Hormone Receptor Testing,
5 heard on the 9th day of September, A.D., 2008
6 before the Honourable Justice Margaret A. Cameron,
7 Commissioner, at the Commission of Inquiry, St.
8 John's, Newfoundland and Labrador and was
9 transcribed by me to the best of my ability by
10 means of a sound apparatus.
11 Dated at St. John's, Newfoundland and Labrador
12 this 9th day of September, A.D., 2008
13 Judy Moss

<p>-\$-</p> <p>\$180.00 [1] 49:17 \$20.00 [1] 49:16</p> <hr/> <p>-'-</p> <p>'02 [1] 251:25 '04 [1] 208:7 '97 [1] 114:23 '98 [1] 114:23 '99 [1] 114:23</p> <hr/> <p>---</p> <p>-her [1] 262:20 -when [1] 115:1</p> <hr/> <p>-0-</p> <p>0174 [1] 247:19 0245 [1] 106:2</p> <hr/> <p>-1-</p> <p>1 [5] 146:12 161:7 211:8 241:6 336:21 10 [15] 67:6,24 75:15 76:10 96:9 167:6,14 168:6 171:21 172:12,24 211:7 248:17 302:16,17 10/15 [1] 179:4 100 [19] 23:12 59:12 60:24 76:20 81:14 124:19 224:7 285:23 286:1 287:16,19 288:1 310:1 311:8,10,13 318:23 320:9 320:13 1000 [1] 37:17 104 [2] 329:5,5 106 [3] 3:2,3,4 10th [3] 16:12 271:3 323:14 117 [3] 329:6,19 330:25 11:34 [1] 269:16 11th [7] 248:13 250:21 336:14,20 342:20 347:23 349:7 12 [2] 95:8 287:9 12th [1] 292:9 130 [1] 182:17 13th [3] 337:20 338:6 345:6 14.4 [1] 77:10 15 [7] 105:19 159:7 194:3 246:9 248:10,17 253:24 15-18 [1] 346:19 15-year [1] 104:8 17 [1] 32:24 17th [4] 208:4 246:7 303:17 305:14 18 [1] 32:24 18th [1] 327:7 19 [3] 195:24 203:14 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Inquiry on Hormone Receptor Testing

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