COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON--COMMISSIONER

October 22, 2008

Appearances:

Bernard Coffey, Q.C. . . . . Commission Co-counsel
Sandra Chaytor, Q.C. . . . . Commission Co-counsel

Rolf Pritchard. . . . . Her Majesty in Right of NL

Peter Browne, Q.C./Jane Hennebury . . . Doctors Kara Laing et al

Daniel Simmons . . . . . Eastern Regional Integrated
. . . . . Health Authority

Chesley Crosbie, Q.C... . . . . Members of the Breast Cancer
. . . . . Testing Class Action

Mark Pike, Q.C. . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

LIST OF EXHIBITS

TABLE OF CONTENTS

MS. HEATHER PREDHAM--RESUMES THE STAND

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor?

MS. HEATHER PREDHAM, RESUMES STAND, EXAMINATION BY SANDRA CHAYTOR, Q.C. (CONT'D)

CHAYTOR, Q.C.:

Q. Good morning, Commissioner. Good morning, Ms. Predham.

MS. PREDHAM:

A. Good morning.

CHAYTOR, Q.C.:

Q. If we could have, please, 3039? Ms. Predham, this is the e-mail that I showed you yesterday between yourself and Ms. Elliott and it appears to be the first of the e-mails we have between you regarding the briefing note in August 2006, and you'll note it says "find the note attached. I made the changes to the first part." So do I understand that there would have been an earlier version of this?

MS. PREDHAM:

A. There may have been. Ms. Elliott tends to-- she prints it out and works off that, or you know, she would have--I could have printed it out and brought it up to her before she went home, because obviously she's home at this

Page 5

point, and but that's, she tends to work on that--in handwriting, writing on something, rather than bringing things back and forth with e-mail.

CHAYTOR, Q.C.:

Q. And do you have any recollection as to what the changes would have been to the first part? What would have been added or revised?

MS. PREDHAM:

A. No, I would think the first part would be the first two sentences up at the top.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. That's what I would refer to as the first part, you know, and -

CHAYTOR, Q.C.:

Q. Meaning this here, "based on the information, the total patients that were sent"?

MS. PREDHAM:

A. Yes, I have no idea what they could be though.

CHAYTOR, Q.C.:

Q. Now I think that probably, if we look back at 0815, it certainly starts off the same, as you recall the briefing note that you sent to the-

Page 6

-or you prepared for the Board. 0815, please, Registrar? Page two of this one. It's the one that you prepared earlier for the Department.

MS. PREDHAM:

A. Right, and maybe it's the--maybe it's taking out that part. Maybe it's just the way I reworded it.

CHAYTOR, Q.C.:

Q. Okay. So you may have been using or starting with this version?

MS. PREDHAM:

A. I would say, knowing the way that I work, I probably would start with that and update it.

CHAYTOR, Q.C.:

Q. Okay, and back, please, to 3039? And we'll see, of course, on this version then you've included a chart which breaks down according to the various regions.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So this appears to be new from what was done before, this part here, and if we go back to your e-mail, you ask her "how do you want me

Page 7

to address it at the beginning?" and you'll see that you've left blank to. So I take it you're wondering who this is going to.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Did you ever get an answer to that question?

MS. PREDHAM:

A. I must have, if it's addressed towards the end for--but actually, I think, if my memory serves me from yesterday, I think I only said that it was prepared by me and it wasn't to anybody.

CHAYTOR, Q.C.:

Q. Yes. So as you're going through this and drafting this information, you're having communication, I take it, back and forth with Ms. Elliott?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And she's providing you with answers to some of these questions?

MS. PREDHAM:

A. Yes.

Page 8

CHAYTOR, Q.C.:

Q. And then, please, if we look at P-1447? Actually, sorry, first, 3042. This is the version that, on April 11th, you send to Ms. Pilgrim, and by then, you've filled in the beginning to say "prepared by"?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. Then if we look at 1447, please? At close to two p.m. on the same day, then you send the briefing note or the draft that you've prepared to Moira Hennessey and you copy it to Ms. Pilgrim and Ms. Elliott. "Please find the briefing note as attached. I've left it draft as Dr. Williams and Dr. Denic have not seen it as yet. If you have any questions, please do not hesitate to contact me." And you'll see this is what you've sent to her, and what did you mean by you've left it draft because Dr. Williams and Dr. Denic hadn't seen it?

MS. PREDHAM:

A. I would assume if they had any changes, then I'd have to make changes to that, and I guess,

Page 9

I was saying it wasn't signed off with that. I must say, last night, I was--I felt bad that I can't remember anything about that. So I went through my notes trying to see if I could--you know, for that period of time, if I could--you know how your memory goes, if you think of one thing, maybe you can think of another, and I was thinking while I was doing that, like it was an odd note to end up going to the Minister when you look at the one the fall before, and of course, I never realized where this went until this process had occurred, because the other one was, you know, formatted a certain way and everybody had seen it and had feedback on it. So I can't remember. I certainly didn't put the same weight to it as I did the one the previous November, and I really have no--there was nothing that twigged my memory.

But during that period of time, as I've mentioned about the context, things that happened that August, I realized when I was going through my notes, I've--the things that have happened that were going on at the same time, I've been interviewed by the police,

Page 10

I've been interviewed by the Child Youth Advocate. I've been interviewed by professional organization, and I'm going to be pending to appear at their disciplinary board, and I've been at an arbitration hearing, all for things that happened in August 2006. So I don't think my attention was on this. I certainly didn't see it, at the time, as a briefing note to the Minister, and really, I have no memory, other than what I'm seeing here.

CHAYTOR, Q.C.:

Q. And when you say you didn't give it the same weight that you gave the other briefing note, what you're saying is that you don't think you paid the same attention to it -

MS. PREDHAM:

A. I would have paid the -

CHAYTOR, Q.C.:

Q. - because of other things that were going on?

MS. PREDHAM:

A. No, no, I would have paid the same attention to it, but I didn't--it was just something I had to do. It wasn't--you know, it was just another task that I had to do and I didn't

Page 11

focus in on it.

CHAYTOR, Q.C.:

Q. And that--did that ever change though in your work existence, the whole time you're dealing with this, in terms of your having to deal with many tasks and serious issues at the same time?

MS. PREDHAM:

A. It was more intense from the end of '05 onto the beginning of '07. It was much more intense.

CHAYTOR, Q.C.:

Q. Right on through this period?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Yes. So what do you mean by you didn't give the same weight to it as you had the one the end of July?

MS. PREDHAM:

A. Well, I didn't see it as a--you know, this was an information document to--and I'm assuming why I can't remember anything, you know, and really I shouldn't possibly speculate, but I'm just trying to understand why I can't remember

Page 12

anything about this briefing note.

CHAYTOR, Q.C.:

Q. Yes, okay, and of course, you knew it was going to the Minister, at least, because it's going to Moira Hennessey?

MS. PREDHAM:

A. I may--I probably never thought that through. All I knew, it was going to Ms. Hennessey.

CHAYTOR, Q.C.:

Q. Okay. Did you receive any feedback or did you send it on to Dr. Williams and Dr. Denic, and if so, did you receive any feedback from them?

MS. PREDHAM:

A. I don't recall. I would have sent it on obviously because I said that there, I was going to do that, but I don't remember anything about it.

CHAYTOR, Q.C.:

Q. And do you--did you have any subsequent conversation then with Ms. Hennessey about the note?

MS. PREDHAM:

A. I don't remember speaking to her. The only one I remember speaking to is Ms. McCormack and that's only a vague memory.

Page 13

CHAYTOR, Q.C.:
Q. And then did you say you don't recall ever hearing back from Ms. Hennessey to say "well, can we now deal with this? Can it be something other than draft? Have you got the approval with Dr. Williams?" You don't recall any discussion along those lines?
MS. PREDHAM:
A. Nothing.
CHAYTOR, Q.C.:
Q. If we could have, please, P-0820? And this is an e-mail exchange between Ms. McCormack and Ms. Hennessey and it originates with Ms. McCormack had some questions. It appears Ms. Hennessey is out of town and she writes a series of questions. It says "I have received the briefing note from Yvonne, as you directed. I still have a few questions," and she has a question about the panel, questions about the 28 patients whose test results were confirmed negative by the panel. "Thirdly, the patients who ER/PR status changed from negative to positive, 208. With no treatment recommendations, the comments section advises some of these patients were considered low

Page 14

risk," and she goes on from there and asks "does this mean these patients all have metastatic disease or do we know how many of the 208 do?" She has a question of the 56 patients with DCIS and "thanks for any clarification you can provide" and she made the other changes that Ms. Hennessey has recommended.
And then there's a reply on August 16th from Ms. Hennessey to those questions and she indicates "there are 39 patients confirmed with DCIS and 14 still under review. I don't know when the reviews will be completed or if these patients have been notified. If you need this info today, you can check with Heather Predham directly." And where would Ms. Hennessey get the 39 patients confirmed with DCIS and 14 still under review?
MS. PREDHAM:
A. Unless it's in my briefing note, I would assume that I must have told her, but I'm not sure.
CHAYTOR, Q.C.:
Q. And you'll see then, this is how Ms. Hennessey apparently has done some revisions to the

Page 15

table that you had provided, and you'll recall, in terms of dealing with the deceased, you had, I believe, broken down the number of deceased in what you had provided.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Yes, you had a paragraph which indicated that 101 of them had been retested?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And she's put in here 176 and refers to the ethics review, which was in your note. "A public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health." So Ms. Hennessey is indicating to Ms. McCormack, if she does need any further information, then she can get it from you, and you do recall having had--you have a vague recollection of some discussion with Ms. McCormack?
MS. PREDHAM:
A. Yes.

Page 16

CHAYTOR, Q.C.:
Q. Do you recall what was discussed? What issues did she come back that she needed further clarification about?
MS. PREDHAM:
A. Really all I can remember is that she didn't have a lot of knowledge about the issue as a whole, and I was walking her through that and that's the extent of my memory.
CHAYTOR, Q.C.:
Q. So for example, here she had questions regarding some of the--like the role of the panel, do you recall did you discuss the role of the panel with her?
MS. PREDHAM:
A. I may have. Like I said, I only remember, you know, that feeling that, you know, she didn't know much about the issue and that I had to go back and explain estrogen receptors, you know, the fundamentals.
CHAYTOR, Q.C.:
Q. And do you recall whether or not you had to clarify any numbers with her?
MS. PREDHAM:
A. I don't recall.

Page 17

CHAYTOR, Q.C.:
Q. And do you recall whether or not you discussed with her the external reviews and the stage at which the external reviews were?
MS. PREDHAM:
A. Like I said, that's the only memory I have of it.
CHAYTOR, Q.C.:
Q. So you have no recollection of that either?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and if we could have, please, P-0192? And Ms. McCormack again is writing to Ms. Hennessey and this is on August 17th. "I was able to clarify the information on the Newfoundland panel and their role with Heather Predham." So it appears that you've had a conversation with her on that issue. "I included an extra bullet under background, last bullet, to describe the Newfoundland Labrador panel and their role. In the introduction to the chart, I made reference again to the panel," and in her opinion, the note is now clear, and "with your approval,

Page 18

I'll forward to Gary," and she's just directing here that it be put into Eastern's directory within their system. And you'll see that here's what it now looks like, and there's background and she's referred to the extra bullet on the panel, and then she refers again to the panel in putting forward the numbers, and most of these numbers, of course, are what were provided by you, with the description, with the exception, as I've pointed out to you, about the 176 deceased and no reference to the 101.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. I believe otherwise it's fairly standard, and then "currently there are two legal claims that have been filed," and there's reference to Verna Doucette and Michelle Hanlon's claims. Do you recall discussion with Ms. McCormack around that?
MS. PREDHAM:
A. No. Like I said, I only have this vague memory of that phone call.
CHAYTOR, Q.C.:

Page 19

Q. And you'll see then, there's a section of impacts of treatment with Tamoxifen. Do you recall any discussion about the benefits of Tamoxifen or the purpose of Tamoxifen?
MS. PREDHAM:
A. No, and I wouldn't be able to tell her that detail either.
CHAYTOR, Q.C.:
Q. Okay, and reasons for the erroneous results and steps taken to prevent recurrence. Do you recall any discussion around that?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And then action required, just says "should the Premier need further details, Eastern Health, as well as their legal counsel, will be available." Do you recall advising either Ms. McCormack or Ms. Hennessey that Eastern Health or its solicitor could make themselves available?
MS. PREDHAM:
A. Absolutely not, but I only have a vague memory of that phone call, but I certainly wouldn't say that.

Page 20

CHAYTOR, Q.C.:
Q. Okay, and this is an earlier draft. I'll take you to the final version. Was this draft shared with you?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And if we look at page six of this document, there's another e-mail exchange between Ms. McCormack and Ms. Hennessey and she says "attached is the final copy of the above" and you'll see that it's now August 18th. So "attached is the final copy of the above briefing note, if you approve of same. I had to go back to Heather to ask how many women were most impacted by the change in status of the ER/PR receptor testing." So it appears that there's been another discussion with Ms. McCormack, and do you recall that, having at least a second discussion with her?
MS. PREDHAM:
A. Again, I only have a vague memory of talking to her and there's nothing else. I can't remember if it was once or twice.
CHAYTOR, Q.C.:

Page 21

Q. And so do you recall this question, that she goes back to ask you how many women were most impacted?
MS. PREDHAM:
A. I don't recall the question, but looking back at the briefing note, I can see where 22 would come from.
CHAYTOR, Q.C.:
Q. So you have no doubt that you would have provided her with that number?
MS. PREDHAM:
A. If she had called and asked me who were the most impacted, I would have referenced those two groups, because that's what I felt were the most impacted people.
CHAYTOR, Q.C.:
Q. And those two groups being the 13 and the nine?
MS. PREDHAM:
A. And the nine.
CHAYTOR, Q.C.:
Q. "She gave me the number 22 as indicated on the third page of the briefing note. Gary also wanted to know how many were likely to initiate legal action and according to

Page 22

Heather, any or all of the 939 women or their families could so." Do you recall having a discussion with her then around that point?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And is that likely something that you would have said?
MS. PREDHAM:
A. Well, I could have said that. Well, it's true. So I could have said that.
CHAYTOR, Q.C.:
Q. And "exact numbers would not be known at this time. She explained that even if the results were correct from the initial testing to the retesting at Mount Sinai, the stress caused to some women and families by knowing they were being retested, how long they had to wait for information, etcetera, could be a basis to initiate an action or to participate in the class action, if that's the way that this proceeds." So the idea that people could initiate actions based on the stress caused to them, that's something that you would have been cognizant of that could happen?

Page 23

MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then if we look at page ten of this, you'll see that this is what she's indicating at that point is to be the final draft, and on page ten, in the summary, there's reference now to the "legal action initiated by Mrs. Myrtle Lewis as a result of misdiagnosis and is not linked to the problems described in this note with the ER/PR receptor test which had to be repeated." Would you have been the source of that information to the Government?
MS. PREDHAM:
A. I may have been. Like I said, I can't remember any details of that conversation, just the fact that I talked to her, but I may have been.
CHAYTOR, Q.C.:
Q. And I believe we saw an e-mail earlier that we referred to yesterday, where you were distinguishing between the action by Ms. Lewis.
MS. PREDHAM:
A. Yes.

Page 24

CHAYTOR, Q.C.:
Q. And that of the ER/PR.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So that sounds consistent with that. "Eastern Health advises 22 women were greatly impacted by the change in status of the ER/PR receptor tests. These women had changes in the progress of their disease from the initial confirmation of the disease and the beginning of their treatment to the retesting done at Mount Sinai." And does that sound consistent with if you had been asked the question of how many were most impacted? Is that the type of answer you would have given?
MS. PREDHAM:
A. Well, I would come up with 22, but that's not really the way that I would have put it, and there's no period after Sinai. It looks like there should be more to it, because that's only one aspect of it.
CHAYTOR, Q.C.:
Q. Okay, so what else would you have added?\
MS. PREDHAM:

Page 25

A. Well, you know, there was two people, people who were already on Tamoxifen because of metastases and other ones who the panel felt that there was a progression of the disease in that time period, and of course, like 22 wasn't an all-inclusive number. It was more of a sense. It was only the ones that the panel had verbalized that.

CHAYTOR, Q.C.:

Q. And I know you have no recollection though of your discussion with Ms. McCormack, but would you have made that clear to her, do you think, that "I'm not sure of this number"?

MS. PREDHAM:

A. Well, my usual practice, as I went forward, was always to have that. There was always provisos and whenever I talked about those two groups, I always said that that was--you know, it wasn't a validated number. It wasn't anything that the panel set out to say, but it was something that was in that discussion. So whenever I discussed those two criteria, that's usually the context that I put it in.

CHAYTOR, Q.C.:

Q. So I'm just wondering then, in terms of her

Page 26

taking away from it, 22 women were greatly impacted, are you saying you would have--if this had been shared with you, you would have sought to clarify that further?

MS. PREDHAM:

A. Well, as long as she understood that that wasn't--you know, I wasn't saying there was only 22. I was saying that we identified 22, but also the second part of that doesn't fully describe it to what I would normally say.

CHAYTOR, Q.C.:

Q. And in coming up with the 22, were you--did you go back--this is now August of 2006. Did you go back and consult with any of the oncologists to let them know that, "This is a question that is coming from the government and how can I best answer this, I've taken notes as we've gone along and when people make comments about this person is impacted or this person has a metastases, I've made those notes", and that's what we understood from your evidence is how you -

MS. PREDHAM:

A. Uh-hm.

CHAYTOR, Q.C.:

Page 27

Q. Were keeping track, but you go back then and ask any oncologists how can I assess this?

MS. PREDHAM:

A. No, I did not.

CHAYTOR, Q.C.:

Q. Okay. So nobody assisted you in coming up with this at this point?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And you, yourself, didn't go back and do any review of your own notes to see if there were others?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And in terms of saying 22 women being greatly impacted, do you recall did you ever use the word "greatly" or is that a word -

MS. PREDHAM:

A. Well, I would have had--I would have had, I guess, an adverb to describe it because, you know, they were all impacted, so there would have been some differentiation because that's what I was trying to do with the 22 number,

Page 28

was to differentiate it, so I'd have to have some word to describe a more intense level of being impacted.

CHAYTOR, Q.C.:

Q. So it wasn't your opinion that it was only 22 people impacted? If you're using the number 22, you're seeing those as potentially the ones that are most impacted?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-2618. This is an e-mail exchange then between myself and Mr. Simmons, and Mr. Simmons--it starts with a question, I believe, from myself on August 18th, 2008, and "Could you please ask Heather Predham the follow for us. In the August 18th, 2006, briefing note for the premier/cabinet secretariat, how were the 22 people noted to have been impacted identified, what criteria was used; also please provide a list of their names". "Heather Predham does remember a call from Marilyn Predham (sic.) after she sent the breakdown of retest results to the department, but she does not recall any

Page 29

detail of what they discussed about the patients who were most impacted by changes in test results. From looking back at the table Heather prepared on August 11th", which is P-1447, and we've already looked at that, "she thinks it is most likely that Ms. McCormack questioned her about which groups were likely to be most greatly impacted, and that Heather identified two groups. One was the 13 who had changed from negative to positive, who had not been placed on Tamoxifen for their original disease, but who had been placed on Tamoxifen because they had developed metastatic disease before the retesting. The other was the nine who had a change from negative to positive for whom the panel recommended that they be placed on Tamoxifen and whose disease had progressed in the interim. These 22 patients were ones with change results who had not received Tamoxifen when they otherwise might have, and whose disease had progressed. While it is impossible to say whether their disease would or would not have progressed had they received Tamoxifen earlier, Heather says that she would have identified them as the ones with the

Page 30

greatest likelihood of having been impacted. Heather says that she cannot put her hands immediately on the list of 13 and 9, it may be among her materials. Alternatively, it may be able to be reconstructed. Do you want us to follow up". "Yes, please, that would be helpful, and also could Heather explain the distinction between the 13 and the 9, what does it mean that the disease had progressed in the 9, did they have more than one ER/PR test conducted prior to the retesting at Mount Sinai". The answer back is, and this looks like it may be cut from an answer that you gave to Mr. Simmons, is that correct?

MS. PREDHAM:

A. I do believe so.

CHAYTOR, Q.C.:

Q. It's in quotation marks there and it's a different type--different colour type, and the answer that comes back is, "The 13 patients were patients who were diagnosed with breast cancer and were considered ER/PR negative. Because of that, Tamoxifen was not in their treatment plan at that time. Upon retesting of that original specimen, there was a change

Page 31

which would cause them to be considered positive now. When the panel reviewed their charts, it was determined that during the time period between the original test and the retest, they had been diagnosed with a recurrence -

MS. PREDHAM:

A. Metastases.

CHAYTOR, Q.C.:

Q. "Metastases", thank you, "which was then treated with Tamoxifen. So from a categorizing point of view, they would be in a group with no recommendations. However, it was clear from the conversation at the panel table that earlier treatment with Tamoxifen may have had an impact". First of all, I just want to stop there. So did those 13 all have metastases, or were they also in the--included in the 13, a recurrence of their original disease?

MS. PREDHAM:

A. I can't remember right now, but they must have. If I put that there, I guess I wasn't clear. I hadn't gone back at that point to identify the 13, so I just wanted to make sure

Page 32

I didn't say they were all metastases.

CHAYTOR, Q.C.:

Q. And in going back and getting this answer for us, what did you have to do? Did you have a list of the patients or what did you consult?

MS. PREDHAM:

A. I had to go back through my notes that I took during the panelling and verify it through there. I didn't have a list. I couldn't find a list with 13 and 9 on it. I could find a list with so many on it, but not 13 and 9.

CHAYTOR, Q.C.:

Q. And were you able to determine whether or not amongst the 22 that you provided, any of the patients you provided were, in fact, deceased at the time that they were panelled?

MS. PREDHAM:

A. I can't remember if--I can't remember. I didn't think I did.

CHAYTOR, Q.C.:

Q. And if there was a patient who was deceased at the time, that wouldn't have been captured in your notes?

MS. PREDHAM:

A. Well, it should be, unless we discovered after

Page 33

they were panelling that they were deceased.
CHAYTOR, Q.C.:
Q. So it could be that a patient ended up in the 22, and the patient was deceased, but at the time the panel is discussing this patient, they didn't realize that?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "The other nine were patients who were also diagnosed with breast cancer and were considered ER/PR negative, and again Tamoxifen was not in their treatment plan at that time. Upon retesting of that original specimen, there was a change which would cause them to be considered positive now. When the panel reviewed their charts, it was determined that during the time period between the original test and the retest, their disease had progressed. Not, I guess, significantly enough to warrant being placed on adjuvant therapy, but enough that the clinicians around the table discussed that the lack of Tamoxifen may have had an impact. From a categorizing point of view, they would be in the group with

Page 34

a recommendation for treatment", and what did that mean, what do you recall being discussed about their disease hadn't progressed significantly enough for them to--warrant them having been placed on adjuvant therapy?
MS. PREDHAM:
A. I was--I'm guessing there that it hadn't--disease progressed enough, and, you know, at this point, I mean, I've only known about this for the past three years, I don't know much about cancer therapy. This was my listening to people around the table.
CHAYTOR, Q.C.:
Q. And referring without, of course, mentioning the name, the one patient that was deceased, you gave us this list of names we--go back, I believe, and look for--please provide the names of the 22 and you're working on it. So you were able to go back through your notes, and those would be the notes that--your spreadsheets, you're at the panel meetings, and you record impacted by some of the names of those people?
MS. PREDHAM:
A. Yes.

Page 35

CHAYTOR, Q.C.:
Q. So if were to sit with you or try and reconstruct that, you'd be able to point out the 22 references where people are impacted?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then did you actually have to pull the charts to reconstruct this?
MS. PREDHAM:
A. No, I didn't then. I just went back to--I just wanted to have the information I had at the time. I didn't pull any charts or look at anything else.
CHAYTOR, Q.C.:
Q. And how did you know who was in the 13 and who was in the 9?
MS. PREDHAM:
A. It was based on the recommendations and which category that they were in.
CHAYTOR, Q.C.:
Q. So who needed to get the treatment versus those who already had treatment?
MS. PREDHAM:
A. Yes.

Page 36

CHAYTOR, Q.C.:
Q. And the one patient who was deceased, our review indicates that she was panelled on October 20th, 2005, and again on November 17th, 2005, and the first meeting notes, she was deceased and not to be retested, and then the second meeting gave the Mount Sinai results. So it appears someone had requested her specimen to be retested, although she was known to be deceased. So in going through and coming up with the list of 22, though, and the fact that she was deceased, that didn't come to your attention?
MS. PREDHAM:
A. I don't recall that one of them was deceased.
CHAYTOR, Q.C.:
Q. Do you recall any other discussion around the table about deceased patients and whether or not they would fit into the category of those most impacted?
MS. PREDHAM:
A. As far as I was aware, we did not knowingly talk about any deceased patients.
CHAYTOR, Q.C.:
Q. And again in terms of the--I believe you

Page 37

mentioned this yesterday, the 22 was not intended to be exclusive?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. That you're not surprised that there would be others with metastatic disease or recurrences that were not captured in your 22?

MS. PREDHAM:

A. Oh, absolutely not.

CHAYTOR, Q.C.:

Q. Up until the time of August '06 when you gave that number?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-0125, page 31. This, Ms. Predham, we understand is the final version which ends up copied to the premier, members of his staff, Mr. Thompson, Mr. Cake, whose name we're referred to earlier, and I'll just take you to the end here first. It's indicated to be prepared by/approved by Heather Predham, Eastern Health; Moira Hennessey, from the department, reviewed by

Page 38

Marilyn McCormack; Gary Cake, Cabinet Secretariat. Do you agree that you prepared this note?

MS. PREDHAM:

A. No, I didn't prepare that note. I prepared "a" note that was going to Ms. Hennessey, but I did not prepare that note.

CHAYTOR, Q.C.:

Q. Okay, and did you ever see this final version of the note?

MS. PREDHAM:

A. Never.

CHAYTOR, Q.C.:

Q. I take it, until this process came -

MS. PREDHAM:

A. Yes, until this process.

CHAYTOR, Q.C.:

Q. Okay. Just take you through then and ask you what portions that you did provide the information for, and by the way, before you signed off on providing the number 22 to Marilyn McCormack, and I realize that you only have vague recollections around the whole thing, but would you have gone back and also consulted with Ms. Pilgrim and Ms. Elliott

Page 39

prior to releasing that information?

MS. PREDHAM:

A. Well, not prior. If--you know, I think the way it happened is that Ms. Pilgrim put her in touch with me and I definitely had a conversation with Ms. Pilgrim about what she wanted, or information that she had after that, and that was when it was discovered that apparently somebody was upset that we were talking directly to her, and--but that was, that was all.

CHAYTOR, Q.C.:

Q. So when did that come up that someone was upset that you were talking directly to her?

MS. PREDHAM:

A. It was after--it wasn't very long after, but it--and again, you know, and that's probably why the conversation sticks in my mind, the limited amount it does, was that someone had said that we shouldn't--somebody in the Department of Health was upset because we were talking directly there and the line of communication was through the Department of Health.

CHAYTOR, Q.C.:

Page 40

Q. And that got communicated to you by Ms. Pilgrim?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And so you would have felt comfortable going back to Ms. McCormack and providing her information regarding the panel, regarding the 22, whatever her questions were to you at the time?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. You would have provided that information and not felt that you needed to go back to Ms. Pilgrim or Ms. Elliott for sign off on that?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. You would have felt comfortable just giving that yourself, that information?

MS. PREDHAM:

A. Yes, Ms. Pilgrim asked me to do that. She would know the type of things that I would say because that was the information that I had.

Page 41

CHAYTOR, Q.C.:
Q. Perhaps we'll just go through and you can tell us then what amongst this would have been the information that you would have provided, and the background refers to May, 2005, the lab discovered some inconsistent results, and refers to specifically ER and PR. Would that be the type of information in trying to give the background to Ms. McCormack?
MS. PREDHAM:
A. Could have been.
CHAYTOR, Q.C.:
Q. And the result, the receptor test direct the treatment to be provided. So that's the discussion around Tamoxifen?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. "Since the discovery of these inconsistent results, Eastern Health has sent", and we've seen that you provided the 939 number, that's correct?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

Page 42

Q. Okay, "test results have been received on 923".
MS. PREDHAM:
A. I believe that's the numbers from the briefing note.
CHAYTOR, Q.C.:
Q. Yes. "Eastern Health established a panel of professionals, including medical, oncology, pathology, surgery, and quality services, who reviewed the test results". So that might have come out of your conversation with Ms. McCormack?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And the current status then, the pathology reports, the total number of patients, 923 returned. "The following table details the results from Mount Sinai and also provides information on the 422 test results with changes that were reviewed by the Newfoundland and Labrador panel upon receipt", and then again most of this information appears to be what you had in your original, and I take it you've had a chance since to look over this

Page 43

note and is there anything else that--the only thing I could note at the time was the 176. You had also provided the number 101.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Having been retested. Other than that, did this appear to be basically the information that you provided?
MS. PREDHAM:
A. There was nothing that struck me as being dramatically different.
CHAYTOR, Q.C.:
Q. Okay, and then the issue of the two legal claims, you don't recall having any discussion around that?
MS. PREDHAM:
A. I think that was in the briefing note.
CHAYTOR, Q.C.:
Q. Right, yes, it was, thank you. "Recent media reports identified Myrtle Lewis has joined other women who have signed on to take part in a class action", and the reference here to Ms. Myrtle Lewis. Statement of Claim filed by Mr. Ches Crosbie was served to the Defendant,

Page 44

Eastern Health, on July 7th, 2006. Would you likely be the source of that type of information?
MS. PREDHAM:
A. I may have been. Now my memory of my conversation with her was I was over at the Health Sciences and I was in someone else's office when I talked to her, so I most likely didn't have the date on hand when the Statement of Claim was served, but the type of issue there -
CHAYTOR, Q.C.:
Q. Yes, and the date that it was served, though, on Eastern Health, I take it, would have to come from within Eastern Health to be able to provide that date?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you're not aware of anyone else from Eastern Health having discussion about this briefing note with anyone from the government other than yourself?
MS. PREDHAM:
A. No.

Page 45

CHAYTOR, Q.C.:
Q. And then summary, "The legal action initiated", again that reference to it being a different--a misdiagnosis, and that's probably something you would have said along those lines. "Eastern Health then advised 22 women were impacted by the change in status of the ER/PR receptor test. These women had changes in the progress of their disease from the initial confirmation and the beginning of their treatment to the retesting done at Mount Sinai".
MS. PREDHAM:
A. And that's certainly not what I would have said there.
CHAYTOR, Q.C.:
Q. Okay, and it's been the subject of some discussion here, the fact that the word "greatly" is taken out. So when you were providing the number 22, you were providing that to indicate how many people were most impacted?
MS. PREDHAM:
A. Yes. I--you know, what I've always said is that they were all impacted, and that, you

Page 46

know, as I said right from the beginning, those 22 were only to give some sense that you couldn't just categorize these groups as, you know, better or worse. You know, like, it was--there was nuances in each of the groups, and I would have had that discussion with her. I certainly wouldn't have put it--I wouldn't have written that paragraph.
CHAYTOR, Q.C.:
Q. And had this come back to you for review, would you have taken exception to that paragraph?
MS. PREDHAM:
A. Oh, yes, because it's incorrect.
CHAYTOR, Q.C.:
Q. And, "However, all of the 939 patients, or families of those who have died whose tests results were reviewed, could potentially become applicants in a class action lawsuit", and this in reading it would indicate that 939 patients or families of those who have died would leave the inference perhaps that, well, all of the deceased patients, all 176 have been retested and reviewed. 939 were not reviewed?

Page 47

MS. PREDHAM:
A. No, no, they weren't, none of the deceased were reviewed.
CHAYTOR, Q.C.:
Q. "could potentially become applicants in the class action. The basis of their claims may differ depending on the criteria the lawyer initiating has included in his claim for damages, not only the problem with the lab where test results were inaccurate, but also the stress suffered by those who were told in advance that the testing was being repeated, and the time they were required to wait before information was available to them. Currently legal counsel for Eastern Health is reviewing the legal position for Eastern Health". So in terms of that, would you have provided that information or that type of information?
MS. PREDHAM:
A. That's not exactly what I said in the briefing note.
CHAYTOR, Q.C.:
Q. It's a little bit different, and is there any part of it that you would take exception to?
MS. PREDHAM:

Page 48

A. Well, it seemed like a done deal there. Mine was more, you know, potential for anything else, like, it was--you know, we did have two claims, but we could have had others.
CHAYTOR, Q.C.:
Q. And then the impacts of treatment with Tamoxifen, and we've had some discussion about that.
MS. PREDHAM:
A. I couldn't have given her that information.
CHAYTOR, Q.C.:
Q. You could not have?
MS. PREDHAM:
A. No. I would know that it wasn't a benign drug, there were impacts of taking it, and I did know that if you had a DVT, which was a blood clot in the leg, that you could have--you wouldn't be able to take it, and I did know that there was potential for endometrial cancer, but I wouldn't be able to go through the abnormal growth, the hair and nail thinning, fertility problems. I have no knowledge of that.
CHAYTOR, Q.C.:
Q. "And the patients, however, who did not

Page 49

receive Tamoxifen, but are ER/PR positive, may experience further problems with cancer". How about a statement to that effect?

MS. PREDHAM:

A. I have no knowledge of that.

CHAYTOR, Q.C.:

Q. And then we have, "Reasons for the erroneous results and steps taken to prevent reoccurrence. Eastern Health engaged external consultants to review the procedures at the laboratory. When all reports are received, they will be reviewed and the recommendations will be implemented. The goal is to have the laboratory accredited. Until these processes are completed, all samples will continue to be retested at Mount Sinai". Did you provide that information to Ms. McCormack?

MS. PREDHAM:

A. I don't think so because I wouldn't have said that.

CHAYTOR, Q.C.:

Q. What would you have said?

MS. PREDHAM:

A. Well, the reviews had been done and the--it sounds like it's in the future, when actually

Page 50

it was ongoing at that time.

CHAYTOR, Q.C.:

Q. So if you had a discussion with Ms. McCormack, would you have told her that, that the reviews are done, we have the reports, we're working on the recommendations?

MS. PREDHAM:

A. Yes, and I would have to direct her to Mr. Gulliver or Dr. Denic to get a further update on that, if I had that discussion with her.

CHAYTOR, Q.C.:

Q. But you have no recollection of any discussion. So if Ms. McCormack says otherwise, and that this, in fact, is the impression that she was left with from your discussion, and she does have a clear recollection, can you take issue with that?

MS. PREDHAM:

A. I would have to because that wasn't the information that--I mean, I knew the results were back, I knew that Mr. Gulliver and Dr. Cook originally, and then Dr. Denic, were developing the recommendations, and were in the process of implementing them. I didn't know what they were doing and I didn't know

Page 51

any of the details of that, but I wouldn't have said that because I knew different.

CHAYTOR, Q.C.:

Q. And if we could just look at what Ms. McCormack said, please. It's the transcript of June 12th, 2008, at page 287. On the bottom here, you'll see I'm directing her to the same portion and the reasons for erroneous results. She says, "I probably drafted that having a discussion with Moira and Heather Predham". "Okay, and are you able to say that you discussed this with Ms. Hennessey". "Yes, I'm sure that we did. The note went back and forth and that was my understanding of what was happening from Health's perspective". "Okay, and you also recall discussing it with Ms. Predham". "Yes". "What did you understand was the stage of the external consultant's review". "That it was ongoing and that there was no concern at that time regarding current patients because the samples were being tested, retested or tested outside the province". "Who told you that the review was ongoing". "Heather". "And did she indicate to you that the reviewers had been

Page 52

back in the spring". "No, I understood the review was ongoing as we talked". "Did you understand that it was true of all of it, or was there just some piece of it that they were waiting on. What exactly did she tell you". "I understood the review was ongoing, that they were waiting for a report, which would provide them with recommendations to accredit the lab, and that they intended to implement the recommendations, and at the current time there was no concern about the present testing because it was being done out of the province". "Did she tell you there was one report that they were waiting on, or did she tell you they had already received certain reports". "I wasn't told that there was any reports ever received. My understanding was the actual review and the consultants were currently involved in reviewing the procedures at the laboratory". "So were you told that they had actually already been in twice, and had gone, and that there were reports within Eastern Health". "No, I was not". "Based on your discussion with Ms. Predham, does that surprise you that is the case". "I've since

Page 53

heard that they had actually received some reports, but I was not told that". "Okay, and based on your discussion that you had with her, does that surprise you". "Yes, I would have thought if they had reports that she would have said the consultants had finished their work or finished part of their work and that they had, you know, and shared the findings, but I did not know that, and obviously I don't know if Moira knew it, but she reviewed the note and I would assume if she looked at it and said--and was aware that there had been external consultants reports received, internal or otherwise, that she would have corrected that information because she would have known that the information was going forward to the premier's office. I will be very disappointed if I had thought she'd known, and I don't know if she did know it, but if she did know it, and had not shared that with me--because that would be sending forward incorrect information". "Do you specifically remember discussing that portion of the note with Ms. Hennessey". "I don't specifically recall discussing that particular

Page 54

part of the note, but as I said, I mean, when the note was in its final stage, it went to Moira for approval". "So what you're saying is that you drafted this portion of the note based on information given to you by Ms. Predham". "Yes". "That it was sent back to Ms. Hennessey for review". "Yes, and there was no discussion back from Ms. Hennessey as to any inaccuracy in that portion of the note". So, Ms. Predham, it appears that Ms. McCormack has clearly said that she received the information from you. Are you able to respond or refute that?

MS. PREDHAM:

A. Well my only response since I can't remember the conversation with her, is that I wouldn't have said that and if it was so important to make sure that the information was accurate that was going to the Premier, you would think that based on a verbal conversation she would send me the draft of that briefing note to confirm that she had got it correct. And that's all I can say about that.

CHAYTOR, Q.C.:

Q. Is there anything else at all that you can

Page 55

recall about--if we could just go back, please, to P-0125? And then, of course, the action I've already asked you about that and you would not have indicated that your legal counsel or officials from Eastern Health would be available. Is there anything else at all that you recall about this briefing note and how it became developed?

MS. PREDHAM:

A. That's it. I have no memory of the one with Ms. Hennessey, I had this vague recollection of a telephone call with Ms. McCormack and I have no other information.

CHAYTOR, Q.C.:

Q. And if we could have, please -

THE COMMISSIONER:

Q. Ms. Predham, regarding the deceased, I just want to make sure I understand exactly what happened in respect of the retest results from the deceased.

MS. PREDHAM:

A. Okay.

THE COMMISSIONER:

Q. I understand you said this morning that accepted in respect of those persons who you

Page 56

did not know were deceased at that time, your view was that non of the deceased were panelled, is that correct?

MS. PREDHAM:

A. Exactly, yes.

THE COMMISSIONER:

Q. And has anything--did anything change in respect of that when the plan was developed to give results to families if they requested it?

MS. PREDHAM:

A. Originally as it worked out, if a family member requested the results and they were confirmed negative, then we would tell them that information. If they had changed, we'd put them in touch with, they would meet with the oncologists or Dr. Laing. As it progressed, when we did the retesting and made the announcement in 2007, we had a lot of discussion on how we would deal with the results that had changed.

THE COMMISSIONER:

Q. Uh-hm.

MS. PREDHAM:

A. And we'd come up with various potential ways, the oncologists didn't feel comfortable

Page 57

dealing with the people who were not their patients.

THE COMMISSIONER:

Q. Uh-hm.

MS. PREDHAM:

A. And then there was the intent to get a consultant oncologist who could talk to families. So it went--it progressed in that note.

THE COMMISSIONER:

Q. Yeah, but so what you're saying is that in addition to those persons who might have, as it were, an error had been reviewed by the panel because their results had changed -

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Some of the families of deceased members would have heard from you in those early days because they received the information about the confirmed negative.

MS. PREDHAM:

A. Or they called in later on.

THE COMMISSIONER:

Q. Okay, and then you reached a point where the

Page 58

new plan was put into action regarding deceased patients where the families themselves had to make the contact?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. So you would have had a number of results, some of which would have been communicated, some of which would have not.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Because we do know that the number of deceased patients were in fact in the early days tested.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And further on up, so you would have had that kind of--for a period of time you were in that category.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Some tested, some not tested, some informed,

Page 59

some not informed.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Then you came up with a larger plan, as it were, the results of which would not--the results in respect of the deceased patients whose families had not already heard, would not be conveyed unless they made contact, is that correct?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And if that family made contact and it was a case where the results had changed, how did you deal with that?

MS. PREDHAM:

A. Up to a certain point, we got an oncologist or Dr. Laing would meet with the family and go over those results.

THE COMMISSIONER:

Q. Yes.

MS. PREDHAM:

A. After a certain point and I'm not sure of the reasoning, they decided that they wouldn't do

Page 60

that any more unless it was their own patients and then, so then we were investigating--trying to obtain an oncologist to do that and we couldn't do that, so then the director of the Cancer Care Program was the contact for those patients and it would go through that -

THE COMMISSIONER:

Q. Ms. Smith.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. So really in respect of deceased patients, what occurred depended on the stage you were in along the way?

MS. PREDHAM:

A. Yes, that's a good way of putting it.

THE COMMISSIONER:

Q. And very few of them would have gone through the panelling process.

MS. PREDHAM:

A. Yes, very few.

THE COMMISSIONER:

Q. And do you know whether or not there is a plan in fact to do that for them? Harkening back to your own concern which you expressed here

Page 61

about what one validly conclude from the data, absent those particular records having been examined in the same way that the earlier ones were.

MS. PREDHAM:

A. Well see, that's--yes, because you can't--that's the problem with only having the panel results and doing any conclusions based on those--these numbers, the 939 and all that because it's not a true analysis of that. And really what the plan of any more information with the deceased, I'm not aware of, I don't know what's going on.

THE COMMISSIONER:

Q. All right, thank you. Sorry, Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, that's fine. If we could have, please, P-1179? And this is an e-mail exchange, Ms. Predham, in which you write to Ms. Elliott, "Please read below, I have no idea how we could have missed this lady so completely." And this is October 4th now, 2006. "Unless she was a consult on request by the physician, but if so, the physician should have told her. I'll keep you updated.

Page 62

Meanwhile, we have another lady who has died but converted. Her husband is in Corner Brook." And there's discussion about her. And you will see here the details on it is "A lady called Nancy on Monday asking if she had been retested. Apparently she had called in the fall asking if there was retesting and would she be involved. She was told yes and that someone would be in touch. She called in on Monday asking if there's been any word on her retesting as she hadn't heard anything. She was diagnosed with cancer in 1999, May, 1999, showed faint positivity in less than 20 percent and there's an addendum on her pathology report, November 4th, 2005, with the results: ER, 90; PR 40. I've gone through every scrap of paper related to ER/PR that I have and I cannot find her name anywhere. We certainly didn't panel her. Can we quickly review her via phone or something and then get the letter to her GP." Now, Ms. Predham, obviously this is someone who you would have had her name at some point because she was in fact, called in the fall or she had called in the fall and had advised that she was being

Page 63

retested. So I would assume there would have been a record of her telephone call at that point in time and she would have been--wouldn't she not have been put on a list then at that time to make sure she was included?

MS. PREDHAM:

A. If I'm thinking of the same situation, I think when we looked back, she had called probably the day after the media results came out or it might have been--she called at a very early time and it was more of a general discussion, if I had breast cancer and, you know, if this had happened to me, would I be retested, more of a generic type of conversation. We should have picked up her name in that, but it wasn't because it wasn't identified that she was an actual person at that time.

CHAYTOR, Q.C.:

Q. Well she was told yes, she was going to be retested and that someone would be in touch with her.

MS. PREDHAM:

A. If I'm thinking of the same one, it was when we went back and looked, it was more of a generic type of a conversation that was held,

Page 64

but we didn't pick up her name at that time.

CHAYTOR, Q.C.:

Q. So when you went back and looked, you mean on October 4th, 2006?

MS. PREDHAM:

A. Yes, if I'm thinking of the right case.

CHAYTOR, Q.C.:

Q. So you're able to confirm and then pass on to Dr. Laing and Dr. Denic and others that she had been told she would be retested and someone would be back to her.

MS. PREDHAM:

A. Yes, that's what I have here. But as I recall, it was more generic, we didn't identify, oh yes, this lady has to be retested and we told her yes, you will be retested. It wasn't that type of a conversation, it was more of a generic one that, you know, as this progresses. I can't remember the details right now, but it was more generic than, in fact yes, we're taking down your name.

CHAYTOR, Q.C.:

Q. And it was important for people and you understood at the time with your concerns about your list, it was important for people

Page 65

to self identify.
MS. PREDHAM:
A. Oh definitely and she was--you know, unfortunately she was missed on that route.
CHAYTOR, Q.C.:
Q. So she had called, self identified, fell through the cracks somehow and didn't get retested.
MS. PREDHAM:
A. Oh she did get retested.
CHAYTOR, Q.C.:
Q. Got retested, sorry, didn't get panelled, her retest was done back and put on her--her result was actually put on her chart in November, November 4th, 2005, the addendum is actually added to her chart.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And that happened without her or her physician apparently ever becoming aware?
MS. PREDHAM:
A. No, I believe she was a consult, that the physician had ordered the retest and I believe that the results came back and I'm not sure

Page 66

what happened after that, but -
CHAYTOR, Q.C.:
Q. And who ordered her retest?
MS. PREDHAM:
A. Unless I went back and looked, I wouldn't be able to tell you.
CHAYTOR, Q.C.:
Q. So the physician who ordered the retest also missed her in following up with her to let her know?
MS. PREDHAM:
A. Like I said, I'd have to go back and look, go back through that story again.
CHAYTOR, Q.C.:
Q. But what do you--so you don't now know what happened with this particular patient?
MS. PREDHAM:
A. I can't remember right now.
CHAYTOR, Q.C.:
Q. But it appears if what you've written here back on October 4th, 2005 is correct, is that you had no record of her anywhere.
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:

Page 67

Q. She had not been told her results and for some reason, the pathology addendum got entered on her chart without ever her particular situation coming to the panel?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. She should have, would you agree, she should have been on your list for retesting, having met the criteria in any event.
MS. PREDHAM:
A. Oh yes.
THE COMMISSIONER:
Q. And did you ever have any process for figuring out why these people who fell through the cracks had actually done so, in the sense of why did we miss this person?
MS. PREDHAM:
A. We did work through that and I can't recall for her, there was a lot of different factors that, you know, that contributed to that, but I can't remember specifically for her.
CHAYTOR, Q.C.:
Q. And if we can look, please, at P-3044? And this is a few days before that, September

Page 68

29th, 2006 and there's an inquiry from a husband, you're writing to Ms. Elliott and others that "I've had contact with this gentleman. His wife's ER/PR had not been retested. She was originally ER negative, PR zero and the lab sent it to Mount Sinai when I requested on September 15th. The results came back on the 27th, she did not convert, the results remain the same. I had called three times in the interim and left messages at his house. He did not respond. He called me today in response to this e-mail and I was able to give him the results." And this is the e-mail, I take it, here?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And apparently he had made contact with Ms. Bonnell, is that correct?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could have, please, P-3047? And this appears to be a draft of a panel letter and you will see that the person was panelled

Page 69

March 4th, 2006 and the recommendation of the panel was that she should be offered treatment with Tamoxifen and there's a handwritten note here, "Heather, FYI, this lady never did get contacted. Dr. Laing's office told me to leave it with you." And it's October 6th, 2006, received by courier from Dr. Laing's office and it appears while she had been panelled March 4th, 2006, it's not October 12th, '06 and she still hasn't been told the results. What do you recall about this situation?

MS. PREDHAM:

A. We couldn't find her. She had moved and, you know, it's hard without the names there, she had moved and was being followed up in Ontario and she has no--she was no longer being seen by that group, they had no forwarding address for her, no forwarding doctor and her GP that was listed on that chart as well, had retired and we had lost track of her, we couldn't discover where she went after.

CHAYTOR, Q.C.:

Q. And do you know whether or not today she's been contacted?

Page 70

MS. PREDHAM:

A. Yes, she has been contacted.

CHAYTOR, Q.C.:

Q. And when--around when was she contacted then?

MS. PREDHAM:

A. She was only contacted this summer.

CHAYTOR, Q.C.:

Q. And if we could look, please, at P-3048? And this is an e-mail, you write October 18th, '06 to Leona Barrington and you write, "How's this, Eastern Health is winding up its review of estrogen and progesterone retesting. As many people as possible have been contacted and the results are currently being collated for analysis. Eastern Health anticipates that this review process will be completed by the end of November, is that enough." And do you recall, what were you providing this information for?

MS. PREDHAM:

A. If I recall correctly, I think Ms. Barrington was being contacted by the media and she had either--she may have sent something to me or something which said that we, you know, a little summary of where it is and this was my

Page 71

suggestions of wording.

CHAYTOR, Q.C.:

Q. And I note here, Ms. Predham, that you are saying "as many people as possible have been contacted".

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So that's a qualified statement.

MS. PREDHAM:

A. Oh yes.

CHAYTOR, Q.C.:

Q. Did you ever assert definitively that all patients had been contacted?

MS. PREDHAM:

A. Never.

CHAYTOR, Q.C.:

Q. Do you know if anyone in your department did?

MS. PREDHAM:

A. In our department?

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. Never.

CHAYTOR, Q.C.:

Page 72

Q. Ms. Elliott for example?

MS. PREDHAM:

A. I can't imagine.

CHAYTOR, Q.C.:

Q. Were you ever present when she made such a statement?

MS. PREDHAM:

A. I can't recall.

CHAYTOR, Q.C.:

Q. And where would Ms. Elliott get her information if she were to make such a statement, where would she get her information about patient contacts?

MS. PREDHAM:

A. Oh, from myself or Ms. Parsons.

CHAYTOR, Q.C.:

Q. Okay, and did you ever tell that to Ms. Elliott, that all patients had been contacted?

MS. PREDHAM:

A. I never said all patients had been contacted. I never said that every number was definitive, I've never ever--I always qualified everything that I said.

CHAYTOR, Q.C.:

Q. And did you ever have any direct discussions

Page 73

with Mr. Tilley on that or were you present when it was discussed with Mr. Tilley as to whether or not, do we now have everyone? Has everyone been contacted?

MS. PREDHAM:

A. I can't recall any--I can't recall not, but I can't recall any.

CHAYTOR, Q.C.:

Q. And if you had been -

THE COMMISSIONER:

Q. Sorry if I'm interrupting, there's so many "nots" in that, that I'm not sure what everybody is confirming or denying here.

MS. PREDHAM:

A. I'm not saying that I didn't say anything to Mr. Tilley, but right now I can't think of any -

THE COMMISSIONER:

Q. You didn't discuss the subject with Mr. Tilley or -

MS. PREDHAM:

A. I may have discussed it with him, but right now I can't think of any time that I did.

THE COMMISSIONER:

Q. Okay.

Page 74

CHAYTOR, Q.C.:

Q. And in any event, you would not have told him everyone was contacted.

MS. PREDHAM:

A. I've never said that in my life.

CHAYTOR, Q.C.:

Q. Okay. And if we could have, please, P-1188? And this e-mail exchange begins from yourself, October 26th, 2006 and it goes to a number of people, including Dr. Howell, Dr. Denic, Terry Gulliver, Pam Elliott, Pat Pilgrim, Susan Bonnell, Sharon Smith, Kara Laing and copied to others. And you're writing about a person who was diagnosed with breast cancer in 1999. You give her original results. She had been treated with Tamoxifen for a period and then switched to Femara. "The panel had much discussion and debate on how best to disclose this information to the client. The original intent was a meeting with the clinical chiefs and someone from QRM, but a complicating factor at the time was the media coverage after the DCIS meetings. Upon further review, the panel decided that we had earlier discovered another retro converter who was

Page 75

contacted via the most responsible physician, our usual process. Therefore, the day after the panel meeting, September 8th, 2006, Kara, on behalf of the panel, wrote to the most responsible physician to recommend that she remain off the Femara and not receive any further hormonal therapy." I just want to stop you there for a moment because why would the panel have much discussion on debate of how to best disclose the information to the client or to the patient?

MS. PREDHAM:

A. As I recall, the discussion was around whether you meet with this person or these people, or whether we send a letter. With the-when we discussed the people for the DCIS, the mis-diagnosis patients, it was very clear that they would have to meet with them and go through this, but--and that was their first choice, but then they were concerned that if they contacted somebody and said come in, we have to discuss something with you, the clinical chief was--just because it was in the media at that time, they might automatically think that they were mis-diagnosed. And then

Page 76

when it was discovered that we had already sent a letter about a retro converter, they felt that this was the most appropriate route to go.

CHAYTOR, Q.C.:

Q. Now in terms of how to, though, best disclose the information to the client, we looked the other day at, I think it's P-0057, the disclosure policy for the organization. So it would be, it's fairly straightforward, I would suggest as to how, in such a situation, you inform patients and so why would there have to be a discussion and debate about, well we have a policy in place, here's what we have to do?

MS. PREDHAM:

A. Well it's a guideline, not a policy, but also I guess their discussion was about whether or not this was--telling somebody that they did not have the type of cancer that they had and/or telling them the treatment recommendation that your ER/PR results had changed and now there's a treatment change, you know, this was a conversation between the clinical chiefs and the clinicians that were there. My intent was that they had to be

Page 77

disclosed, how are you going to do it? So, you know, to debate the two sides of it, you'd really have to ask them.

CHAYTOR, Q.C.:

Q. And the media coverage, again, how was that a complicating factor at the time?

MS. PREDHAM:

A. I do remember the comment made by one of the oncologists, I'm not sure which one, but the comment was made that, you know, if we call somebody now to come in for a meeting with us, would they automatically think that they were mis-diagnosed.

CHAYTOR, Q.C.:

Q. And you point out that it's, well not a policy, it's a guideline, but in any event, why wouldn't that guideline be applicable in this case?

MS. PREDHAM:

A. Well, we had just gone through all this time of panelling of these changed results and we had a letter go out, so as they went through this discussion, they decided to keep it with our regular route of sending out a letter.

CHAYTOR, Q.C.:

Page 78

Q. I take it unless there's strong indicators to do otherwise, you follow your guideline?

MS. PREDHAM:

A. Well it's--the guideline is a suggested route and that's what you'd typically would do in a situation. Of course, those guidelines were written for a situation involving one patient with a final outcome and you know, but this was part of a larger process.

CHAYTOR, Q.C.:

Q. But this is one patient with a final outcome. Each of these patients are one patient with a final outcome.

MS. PREDHAM:

A. Oh exactly, but not in the--there's a high volume of them, but the plan that had been decided the previous October was to go through the results and recommended change in treatment and what the clinicians sitting around the table decided that the best route was to follow the route that was planned and write a letter to these people.

CHAYTOR, Q.C.:

Q. And you go on then to say, "Yesterday afternoon, Nancy received a phone call from"--

Page 79

and I take it, it was from the patient?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Apparently one of the doctors sent the letter to the family physician and -

MS. PREDHAM:

A. Then the family physician gave her the letter.

CHAYTOR, Q.C.:

Q. Gave the letter to the patient and "The patient called Nancy to get contact information on the group that is suing Eastern Health, which Nancy declined to give." What do you recall about that?

MS. PREDHAM:

A. I don't recall anything about Nancy declining to give that, all I remember, I was very upset about this, and the way this progressed and, you know, probably if I waited ten more minutes, I wouldn't have said the certain words that I said in this e-mail but I was very mad at the time.

CHAYTOR, Q.C.:

Q. And why were you so upset? What was so upsetting about this?

Page 80

MS. PREDHAM:

A. Well, you know, it was just hard, you know, you wanted to do the right thing and there was no need for this to happen to her.

CHAYTOR, Q.C.:

Q. And so what was it that had happened to the patient that was so upsetting to you? She received the letter and so she's informed by her family physician.

MS. PREDHAM:

A. Well the first person we sent it to sent the letter to her family physician who called her in and said, "this letter is for you" and gave it to her without context, without information.

CHAYTOR, Q.C.:

Q. And was the letter--those letters were copied to the family physicians, were they not?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So in sending the letter then to her, wasn't it--or sending--or copying them to the family physicians, wasn't that a possibility of what could happen that if they're in to see their

Page 81

family physician or the family physician makes contact to make sure the person knows, isn't that what very likely could have happened?

MS. PREDHAM:

A. Well the reason that we, you know, in quality didn't disclose the information, you know, if we were given the direction by the physicians to say yes, you can call the people up and tell them, or the fact that we didn't write a letter to the patients was because they needed the context of what that meant to them.

CHAYTOR, Q.C.:

Q. And you're saying the family physician couldn't give that context?

MS. PREDHAM:

A. He didn't give that context, he just gave the letter, he didn't give any explanation of what it meant. He just gave the letter. Now this is according to the lady who called us.

CHAYTOR, Q.C.:

Q. Yes. And sending out and deciding to go with the letter as opposed to following the guideline of having the patient in, sitting down, speaking with her -

MS. PREDHAM:

Page 82

A. Well we followed the letter because it was more like all the other letters that we had sent.

CHAYTOR, Q.C.:

Q. So what did you think was going to happen by sending the letter? What was supposed to have happened?

MS. PREDHAM:

A. Well the first physician, the most responsible physician should have called her in and sat down and explained that her results had changed and this is the impact on your treatment, that's what I expected to happen.

CHAYTOR, Q.C.:

Q. And you don't have any recollection of Nancy actually refusing to give the lady the information about who is suing Eastern Health?

MS. PREDHAM:

A. No, I don't.

CHAYTOR, Q.C.:

Q. And why would you put that in your e-mail?

MS. PREDHAM:

A. I don't know, obviously I had some information about that at the time, but I don't know why.

CHAYTOR, Q.C.:

Page 83

Q. "So I can only assume that Mr. Crosbie will now have another story. I anticipate that he will call for a total retest of all ER/PR results. We did discuss that at the panel letter, but there is documented false positive rate with this test and five our of 962 falls well within that range. Of course, we can revisit this decision." Is your concern that now the knowledge of this is out there, this retro converter case and that in fact, somebody such as Mr. Crosbie may come forward and say, well what about your positives and let's get them retested? That's your concern?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you're saying five out of 962 and what was your knowledge of the total number of retro converters as of October 26th, 2006?

MS. PREDHAM:

A. Was four out of 962.

CHAYTOR, Q.C.:

Q. Four that what, required treatment change?

MS. PREDHAM:

A. Required treatment change.

Page 84

CHAYTOR, Q.C.:

Q. And total number, however, of retro converters was much higher than that.

MS. PREDHAM:

A. And it really wasn't until November of December that I started to differentiate, it was probably late November that I was differentiating that the numbers that we had from the panelling really didn't reflect the issue that we had because of the, well as I said before, because of the treatment side of it. There was more influences on treatment than just the ER/PR numbers. So it was after this time that I started thinking, you know, that's really not right. These are four that had a treatment change based on the going back down to zero, but that's not all the retro converters.

CHAYTOR, Q.C.:

Q. And this number five our of 962 wouldn't be any indication as to whether or not your test is falling within any, as you seem to indicate there might be an accepted false positive rate.

MS. PREDHAM:

Page 85

A. There was a discussion at the panel level about that and whether or not there was a documented false positive rate, which I've never seen and I didn't get any evidence about that, but -

CHAYTOR, Q.C.:

Q. And you've never come across it in your research?

MS. PREDHAM:

A. I didn't do a lot at the time, but I couldn't find it easily. But there was a discussion at the panel level about that and there was some acceptance that that was acceptable.

CHAYTOR, Q.C.:

Q. But it wouldn't be, in any event, you wouldn't be using five or four to calculate that.

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. That wouldn't be correct.

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. If you're looking to see whether or not you've got a problem with your positives, you're not

Page 86

going to just look at the ones that required a treatment change.

MS. PREDHAM:

A. Absolutely not.

CHAYTOR, Q.C.:

Q. You would have also been aware at this point in time that negative controls were not being used throughout the time period.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what did you understand is the importance of a negative control?

MS. PREDHAM:

A. Well the negative control works against the false positive.

THE COMMISSIONER:

Q. Ms. Predham, can we go back to the content regarding the lady who was the subject of this memo in the first place?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And the point about what was expected of physicians who had been contacted by you,

Page 87

without going into who the particular physician was who sent the letter on to the family physician, what I'm really interested in knowing is whether that person is somebody who you would have known would have received information about what you were doing and what was expected of them.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. So you were in a position where you had reason to believe that when this letter came to that most responsible person, that responsible person--that person would understand what was expected of them, in terms of dealing with this?

MS. PREDHAM:

A. Exactly.

THE COMMISSIONER:

Q. So that's the source of your real frustration with this, the process of falling down at that level?

MS. PREDHAM:

A. There was no need for that person to send that letter on.

Page 88

THE COMMISSIONER:

Q. To the family physician?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And what about family physicians, what was your understanding of what they would have known if that kind of information got to them?

MS. PREDHAM:

A. I understand that they were aware of our process and were aware that they would be getting these letters.

THE COMMISSIONER:

Q. Was that all?

MS. PREDHAM:

A. I think we wrote to the family physicians about that and also I think every letter had, if you required more information, I'm sure that every letter had that on it, about contacting Dr. Laing.

THE COMMISSIONER:

Q. Yes. No, it's just that as I've heard about this process along the way, I have sometimes wondered about the position of a family physician who would have gotten a letter, a

Page 89

general letter about the subject and then maybe has a number of patients and he would have, or she would have gotten copies of letters regarding their patients, and then I would anticipate that it would not be unusual to find those patients walking through the door. My question was whether or not the family physicians were really in a position to answer the questions of their patients?

MS. PREDHAM:

A. And what I found in, you know, after the fact of, especially after the class action lawsuit letter went and there was some feedback, I had a discussion with the family physicians then and also when we were doing the verification of contact, the majority of them were aware and, you know, took the letter and, you know, did what was in it. Took it as, okay, this is the recommendation for treatment and this is what we'll do, and didn't have a problem with it. You know, they understood what that was and they appreciated that additional information, rather than just getting a copy of the pathology report where they would have to, I guess, consider that. That was the

Page 90

feedback that I got.

THE COMMISSIONER:

Q. So what you're saying is the majority of the family physicians would have appreciated the fact that there had been a panel?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. But how many of those people would not have been patients of the Cancer Clinic in any event?

MS. PREDHAM:

A. I'm not sure.

THE COMMISSIONER:

Q. Were not most of them patients of the Cancer Clinic?

MS. PREDHAM:

A. They were, but they could have been discharged a couple of years before and now being followed by their family doctor. You know, if somebody had cancer in, say, '97 and they were discharged and now their family doctor is following them.

THE COMMISSIONER:

Q. Would you not expect that people who were

Page 91

patients of the Cancer Clinic would stay with them for at least five years?

MS. PREDHAM:

A. I'm not sure what the criteria discharge is from the Cancer Clinic.

THE COMMISSIONER:

Q. Thank you. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. And Ms. Predham, you go on to write "This entire ER/PR review has been very difficult and drawn out, with constant hard and difficult decisions being made. The only thing making it bearable at all was that we were doing what we had to do to make it right for our patients. We were always doing the "right thing". Personally this, combined with the two situations involving Dr. Ganguly in the past two weeks has left me totally and absolutely disheartened." And first of all, what were the two situations with Dr. Ganguly? Did that have anything to do with ER/PR?

MS. PREDHAM:

A. I can only think of one and it did.

CHAYTOR, Q.C.:

Q. And what was the situation there, did it also

Page 92

involve patient contacts?

MS. PREDHAM:

A. Yes, it did.

CHAYTOR, Q.C.:

Q. And what happened?

MS. PREDHAM:

A. A patient who--we sent a panel letter to Dr. Ganguly, but he didn't call this patient in. She went back for her annual check up and when he saw her there, he disclosed the information to her then.

CHAYTOR, Q.C.:

Q. So there had been some gap in time between the panel letter going out and Dr. Ganguly relaying the information to the patient.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And at this point in time, what you've written here, you certainly appear to be distressed.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you sent that to a large number of people, including the people you report to. What

Page 93

happened? Did anyone contact you, see how you're doing with this, the level of stress that you're obviously under and how this had impacted you, did anyone come to you, speak to you to see if you're okay to continue carrying out what you had been asked to do.

MS. PREDHAM:

A. No, not from that perspective, but I guess, you know, there was a lot of discussions on how hard this all was. We had a new department, you know, that was established and we still, up to this point, we didn't have all our staff in place yet. So it was a very difficult time and everybody was going through a difficult time.

CHAYTOR, Q.C.:

Q. And it appears this, then the first page of this e-mail, it appears that there's to be a meeting then, from Dr. Howell "re: 4:30 meeting today," same day. So was there a meeting then held of the group to discuss this issue and where things stand?

MS. PREDHAM:

A. I wasn't involved in a meeting.

CHAYTOR, Q.C.:

Page 94

Q. You weren't there?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and so after you sent out this e-mail, did you have any response at all from anyone?

MS. PREDHAM:

A. Yes. I think I talked to several people on that list and gave more information.

CHAYTOR, Q.C.:

Q. So you had several of the people that you contacted phone you to get more information about "what's going on here?"

MS. PREDHAM:

A. Or just to generally discuss that issue.

CHAYTOR, Q.C.:

Q. And who do you recall contacting you?

MS. PREDHAM:

A. I remember speaking to Ms. Smith and I remember speaking to Ms. Pilgrim.

CHAYTOR, Q.C.:

Q. Anyone else?

MS. PREDHAM:

A. I don't recall.

CHAYTOR, Q.C.:

Page 95

Q. And if we could have, please, P-0424? This is an e-mail about organizing a presentation and it goes to Mr. Tilley, November 6th, 2006, we understand, and "on Monday, November 20th, at five p.m., Dr. Howell is organizing a presentation by Heather Predham and Dr. Denic, among others, on ER/PR review with a view to having a presentation then to the executive on November 21st." So what--were you involved then in those presentations, and if so, what was your role?

MS. PREDHAM:

A. I wasn't involved in presentation at all.

CHAYTOR, Q.C.:

Q. You didn't give any presentation?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And at this point in time, was it contemplated that you might be involved in making a presentation?

MS. PREDHAM:

A. I don't recall. I wasn't involved in at all.

CHAYTOR, Q.C.:

Q. And the discussion here was "who do you see

Page 96

giving the presentation to executive, Dr. Denic and Heather Predham, plus legal counsel." Do you recall any other discussion around that?

MS. PREDHAM:

A. No. I know a presentation was given to executive. I'm not sure of the date. It was in November or December. I thought possibly it was December. But I didn't give a presentation.

CHAYTOR, Q.C.:

Q. You attended the presentation?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could look, please, at P-2662? And it appears November 16th that you're having communication with Dr. Denic, "here are the numbers. If you need anything else, call me." And the subject line was briefing note to the Minister and then you say "I'm not sure why the subject came up as it did, so I've resent it to make sure you have the right document." Were you, at this point in time, also preparing a briefing note for Minister

Page 97

Osborne?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and summary of the numbers, what is that you're preparing for Dr. Denic?
MS. PREDHAM:
A. I think Dr. Denic wanted to have--I guess with the timing, it must have been for his presentation, because he did do a presentation to executive. So I guess he wanted the latest numbers.
CHAYTOR, Q.C.:
Q. Okay, and so the document that ultimately goes to Minister Osborne later in November, the numbers in that document, you would have been the person who put those numbers together?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could have, please, P-2107? And this is an e-mail from yourself, November 19th, 2006 to Ms. Elliott and Ms. Pilgrim. "Hi, I met with Bev Carter, Ford Elms, Don Cook, Nash Denic and Susan Bonnell on Friday

Page 98

afternoon. We reviewed the presentation for Monday and it's very good and comprehensive. As always, Bev's comments in the meeting were a little bit alarmist in nature, but she is only speaking about ER/PR testing at the presentation." So first of all, I take it this is your meeting to assist, at least, in what will be presented. What was your role in coordinating what's going to be presented?
MS. PREDHAM:
A. Well, it's related to--I just happen to go into this meeting. They were already planning on meeting, but Dr. Howell called me and told me that when we went to executive on Tuesday, he felt that I could, as I got here, anticipate I'd be asked if I felt everything was done that could be done in the lab as per the external reviews. So you know, for me to do that cold, I hadn't been involved in anything like that. I expressed my concern about that, and he suggested that these people were getting together about the presentation and maybe if I went over there, I could come up with some idea on how I could, you know, give that concern. So I invited myself to

Page 99

that meeting.
CHAYTOR, Q.C.:
Q. Okay, and so you went there to try and bring yourself up to speed?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. What did you mean by "as always Bev" and I take it you mean Dr. Carter, "comments in the meeting were a little bit alarmist in nature"? What had been your experience with Dr. Carter prior to this to give you the impression that she could tend to be a little alarmist?
MS. PREDHAM:
A. Well, she's very passionate about this and she just tends to make broad statements from time to time. I wasn't overly concerned obviously because I didn't say what it was that was a bit alarming, but you know, like she made that comment back in August of '05 that there were no positives or no negatives for a certain period of time, but when we went and checked, that wasn't accurate. And then, of course, she resigned from the panel, but then she still continued to go to the panel. So, you

Page 100

know, it was just a history of she would make some comments and -
CHAYTOR, Q.C.:
Q. So what kind of comments had you ever heard her make that you could classify as alarmist?
MS. PREDHAM:
A. Well, the fact that we had no positives for a certain period of time.
CHAYTOR, Q.C.:
Q. So back on that?
MS. PREDHAM:
A. Yeah, back, that type of thing.
CHAYTOR, Q.C.:
Q. Okay, and other than that though, had you heard her say anything that -
MS. PREDHAM:
A. Well, I can't think of anything right now.
CHAYTOR, Q.C.:
Q. And do you recall, what was she saying in the meeting that you found to be a little bit alarmist?
MS. PREDHAM:
A. Oh, I can't recall now.
CHAYTOR, Q.C.:
Q. Did it have anything to do with the current

Page 101

condition of the IHC lab?
MS. PREDHAM:
A. Probably not, because I wasn't concerned. If I was concerned about it, I would have told Ms. Elliott and Ms. Pilgrim.
CHAYTOR, Q.C.:
Q. But perhaps were you not concerned because you thought maybe she's exaggerating or being alarmist?
MS. PREDHAM:
A. I would never take it at face value. If anybody said anything to me, I'd always have to check into it, and you know, like we checked into that period of time where she said that there were no positives, I think. I'd always have to check on it anyway.
CHAYTOR, Q.C.:
Q. You go on to write "but she's only speaking about ER/PR testing at the presentation." So might her comments have been about other things in the IHC lab besides ER/PR?
MS. PREDHAM:
A. It could have been about anything. It could have been, you know, the structure of the lab, you know, any kind of broad issue like that.

Page 102

I have no idea. I have no memory of it, but I wasn't overly concerned with whatever it was she said.
CHAYTOR, Q.C.:
Q. And it's indicated here, as you've said, that Dr. Howell has told you that he anticipates you're going to have to speak on the issue of whether everything was done that could have been done, in terms of the external reviews being, I guess, the recommendations carried out, and so that's what prompted you to go to the meeting?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "He arranged for Nash to give me the summary document of the reviewers' recommendations and the lab actions. It has not been updated since June and a lot of the recommendations have ongoing next to it." Did that cause you concern?
MS. PREDHAM:
A. Well, certainly, because it wasn't--you know, I didn't know what had happened or what was the state from June to now.

Page 103

CHAYTOR, Q.C.:
Q. And so what did you do to address that concern? What further inquiries did you make?
MS. PREDHAM:
A. Well, that's what--Friday when I discussed it with these people, we decided that Monday morning, I think Dr. Elms was going to try--or Dr. Carter, were going to try to get a CAP audit and that we would walk through that and see what we had or what we didn't have in terms of that, and most of it, as I said here, would be an audit of documentation, but that's what we did and we didn't do that because I don't think we had the time to get the copy of the audit. There was some difficulty in getting that where it was--it was late Friday afternoon by the time this was over, and when we came in on Monday morning, when we met, we just went through the recommendations. So as whatever was the recommendation, I noted to myself where we were, what was completed and what was still outstanding and what was being worked on.
CHAYTOR, Q.C.:
Q. So this never took place? You never did the -

Page 104

MS. PREDHAM:
A. CAP audit.
CHAYTOR, Q.C.:
Q. And saying that, it wouldn't actually be CAP audit.
MS. PREDHAM:
A. No, no
CHAYTOR, Q.C.:
Q. You would get the requirements for a CAP audit and go through the lab and see, in fact -
MS. PREDHAM:
A. If we -
CHAYTOR, Q.C.:
Q. - if it could pass?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And that didn't take place?
MS. PREDHAM:
A. No, and my recollection of that was it was just because it was late Friday and we were meeting first thing Monday morning.
CHAYTOR, Q.C.:
Q. And did you discuss with--I understood Mr. Gulliver was tasked, and Mr.--or Dr. Cook and

Page 105

maybe by this point it's Dr. Denic, to see that the recommendations were put in place. Did you go and have any discussion as to "well, this hasn't been updated since June. Is this the most current document or have you made any further progress?"

MS. PREDHAM:

A. Well, yes, that was the discussion when I met with them, and so then when--you know, that was--having a documentation that was--having a document that was only updated in June was really of no benefit to me, because I'd have to see what was going on now. So then when we couldn't get the CAP audit, I guess that was a suggestion that came out of it. When we couldn't get that, then we went through the recommendations to see what it was and we updated it.

CHAYTOR, Q.C.:

Q. Okay, and were there things that could be updated?

MS. PREDHAM:

A. Oh yes, yes.

CHAYTOR, Q.C.:

Q. So there were some things that were no longer

Page 106

ongoing, had been completed?

MS. PREDHAM:

A. There were things that were completed. That were things that were in progress, but had progressed further, and there were things that they were having difficulty putting in place or not difficulty, but you know, that needed more work to put in place. In Quality, you know, whenever we have an action plan, we've always--you don't like putting ongoing there. You want to put a bit more detail there. At least you get some kind of state of the nation view when you pick up a document.

CHAYTOR, Q.C.:

Q. And in terms of updating the document then, was the recommendations list updated then in November of 2006 to show what had, in fact, been completed between June and November?

MS. PREDHAM:

A. I didn't do it. I had information--you know, I did it for my benefit, my purpose only, and our whole meeting that Monday morning was solely for, you know, my purpose of going to executive to say this, but I do believe it was updated shortly after.

Page 107

CHAYTOR, Q.C.:

Q. So your purpose in doing this was so you would know the current status of where things were so you could speak to the issue when you had to address executive?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And would you not though, in any event, have--if you're the person who's going to have to speak to you at executive, did you understand then perhaps you have some responsibility to keep on top of this and make sure that the recommendations are being implemented?

MS. PREDHAM:

A. No, and at the time, I was concerned that I was being asked to do this and I was going to be asked this question, because you know, a risk manager is, you know, a middle employee and has no power and it was unusual that I would have to be responsible for this because I wasn't responsible for the entire implementation of it. I was concerned and did tell Ms. Elliott and Ms. Pilgrim of my concern. So the feedback I got was that I

Page 108

could only go and say what I did say, which was "I'm not involved in this review and I took the recommendations and I reviewed the recommendations and there are so many that are in place and there's so many outstanding and if everything goes on under Dr. Elms' direction as is progressing, then they will have completed all the recommendations."

CHAYTOR, Q.C.:

Q. And wouldn't there have been others at the executive meeting and the presentation that could have spoke to it? Why were you being asked to do it, and if you had concerns in doing it?

MS. PREDHAM:

A. I have no idea, but yes, Dr. Denic certainly could have spoken to it. Mr. Gulliver was at the executive meeting and Dr. Howell could have spoken to it.

CHAYTOR, Q.C.:

Q. And in terms of the update to the recommendations list, the one that you received was June and so you're saying it was updated then in November?

MS. PREDHAM:

Page 109

A. I updated it for myself. I think it got updated. That was the only--up to that point, that was the only time I ever even saw the recommendation list.
CHAYTOR, Q.C.:
Q. And did you ever subsequently see any updated versions?
MS. PREDHAM:
A. I think I did.
CHAYTOR, Q.C.:
Q. And in February 2007, the testing was re-instituted and do you know, at that point in time, how current the recommendations list was? How most recent to February of 2007 that recommendations list had been updated?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. If we could look, please, at P-3061? And this is further down the road, May 16th, 2007, and you're e-mailing directly to Mr. Tilley. "Here are the recommendations from the two peer reviews, the one was updated June 2006. There must be another one updated in November after I went through, and I know Terry was

Page 110

updating it again for Oscar last week." And the one that you provide then to Mr. Tilley -
MS. PREDHAM:
A. Yeah, my notes on it.
CHAYTOR, Q.C.:
Q. This is June of 2006?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So in June of 2006--sorry, in May of 2007, you're giving Mr. Tilley the June 30th, 2006 version and those notes on here, this is your handwriting, is it?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So you're saying this is notes you would have made at the time of going through the recommendation list in November?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And in terms of it being updated again, you did handwritten notes on it in November, and Mr. Gulliver was updating it in May of 2007?

Page 111

MS. PREDHAM:
A. I must have heard Mr. Gulliver say he was in the process of updating it again.
CHAYTOR, Q.C.:
Q. And were you aware of any other updates in between?
MS. PREDHAM:
A. No, and normally I wouldn't know. It was just the fact that the one I had was dated in June and I assumed they must have updated one after I went through, and I heard Mr. Gulliver say that he was updating it again.
CHAYTOR, Q.C.:
Q. Okay, and prior to the testing coming back in February of 2007, did you do a CAP style review or audit of the lab?
MS. PREDHAM:
A. I did not.
CHAYTOR, Q.C.:
Q. Do you know whether or not anyone did?
MS. PREDHAM:
A. I'm not aware of it.
CHAYTOR, Q.C.:
Q. And why not? If that's something you thought would have been beneficial back in November of

Page 112

'06, why not do it before testing resumed?
MS. PREDHAM:
A. Because other than this in November, this visit to executive, I wasn't involved in any of the implementation of the recommendations in the lab.
CHAYTOR, Q.C.:
Q. And why, on May 16th, 2007, are you involved in sending the recommendations to Mr. Tilley?
MS. PREDHAM:
A. I distinctly remember this. I was walking up Signal Hill and I got a page from Mr. Tilley who was asking me if--he was looking for the recommendations, the spreadsheet, and my office is in Southcott Hall, which I was almost up to the Battery actually, and so I cut across the field and I went over and e-mailed it to him, and I said "this is all I have. I don't have anything else."
CHAYTOR, Q.C.:
Q. And that sticks out clearly in your mind?
MS. PREDHAM:
A. Well, that was an unusual circumstance, yes.
CHAYTOR, Q.C.:
Q. To receive the phone call from Mr. Tilley?

Page 113

MS. PREDHAM:
A. Yeah, while I was walking up Signal Hill.
CHAYTOR, Q.C.:
Q. And he was phoning you directly?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And was that -
MS. PREDHAM:
A. Well, actually, you know, that's not quite right. I think he ended up phoning Mrs. Parsons at home and she paged me and I called her back and she told me that Mr. Tilley was looking for me because he was looking for a document he couldn't find.
CHAYTOR, Q.C.:
Q. And what was the urgency on May 16th of him having that document such that he had to track Ms. Parsons down at home and track you down walking up Signal Hill?
MS. PREDHAM:
A. I have no idea. I can't remember that. I just remember that circumstance.
CHAYTOR, Q.C.:
Q. And if there had been a more updated version

Page 114

of the recommendations, I take it you would have sent that to him?
MS. PREDHAM:
A. I told him at the time that I didn't have-- this was the only copy that I had and I didn't know what else was gone on with it.
CHAYTOR, Q.C.:
Q. And did you tell him that the more appropriate person to contact on it might be Dr. Denic or Terry Gulliver?
MS. PREDHAM:
A. Yes, I did.
CHAYTOR, Q.C.:
Q. Why was it, in November of 2006, that you suggested a CAP style audit take place?
MS. PREDHAM:
A. Well, when I met with those people, when they were going through their presentation and they were telling me what they were doing in that, in the discussion, I was trying to figure out how I was going to say that I felt comfortable with what was going on in the lab. You know, how would you have support to make that comment, and during that discussion, I don't think I came up with the CAP style audit, but

Page 115

I think one of--I think Dr. Elms actually came up with that idea.
CHAYTOR, Q.C.:
Q. And if we could have, please, P-2108? And this is the meeting of November 21st, 2006 of the executive management and the guests included Mr. Gulliver and yourself, Doctors Denic, Cook, Elms, Laing and Mr. Boone, and why did you understand Mr. Boone was present? Were you involved in arranging to have him there?
MS. PREDHAM:
A. No, I was not.
CHAYTOR, Q.C.:
Q. And do you understand what was his role? Why was he there?
MS. PREDHAM:
A. I don't know. I can't remember actually now why he was there.
CHAYTOR, Q.C.:
Q. And the following points were raised during the presentation. "The organization cannot speak publicly on the findings and recommendations of the review because there is currently a class action law suit ongoing.

Page 116

This information is protected under the Evidence Act. Discussion ensued regarding the need to share the experience with other pathologists within the province. Dr. Howell and Dan Boone to discuss further prior to making any discussion to discuss the reviewers' report with the provincial pathologists." What do you recall being discussed about that?
MS. PREDHAM:
A. I don't recall. I don't recall that discussion.
CHAYTOR, Q.C.:
Q. And "Quality and Risk Management are confident that the appropriate processes are in place. Heather Predham"--I'm sorry, I should take you up here first. "The organization needs to establish a date when it will return to testing mode. Returning to testing mode requires the confidence of the oncologists and medical staff. Executive agreed to extend ER/PR testing at Mount Sinai for another month. The Medical Advisory Committee is a key group that confidence will need to be restored. MAC has a major quality role and a

Page 117

direct line for reporting to the Board." What do you understand the Medical Advisory Committee's major quality role, what is it?

MS. PREDHAM:

A. Well, it is the approval body for all medical policies and procedures that go in place and any new, you know, Pharmacy and Therapeutics reports to it, so any new process that involves physicians or medical care would go through that Board, Committee.

CHAYTOR, Q.C.:

Q. And do you know when you did your brief review of the lab, in November '06, before you were able to speak to the executive management team, did you make inquiries as to where the documentation phase, how many of the recommendations, in terms of documentation, standard operating procedures and policies that were recommended be implemented? Did you inquire as to what stage all of that was at?

MS. PREDHAM:

A. Well, I did as I went through the recommendations.

CHAYTOR, Q.C.:

Q. And did you understand--what did you

Page 118

understand the stage to be with respect to adopting a fixation policy?

MS. PREDHAM:

A. I can't remember right now. You know, I'd have to go back and look and see whatever they told me.

CHAYTOR, Q.C.:

Q. And are you able to determine that from your handwritten notes on that document or would you have it anywhere else?

MS. PREDHAM:

A. I don't know if I'd have it anywhere else. I might be able to determine it there.

CHAYTOR, Q.C.:

Q. Okay, and in terms of standard operating procedures for running the test, were you able to see any standard operating procedures?

MS. PREDHAM:

A. I can't recall what I saw. They did have some documentation in place and they had the parameters much better documented. The documentation was much better, or well, couldn't be much worse, but it was--well, there was a lot more documentation in the lab.

CHAYTOR, Q.C.:

Page 119

Q. I'm sorry, did you say it couldn't get much worse?

MS. PREDHAM:

A. There was a lot of documentation in the lab when I went down.

CHAYTOR, Q.C.:

Q. Yes, and did you just say it couldn't have been much worse?

THE COMMISSIONER:

Q. Originally.

MS. PREDHAM:

A. Yes, I did.

CHAYTOR, Q.C.:

Q. And if--this here says, "Quality and risk management are confident that the appropriate processes are in place. Heather Predham advised that there are some recommendations from the review that have yet to be implemented. It is important to ensure that quality assurance monitoring processes are in place and can be sustained and monitored into the future. Documentation is of paramount importance and must be monitored and reviewed". So would you have, in giving your presentation, indicated that quality and risk

Page 120

management are confident that the appropriate processes are in place?

MS. PREDHAM:

A. No, because that doesn't fit with the rest of the paragraph. What I said was what's in the rest of the paragraph.

CHAYTOR, Q.C.:

Q. So you told the group that some recommendations that, in fact, been implemented, and you emphasized the importance of ensuring that appropriate QA monitoring processes are in place?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So indicating that perhaps up to this point in time, they weren't all in place?

MS. PREDHAM:

A. No, they weren't.

CHAYTOR, Q.C.:

Q. And did you have concern that there hadn't been a process put in place to sustain and monitor those processes into the future?

MS. PREDHAM:

A. The difficult thing with anything that you do

Page 121

in quality is making sure that you maintain it and you have some process in place that you're going to check and make sure that it is maintained. So some kind of audit system in place that you would go back and check. Because, you know, for all best intentions, you know, you have to plan for that at the beginning to make sure that things are going to carry on, and I just wanted to make sure, okay, it's fine to put this documentation in place, but you're going to have to make sure that you go and check and make sure that it's--this is a new process, people have to be trained in it, but you also have to make sure it's being maintained.

CHAYTOR, Q.C.:

Q. And what did you understand that the lab had in place as of November, 2006, to ensure that?

MS. PREDHAM:

A. Well, for the processes that were in, it was very clear from the discussion that I had that they were going to have to do regular audits, documentation audits, that entire process.

CHAYTOR, Q.C.:

Q. And who would be overseeing that?

Page 122

MS. PREDHAM:

A. Well, ultimately it would be Dr. Denic and Mr. Gulliver, but Dr. Elms was the IHC chief or division chair, whatever the term is, and I think at that process they were hiring a quality person for the lab to assist in that area.

CHAYTOR, Q.C.:

Q. Given that the recommendations hadn't been updated since June of '06, and given that you were able to determine that there were still a number of things that needed to be done, and perhaps the testing--it was being thought that maybe within a month the testing could come back on line, did you think perhaps someone from your department, someone from risk management, should get involved at this stage to ensure that everything is in place prior to the testing resuming?

MS. PREDHAM:

A. Other than this, we weren't asked to get involved.

CHAYTOR, Q.C.:

Q. And did you from risk management and quality, perhaps wear the quality hat here even more so, think that maybe that would be a good idea, that someone needs to be involved from your department?

Page 123

MS. PREDHAM:

A. Well, there was also the process of setting up a quality assurance committee in the lab and the quality and safety leader that's linked to the lab was involved in that.

CHAYTOR, Q.C.:

Q. And so that person was whom at that point in time?

MS. PREDHAM:

A. Janet Laidley.

CHAYTOR, Q.C.:

Q. And she's in your department?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So she was involved in helping oversee that the recommendations were carried out?

MS. PREDHAM:

A. I'm not sure exactly what they were doing. I know that she was working with Dr. Carter in developing that committee and processes, and I know they were involved with development of policies.

Page 124

THE COMMISSIONER:

Q. Ms. Predham, did you in the process of going into the laboratory, either your work initially when you went to have a look at it in that summer--late summer of 2005, or thereafter form any view as to the appreciation or lack of it within the laboratory about the need for documentation, for SOPs, for all that kind of thing that you are saying is so important to be not only put in place, but sustained?

MS. PREDHAM:

A. I found that they were all quite willing to do that, they could see the purpose of it, and, yes, we'll do that. I just found that in other areas--you know, the past ten years of working in quality, that you really need to make sure people go back and check these things. You can't just assume that you put them in place and it's going to work out forever.

THE COMMISSIONER:

Q. But let us say that the documentation that was in place in the laboratory, you would concede

Page 125

was less than ideal?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. But nobody seemed to have done anything about it for a long period of time, so the question which is raised in my mind then is whether there was really an appreciation for the desirability or the need for these documents?
MS. PREDHAM:
A. It was--I can certainly see your concern, and it was--it was unusual circumstance because the lab, in all my experience with doing things in the lab, had top of the line documentation, had very good auditing processes. It was just like this area--it was an oversight that the level of documentation didn't equal other areas that I had seen, but once it was brought to everybody's attention, then it was, like, you're right, we should be documenting these things and we should be doing them, but it was a--I just found it unusual when I first went into that lab because I didn't expect that. I expected what I had seen in other parts of the lab.

Page 126

CHAYTOR, Q.C.:
Q. And your opinion that the documentation couldn't have been much worse, at the time did you tell people that was your opinion, did you tell others within Eastern Health that your opinion was that this was pretty bad in terms of what you were seeing for lack of documentation?
MS. PREDHAM:
A. Everyone knew my concerns about documentation in the lab.
CHAYTOR, Q.C.:
Q. Okay, and the test resumed then, as we said, in February, 2007. Were you or the Quality Initiatives Department involved in signing off that the recommendations had been implemented and everything was satisfactory to resume the testing?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Nobody asked you to do that?
MS. PREDHAM:
A. No, that wouldn't be our responsibility anyway. It would be the leadership team of the program.
CHAYTOR, Q.C.:
Q. And even given a situation such as this where so many concerns had been involved, risk management or quality would not have any responsibility to ensure that, in fact, the tests--things were ready to go?
MS. PREDHAM:
A. No, the leadership team is responsible for the lab and they report to VP Medical, and that's where the responsibility would lie.
CHAYTOR, Q.C.:
Q. And if we could look at, please, 3053, please.
THE COMMISSIONER:
Q. Ms. Chaytor, where we can find a spot, we'll break for the morning break.
CHAYTOR, Q.C.:
Q. This is an e-mail exchange between yourself and Dr. Howell, November 23rd, 2006, ER/PR data clean up is the subject. "Are we able to scrub datasheet on contact/conversions before meeting with the minister today. Oscar". You go back with a very good question, "This is the latest summary of numbers. Is this okay. I'm not sure what scrub means".

Page 127

Page 128

MS. PREDHAM:
A. Even reading that sentence today, I still don't know what the sentence means.
CHAYTOR, Q.C.:
Q. And did Dr. Howell ever tell you what he meant?
MS. PREDHAM:
A. As far as I know, I basically called him and said this is all I have, you know, so I'm not really sure what you're talking about.
CHAYTOR, Q.C.:
Q. What you're asking me to do here?
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. And did he--do you recall any response that you received?
MS. PREDHAM:
A. Oh, he--well, I guess that's--no, I don't recall any response.
CHAYTOR, Q.C.:
Q. So he's obviously--this is getting ready to give the minister a briefing, and this would be the start, I take it, of a briefing note to the minister?

Page 129

MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you see here in giving your total retested, 939, you refer to those who are converted, you refer to those who--the two bolded groups that we've had some discussion about in your evidence.
MS. PREDHAM:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. That you felt could have been potentially impacted, the 13 and the 9, and you talk about the DCIS, the retro convertors, and the patients who are deceased, and how many had results received. If we could look then, please, at P-3056. This is an e-mail then from yourself again to--this time you include Susan Bonnell, Leona Barrington, and Dr. Howell, "Summary of numbers. See how this looks". I don't think we have the attachment. Let's try 3054. Your e-mail, and this is the latest numbers to Pam Elliott and Debbie Parsons, and then if we could try, 3056, please. That's the same one, isn't it? 3054,

Page 130

again. Yes, this one does have the attachment. This is how the latest looks, and you'll see here, Ms. Predham, it looks fairly similar except we don't use the word "converted" any more, the word "no change" and "change" are used.
MS. PREDHAM:
A. Dr. Howell never liked that term "converted".
CHAYTOR, Q.C.:
Q. So perhaps his reference to scrubbing included cleaning up the use of that word?
MS. PREDHAM:
A. Could be.
CHAYTOR, Q.C.:
Q. Could be, okay, and what was his problem with using the word "converted"?
MS. PREDHAM:
A. I can't recall now. I just remembered that he didn't--he wondered who came up with that term. He didn't like it.
CHAYTOR, Q.C.:
Q. And the group that you indicate as being potentially impacted, the 13 are there. I don't see any reference to the other 9 that you had consistently referred to as also

Page 131

thinking had been impacted.
MS. PREDHAM:
A. No, you're right.
CHAYTOR, Q.C.:
Q. Do you recall why that got deleted from this?
MS. PREDHAM:
A. I have no idea.
CHAYTOR, Q.C.:
Q. And the section about the DCIS, I don't see any reference to DCIS. We see originally diagnosis revised, but no reference to spelling out DCIS which you had in your original draft, and do you recall how that came up or why that would have been changed?
MS. PREDHAM:
A. No, I don't.
CHAYTOR, Q.C.:
Q. We do see DCIS up here mentioned, 52 of them. So I take it that's 52 that had no change in results, DCIS patients?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could then, please, look at 3057, and I believe this is the--you're sending to

Page 132

Ms. Pilgrim, briefing note, "Summary of numbers", and if we could look at--this appears to be the same as the document that I showed you with those changes made, and if we could look, please, at 314, page 10, and this apparently is the final version that ends up going to the minister, and did you draft this version or somebody else?
MS. PREDHAM:
A. Somebody else would have done that.
CHAYTOR, Q.C.:
Q. And you provided the numbers, I take it?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And do you know who drafted it?
MS. PREDHAM:
A. It looks like something communications would do up, but other than the fact that it looks like that, I don't know.
CHAYTOR, Q.C.:
Q. Okay, but otherwise the numbers are yours, the 939 results obtained and reviewed, 763, this is the data you included, and the reference to the group including those who are identified

Page 133

as being potentially impacted, those not placed on Tamoxifen for their original disease, that 13 are referred to. Are the other nine that you had identified referred to in there?

MS. PREDHAM:

A. No, they don't seem to be there.

CHAYTOR, Q.C.:

Q. And again the use of the word "converted" is also not there. Is there any other change or is this basically the information then that you provided?

MS. PREDHAM:

A. It seems to be the information I provided.

CHAYTOR, Q.C.:

Q. And do you know why any changes were made otherwise in the text of--apart from the substance of what's here, why the changes were made in the text and how it's laid out?

MS. PREDHAM:

A. Oh, I have no idea.

CHAYTOR, Q.C.:

Q. Okay. Thank you, Commissioner, this is a good place for a break.

THE COMMISSIONER:

Page 134

Q. Take fifteen minutes.

(BREAK)

THE COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. P-3053, please, Registrar. This is the first version that you came up with, and you'll see here the detail that you were giving at the time in terms of what the various information meant, for example, what confirmed negative meant. We've already spoke to you about the nine that you identified as being potentially impacted, and then confirmed negative, 28, and you give some detail as to what's meant by that, and then confirmed positive, and you give detail as to what is meant by that. Then if we look at 3054 again, a couple of hours later then you have this version, and you'll see that the detail around those confirmed positive, the confirmed negative, that detail is also omitted as well as what the--the detail around the 341 and what was meant by the confirmed negative. Do you know why did you--why did you delete that information?

Page 135

MS. PREDHAM:

A. It must have been on the suggestion of someone. It could have been Dr. Howell. I can't remember.

CHAYTOR, Q.C.:

Q. And then if we look then, please, at P-0314 again, we'll see that again what goes forward here is just confirmed negative 341, confirmed negative from panel 28, confirmed positive 12, without the detailed explanation that you had given as to what that means?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And along with the nine people not being referenced either. So is that perhaps what it meant to scrub the data?

MS. PREDHAM:

A. Oh, it--possibly. I recall cannot remember now. I can remember asking the question, but I can't remember.

CHAYTOR, Q.C.:

Q. And it would have been Dr. Howell that you would have taken your direction from in terms of what came out or stayed in in the briefing

Page 136

note for the minister?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. If we could have, please, P-0183. This is an e-mail from Ms. Bonnell to a number of people, including yourself and it refers to error rate, "Attached to this e-mail, you will see Heather's explanation of her error rate", and it goes on to say, "We will begin the briefing session with an explanation that this is an unprecedented event because of the class action, but that we believe we had an obligation to inform the general public about our outcomes and to provide the reporters with an opportunity to fully understand the test procedure and our actions since May, 2005, so that they can report effectively on the issue. However, because of the lawsuit, we are limited in what we can talk about in terms of causative factors. This will have to be dealt with by the court. Secondly, we will not be talking about any individual cases. This information is protected and can only be discussed between the patient and the care

Page 137

provider. Please review the attached. I am very open to your concerns, suggestions, ideas. Following our meeting with Dan, I think I have a sense of how far we can go, but Heather will be sharing all of this, as well as the Q & A with him, and hope to get his feedback as well". First of all, this is what she attaches and you had sent to her on December 7th, 2006, an explanation of the error rate, and perhaps you can just take us through that and explain what it is you came up with?

MS. PREDHAM:

A. Well, it was embarrassing enough that Susan sent this around to other people, let alone that I'm having to explain this publicly, but--and just from a math perspective, but Ms. Bonnell had contacted me the day before and I guess it was one of those days when you just--you know, you have somebody saying this is what I think, how about if we did this, how about if we, you know, subtracted this group, we did this, we did this, and I really wasn't getting what she was saying, and I actually had to go home and think about what she was

Page 138

saying as potential for an error rate. So when we worked through that--this was--I guess, this was our discussion, and I worked through it with--you know, just to highlight that, and shared it with her.

CHAYTOR, Q.C.:

Q. So who were you having the discussion with, was it just with Ms. Bonnell?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And how did the idea of an error rate even come up with Ms. Bonnell?

MS. PREDHAM:

A. She felt very strongly with going out with something substantive to the media at that time.

CHAYTOR, Q.C.:

Q. Yes, and she's indicating, I guess, then to you that they're going to want to know, the public through the media are going to want to know what was your error rate, how often did you get the test right, how often did you get the test wrong?

MS. PREDHAM:

Page 139

A. Exactly.

CHAYTOR, Q.C.:

Q. And so Ms. Bonnell was telling you that would be a subject of some concern, she's suspecting?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And so then you set out to try and figure out an error rate?

MS. PREDHAM:

A. Well, we discussed it on the phone, you know, what would you--what would you have under the total number, and then we didn't know about the results of deceased, so we'd have to subtract them, and then, of course, we had other issues that we had into it, so you'd have to take them out, and--we just had that discussion and I can remember that afternoon, I just--I couldn't keep track of what she was saying. So I said I'm going to have to get back to you, and I really couldn't do it justice at work, so I went home and sat down and tried to think about what she was saying, or what she was doing, and this is what -

Page 140

CHAYTOR, Q.C.:

Q. So are you saying it was Ms. Bonnell trying to come up with--and was giving you these figures, or -

MS. PREDHAM:

A. Oh, no, we were just--you know, we were talking about it, and I would say these are the numbers that I have, and then--so then we would talk about it, you know, well--and I most likely brought up the fact that the deceased aren't all retested. So, you know, how will be take that. So then we just talked through that that way.

CHAYTOR, Q.C.:

Q. And did anyone else assist you in coming up with this error rate?

MS. PREDHAM:

A. Oh, no.

CHAYTOR, Q.C.:

Q. This is just you and Ms. Bonnell?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And so you start off with 939, the original identified negatives, 2760 total number of

Page 141

cases. Now did you have any concerns using that as your denominator?

MS. PREDHAM:

A. No, I didn't--I can't remember why we picked that one as opposed to any other, but, no.

CHAYTOR, Q.C.:

Q. And given the fact that not all of the cases had been retested -

MS. PREDHAM:

A. And I can say to you right now, even before we go through it all -

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. You know, the gist of me seeing this when I typed it out, and seeing it, and thinking about it, this is when it really struck home that the numbers I had were not the numbers to do any type of error rate with, and like I mentioned to you a couple of times before, this was--you know, it really struck home then that this was not a picture of conversions or anything because it was the way people were treated, and there were so many other factors, that there wasn't any consistency with how it

Page 142

was applied, it was very individual. So, you know--and again this was very superficial, just myself and Ms. Bonnell talking, and that's why I was a little bit perturbed that she circulated it around to people.

CHAYTOR, Q.C.:

Q. So even when you were doing it--doing this, you realized this was not an appropriate or accurate way to do it?

MS. PREDHAM:

A. Well, I did it, and then when I--I was thinking about it, and, you know, subsequently I said these are the wrong numbers, these are not the numbers to be figuring out what an error rate is.

CHAYTOR, Q.C.:

Q. And tell us then--tell us which of the numbers, or what is it about this that caused you concern upon further reflection upon it?

MS. PREDHAM:

A. Well, for one issue, taking the deceased out, not having the complete number of the deceased because, you know, that--you're not getting a true picture there, the fact that you don't know--the fact that you're going by clinical

Page 143

recommendation of change. So here we have 369 confirmed negative, but someone can be confirmed negative and actually have a change. They could have been 0, and come back as 5, and whatever on the PR, but they're still confirmed negative, given the circumstances of their case. So it really wasn't giving a--you couldn't say that they didn't change, and you'd also need to have input from the lab from a technical side that what is more concerning to them, is it a 0 to a 5, is it a 0 to a 25, is it a 0 to a 90, or if 30 percent change is the same from 0 to 30, is it the same concern level then from 10 to 40, or is it the same concern level from 60 to 90, because that's the other aspect of it. We hadn't seen any--you know, there were some positives who did change in the number, but what does that mean.

CHAYTOR, Q.C.:

Q. And at what point did you realize this? On December 7th, 2006, after you've had some quiet and time to get it clear in your head, the next morning you shoot it off to Ms. Bonnell. So I take it at the time you did it,

Page 144

you were confident enough with what you had done to share it with her, you didn't just scrap it and say, look, Ms. Bonnell, we can't do this?

MS. PREDHAM:

A. Well, it was--this was myself and Susan talking about an error rate. This was not--this was not something--I didn't think this was going farther than her and me and we would carry on this conversation, but then when she circulated it around to everybody and it looked like, you know--I was concerned that somebody would go out with these numbers or something because I had said them, but I started to get--as I worked through this, I started getting concerned that this was really not giving the picture, this was really giving a false picture.

CHAYTOR, Q.C.:

Q. So while you were working through it, but you still nonetheless provided it to Ms. Bonnell?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what did you understand Ms. Bonnell was

Page 145

going to do with it?
MS. PREDHAM:
A. Oh, I thought we would just continue to talk about it at that time. I didn't realize she was going to circulate it around to people.
CHAYTOR, Q.C.:
Q. So you realized then just a few minutes later, within the same hour, she does share it with a larger group. So what did you do about that?
MS. PREDHAM:
A. I believe I called her after that.
CHAYTOR, Q.C.:
Q. Did you e-mail the group and say ignore that document, I really don't think you can put any reliance in it, here are the issues that I've identified?
MS. PREDHAM:
A. No, I don't--I didn't e-mail anybody. I know I did talk to--I brought up my concerns on numerous times with Dr. Howell and with Susan.
CHAYTOR, Q.C.:
Q. And in terms of the overall group that we see here, was there actually a meeting of this group around this date or shortly thereafter in preparation for the media technical

Page 146

briefing?
MS. PREDHAM:
A. I think she referenced a meeting. I really can't remember any meeting.
CHAYTOR, Q.C.:
Q. You don't remember a meeting to discuss the--getting ready for the media technical briefing?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And do you recall a conference call then or some other means of communication amongst the group members?
MS. PREDHAM:
A. I have a very clear memory of being in the parking lot of Southcott Hall on a cell phone talking to Ms. Bonnell and Dr. Howell about numbers, and I was explaining this concern of mine that the numbers that came from the panel did not reflect what was actually going on with the numbers, so it--because of the clinical impact of these numbers, it really wasn't giving an accurate picture, it wasn't giving an error rate as such, it wasn't giving

Page 147

that kind of perception because as we can see with the retro convertors, you weren't identifying all ones that retro converted, it was only the ones that had a clinical impact.
CHAYTOR, Q.C.:
Q. But those were the same numbers you gave to the minister just the week before?
MS. PREDHAM:
A. Yes, but that was the only numbers I had.
CHAYTOR, Q.C.:
Q. So now you have a concern about the numbers. Which numbers are now of concern to you?
MS. PREDHAM:
A. It wasn't the numbers that I was concerned about, it was using the numbers. It was coming out and saying this is the error rate for the test and using the numbers from the panel as a calculator for the error rate of the test.
CHAYTOR, Q.C.:
Q. Okay, and that was because why?
MS. PREDHAM:
A. Because--because, as I explained, the numbers that were listed out were what happened to people, what happened to individual people,

Page 148

based on their clinical presentation and the disease process that they had, but it wasn't based on from a technical perspective what actually happened. If somebody was zero/zero and then came back as 2/2, then as far as I understand it from a lab perspective, that's very significant, that is a conversion because it's gone from no positivity to some positivity.
CHAYTOR, Q.C.:
Q. Well, there's 28 of those.
MS. PREDHAM:
A. Yes, but in our results, they are confirmed negative.
CHAYTOR, Q.C.:
Q. Yes, but if you're concerned that to give the full picture, you just add in the 28, wouldn't you?
MS. PREDHAM:
A. But there was lots of ones that changed a little bit. These are my concerns with that, you know, and I'm not a lab person, I'm not an oncologist, but when I saw that the numbers that I was doing from the panelling--up to that point they had never been used to

Page 149

calculate an error rate before.
CHAYTOR, Q.C.:
Q. So is it just the wording of an error rate that's of concern to you, or--you have numbers and you're confident enough in your numbers to provide them to the minister.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Just a week before. So the numbers would suggest how many had changes in their treatment, how many required--had changes in their results based on your numbers.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Of what went forward. So what's wrong with figuring out, well, how many out of who we retested had changes in their results, how many out of who we retested had changes in their treatment?
MS. PREDHAM:
A. There's no trouble with saying how many had changes in their treatment.
CHAYTOR, Q.C.:

Page 150

Q. Okay.
MS. PREDHAM:
A. There was no problem there, but saying that this test had an error rate of that, my concern was that it didn't accurately reflect that.
CHAYTOR, Q.C.:
Q. Because your concern was it might be greater than the number of people who had changes in their results because there's the 28 confirmed negatives which, in fact, from a technical lab perspective, really the test change as well/
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So you could add that in and calculate that as well?
MS. PREDHAM:
A. Yes, and like as we've seen with the retro convertors, there was more retro convertors than four.
CHAYTOR, Q.C.:
Q. Yes.
CHAYTOR, Q.C.:
Q. And when did -

Page 151

THE COMMISSIONER:
Q. Let me understand that. What you're raising here, you're saying if you want to look at this from the perspective of the success of the procedure of determining positivity, then you cannot use the clinical decisions to do that?
MS. PREDHAM:
A. Exactly.
THE COMMISSIONER:
Q. Is that -
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. So from your perspective, one would have to look at presumably the numbers received--produced by Mount Sinai, and some presumably somebody else somewhere along the way would have to calculate what is a significant change in those numbers, would going from 12 percent to 13 percent be a real change in the scientific world, and in the same way would in the scientific world going from 12 percent to 90 percent be a change which would not necessarily mean a change in treatment in your

Page 152

world?
MS. PREDHAM:
A. Right.
THE COMMISSIONER:
Q. Okay.
MS. PREDHAM:
A. And this was the problem because it was okay to give the numbers as this is the result of the panel and you do that, but when people started thinking, well, okay, we can calculate an error rate from that, and it really struck home after I went through that process and started thinking about it, that that's not the way to calculate an error rate on this. I had had those preliminary discussions with the Health Research Unit at MUN, and, you know, that's the type of--that type of analysis is the type of analysis to determine what an error rate was.
CHAYTOR, Q.C.:
Q. And you could do, I guess, two calculations. One for technical, and one for clinical.
MS. PREDHAM:
A. Oh, yes, exactly, and that's what you would need to do because you would need to know the

Page 153

impact on the patients, but then you'd also need to know the accuracy of the test. So really--so it's fine, the numbers for the panelling is fine for the minister, this is the impact on the patients or whatever, but the numbers side of it, calculating an error rate or doing that type of analysis, that wouldn't reflect it. That would just be--you know, it wouldn't be accurate.

CHAYTOR, Q.C.:

Q. And you had all the--assuming, of course, there's been other issues with the numbers identified since, but to the best of your ability or knowledge in November and December of 2006, your numbers were accurate at that point?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you had all the numbers then that--or all the data that you would need to be able to calculate the two different clinical--clinically, I guess, what would be determined to be an error rate, and technically what would be determined to be an error rate?

Page 154

MS. PREDHAM:

A. Well--that was well beyond my skill set because, you know, there were certain decision that would have to be made from input from the technical side on exactly what is a significant change from them. You could go--I remember at the time thinking that you possibly could go for the no expressors and then group them into low expressors, and then group them into high expressors, and the low expressors would be 0 to 10, and then you could do a rate of change between those three groups, but that was very preliminary, and also we--you know, it really struck home then that you would really have to identify the deceased, you'd have to get the rest of the deceased retested because, you know, they may have a greater rate of change, or you don't know until you looked at it all.

CHAYTOR, Q.C.:

Q. And in November and December when this was being discussed, you were cognizant of all those issues?

MS. PREDHAM:

A. Yes. Well, this is when it was all coming together in my mind that--you know, when--it was always thought--Dr. Cook and I talked numerous times how we had to get the analysis done at the end of the day, and--you know, so that's when I went over to the Health Research Unit and had some discussions there, and he also--and I think I mentioned this earlier, he thought there may be a possibility that you could do some predictive modelling. So if you had a test result in '97 and you knew that things had changed to increase positivity levels over those seven/eight years, you could calculate in some kind of statistical way what a predicted value based on those changes would be if it was retested, and then compare that to the actual value. So there was some statistical analysis that could be done.

CHAYTOR, Q.C.:

Q. You had those discussions when?

MS. PREDHAM:

A. In May of '06.

CHAYTOR, Q.C.:

Q. In May of '06.

MS. PREDHAM:

A. So the--the other--the other part of it as well is that the other dynamic is that you had a group that we really hadn't identified or nailed down very well in the panel, that, you know, could--would not have been offered Tamoxifen originally because they were--and I can't remember if they were pre or post menopausal, one or the other group was not a candidate for Tamoxifen in the '97/'98, and also some people couldn't take Tamoxifen, but now they were recommended for treatment because the aromatase inhibitors were there. So I guess at this time when Susan sent this out because, of course, I thought it was a preliminary discussion and then she sent it out to everybody, this is what my concern was. It's okay to go out with, you know, what you're going out with, but don't use it to do something else.

CHAYTOR, Q.C.:

Q. And you had also come up with the number of those patients too, how many could now avail of the treatment because the aromatase inhibitors was an option?

MS. PREDHAM:

A. No, I hadn't come up with that.

Page 157

CHAYTOR, Q.C.:
Q. So who was the 13 people, who because of--is that because of the difference in the change of positivity?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Or definition of positivity?
MS. PREDHAM:
A. The definition of what positive was.
CHAYTOR, Q.C.:
Q. And I take it then if you knew all that in May of ’06 or started--had had discussions at that point, why did you bother doing this at all on December 7th ’06 and trying to come up with an error rate?
MS. PREDHAM:
A. Well, I guess, you know, when Susan was talking--it was after--it was after I went through this process that it actually struck home that you cannot do--you can’t do it with this, you can’t attempt to do it with this because there were so many influences on each of these groups and these numbers.
CHAYTOR, Q.C.:

Page 158

Q. And after Susan sent that out to all the group, you didn’t--you didn’t e-mail them or have any communications with all the individuals here to ensure that "I have serious concerns about being able to calculate any error rate, and certainly not on the basis of what I’ve done here"?
MS. PREDHAM:
A. Well, I followed up with Susan and Dr. Howell.
CHAYTOR, Q.C.:
Q. But not the others?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. You say you had a cell phone conversation with Dr. Howell and Susan Bonnell?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. On this same day?
MS. PREDHAM:
A. I’m not sure when that was. It was in the evening, it was dark, and I remember it was in result of my concerns that you couldn’t do that, and that Ms. Bonnell wanted to go out

Page 159

with a number, and that was when Dr. Howell said that the whole point of us doing this process was to offer people Tamoxifen if they weren’t already a candidate. So how about if we just go out with the 117, these are the people that we offered treatment.
CHAYTOR, Q.C.:
Q. And when did that get said by Dr. Howell?
MS. PREDHAM:
A. It was during that phone message, that phone call that I had.
CHAYTOR, Q.C.:
Q. And so Susan Bonnell and Dr. Howell are together on the phone?
MS. PREDHAM:
A. They were either together or it was a three way call. I just remember being on the phone with both of them.
CHAYTOR, Q.C.:
Q. Okay, and were there others then perhaps also on the call?
MS. PREDHAM:
A. Could have been. I don’t recall. I just remember the two of them.
CHAYTOR, Q.C.:

Page 160

Q. So there was some sort of group discussion. Whether it involved three of you or more, you’re not sure. You can’t remember at this point?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And it’s during that discussion that Dr. Howell says we’ll just go out and concentrate on the 117 number?
MS. PREDHAM:
A. Yes, because that was--the purpose that we did the retesting in the first place was to offer people treatment.
CHAYTOR, Q.C.:
Q. And did you tell Dr. Howell your concerns about the 117 number?
MS. PREDHAM:
A. My concerns?
CHAYTOR, Q.C.:
Q. What did you understand the 117 number was?
MS. PREDHAM:
A. The concerns were people that were offered treatment.
CHAYTOR, Q.C.:

Page 161

Q. By whom?
MS. PREDHAM:
A. By the--when they went through the panelling.
CHAYTOR, Q.C.:
Q. And it did not include all of the people who required a change in their treatment?
MS. PREDHAM:
A. Well, they--everyone knew the limitations for these numbers. I mean, that was well known, this was the results of the panelling. This is what the panel decided. It was not anything else outside the panelling that occurred.
CHAYTOR, Q.C.:
Q. Was it well known to those making the decision, including Dr. Howell, that the 117 did not include all of the patients who required a change in treatment, only those that came before the panel and had yet to be offered a change in treatment?
MS. PREDHAM:
A. I would think, but I can't be sure right now what he knew or what he didn't know.
CHAYTOR, Q.C.:
Q. And did you ever clearly articulate that to

Page 162

him?
MS. PREDHAM:
A. I can't remember at that time clearly articulating it.
CHAYTOR, Q.C.:
Q. Well, did you have any concern yourself then, "well, if the decision is now made, they're going with the 117 because the whole focus was who needs a change in treatment," did you have any concern, "well, that's not really accurate because I know there's more than 117. That's just the ones that the panel determined needed a change."
MS. PREDHAM:
A. I don't think that crossed my mind at the time.
CHAYTOR, Q.C.:
Q. But all of the information and all the factors about why you couldn't do an error rate, that crossed your mind?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. What about forgetting about calling it an error rate and just giving all the numbers,

Page 163

was that discussed? Like "let's just tell people what we know."
MS. PREDHAM:
A. Well, the concern--you know, this was outside my comfort level. We had never gone out before when we had law suits and talked to the media, and I think Susan has identified that there, but she wanted to go out with a number, and you know, from my--it was outside my comfort level. This was something we had never done before.
CHAYTOR, Q.C.:
Q. And why was it outside your comfort level? What was your concern?
MS. PREDHAM:
A. Because whenever we had a statement of claim, we never spoke to the media.
CHAYTOR, Q.C.:
Q. And why is that?
MS. PREDHAM:
A. That's the way it always was before I became risk manager and that's the way it always progressed, that whenever there was a statement of claim, that we--it was before the courts and any information that would be

Page 164

released would be released through that process.
CHAYTOR, Q.C.:
Q. Was there a decision made that all of the numbers would not be released?
MS. PREDHAM:
A. I don't remember that. All I remember is that "why don't we go out with that 117?"
CHAYTOR, Q.C.:
Q. And in going with just the 117, did you understand that there wouldn't be reference to the other numbers, including the 300 and whatever number of people with changed results?
MS. PREDHAM:
A. I must have, if I was--you know, I knew that was the number we were going out with, then I would have known that that was the only number we were going out with.
CHAYTOR, Q.C.:
Q. That's the only number, okay. And so you were informed about that.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

Page 165

Q. And part of the discussions in leading up to that decision being made?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And who else was part of that, besides Dr. Howell and yourself and Susan Bonnell?
MS. PREDHAM:
A. Well, I assume Dr. Denic and Dr. Laing were, because they were involved in that, but like I said, that's my memory of the 117 and I've racked my brain about that, of course, for obvious reasons, and that's my only memory is that telephone call.
CHAYTOR, Q.C.:
Q. You gave all the numbers to--well, all but probably the nine, to Minister Osborne on November 23rd.
MS. PREDHAM:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Wasn't anybody thinking "well, this is a briefing note for the Minister. He has to stand up in the House of Assembly. He could very well be asked questions publicly on this

Page 166

issue. He could use the numbers publicly"?
MS. PREDHAM:
A. Ms. Chaytor, the only aspect I had was, again, it was outside my comfort level. Whenever we had a Statement of Claim, we didn't talk to the media.
CHAYTOR, Q.C.:
Q. And the reason for that is because you don't want to say or do anything that could undermine your defence to the action?
MS. PREDHAM:
A. That's your way of putting it. Mine is just that anything that goes on to the Court, it goes through the Court process and gets released that way.
CHAYTOR, Q.C.:
Q. And was that part of the reluctance to saying anything publicly, because you might say something that could undermine your defence?
MS. PREDHAM:
A. That was always our practice.
CHAYTOR, Q.C.:
Q. Okay, and was -
MS. PREDHAM:
A. We had -

Page 167

CHAYTOR, Q.C.:
Q. - and was that part of the thinking though? There must be some thought process "well, it's before the Courts. We can't talk on it." Well, why? There must be some thought as to why that's your position.
MS. PREDHAM:
A. That was--you know, that's just the way things are done. You don't speak to the media if something is ahead of the court because things get released through the Court process. That was--you know, that was just the way things are.
CHAYTOR, Q.C.:
Q. And you never questioned why that's the way things are?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And did you understand or were you ever of the understanding or of the opinion that part of the reason at least for that would be we wouldn't want to do something to undermine our defence?
MS. PREDHAM:

Page 168

A. Well, I guess that makes sense, but you know, the thinking since I've got into this position and was well established before that is if something is in the courts, you don't make comment in the media. If anything is being released, it gets released through the Court process.
CHAYTOR, Q.C.:
Q. And you'd never had a situation like this before though?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. This was unprecedented?
MS. PREDHAM:
A. Yes, and I think even Susan said that. I'd never--it was outside my comfort level. It had never come up before.
CHAYTOR, Q.C.:
Q. And so if you'd had your preference, in December 2006, would there have been a media briefing at all to disclose any information?
MS. PREDHAM:
A. My preference, my comfort level, from what I dealt with and anything else that had a

Page 169

statement of claim, we would not have gone to the media at that time.

CHAYTOR, Q.C.:

Q. So you would have continued to say "the matter is before the courts, and we're not at liberty to discuss the issue"?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So why say anything?

MS. PREDHAM:

A. It wasn't my decision.

CHAYTOR, Q.C.:

Q. And did you have concerns that if we are going to go out there and say anything that we not give part of the information?

MS. PREDHAM:

A. I didn't have--I didn't want to go out and say anything. So I mean, you know, that was -

CHAYTOR, Q.C.:

Q. But was there a greater concern with--you've made the decision to go out and speak, so -

MS. PREDHAM:

A. I didn't make that decision.

CHAYTOR, Q.C.:

Page 170

Q. Yes, but there's a decision made within Eastern Health, they're going to now go do that. Your preference, you're saying, would have been not to say anything. The decision is made to go speak. So was there any concern on your part "well, if you're going to do that, make sure what we say is accurate"?

MS. PREDHAM:

A. My biggest concern was that they not go out with that calculation or make a calculation based on those numbers.

CHAYTOR, Q.C.:

Q. And were you also concerned that they not go out and give all the numbers?

MS. PREDHAM:

A. I can't remember being overly--yeah, I can't remember that concern, and I've expressed my concern about calculating an error rate based on those numbers from a clinical perspective.

CHAYTOR, Q.C.:

Q. And if you go out with the 117 number, are you aware that they also went out with the 2700, approximate 2700 number of the total tests?

MS. PREDHAM:

A. I can't remember, but I think they did. I

Page 171

don't know.

CHAYTOR, Q.C.:

Q. Yes, and were you aware that that was part of the plan, the 117, the 2700, and the 939 that were retested?

MS. PREDHAM:

A. I may have known at the time. I can't remember now.

CHAYTOR, Q.C.:

Q. And to go out and give those numbers, did you have any concern or did anyone who was discussing this have any concern "well, if we go out with those three numbers, perhaps that could be misconstrued and people could do calculations on error rates"?

MS. PREDHAM:

A. The only number I remember going out is the 117.

CHAYTOR, Q.C.:

Q. Were you present at the briefings?

MS. PREDHAM:

A. I did. I wasn't supposed to be, but I asked if I could attend.

CHAYTOR, Q.C.:

Q. And you reviewed the Q and A's?

Page 172

MS. PREDHAM:

A. I don't think I had them until just before the briefing.

CHAYTOR, Q.C.:

Q. Yes, and the press release?

MS. PREDHAM:

A. Again, I don't think I got any of that until just before, the final copies.

CHAYTOR, Q.C.:

Q. So you did have it?

MS. PREDHAM:

A. Just before we went in.

CHAYTOR, Q.C.:

Q. Whatever documentation there was, you were provided with it?

MS. PREDHAM:

A. I believe so.

CHAYTOR, Q.C.:

Q. And that documentation would show those three numbers, correct?

MS. PREDHAM:

A. Oh, I can't remember.

CHAYTOR, Q.C.:

Q. Yes. So whatever documentation was in that, whatever numbers was in that documentation,

Page 173

you had that documentation and those three numbers, there was no concern that people might take those numbers, those are the numbers we're releasing publicly, and do their own calculations and that would be of concern, wouldn't it, to you that "well now they've only taken part of the information and done calculations"?

MS. PREDHAM:

A. It was not a concern at the time. I do know that there was very clearly communicated that we had not given them all the information.

CHAYTOR, Q.C.:

Q. And how was that clearly--you do recall that being at the briefing and hearing that?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And how was that clearly communicated? By whom?

MS. PREDHAM:

A. I think by Ms. Bonnell and I think by Dr. Howell and I know at the first one, the CBC one, I did--they were pressing a lot for this and I just introduced myself and I said "I

Page 174

just want to remind you that we have an action before the Court and we can't tell you everything."

CHAYTOR, Q.C.:

Q. Okay. So at the--you were at the CBC one and you were also at the second one for the greater medium?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what was it that the reporters were asking for?

MS. PREDHAM:

A. If I recall, it was either, you know, how many were wrong or how--you know, it was that type of question, how many tests were wrong.

CHAYTOR, Q.C.:

Q. Did they ask how many overall had changed results?

MS. PREDHAM:

A. I don't recall that.

CHAYTOR, Q.C.:

Q. Okay, and in hearing them ask "how many of your tests were wrong?" what did you understand them to be asking you?

Page 175

MS. PREDHAM:

A. Well, how many tests changed.

CHAYTOR, Q.C.:

Q. Yes, how many tests changed. So you heard them ask that?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And was that question asked repeatedly?

MS. PREDHAM:

A. I do believe.

CHAYTOR, Q.C.:

Q. To the point where you spoke up?

MS. PREDHAM:

A. I did speak up at some point, and it was in reference, just to remind them that there was a law suit pending and usually we don't speak before to the media.

CHAYTOR, Q.C.:

Q. And that there was certain information that you couldn't give them?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what information is it that you couldn't

Page 176

give them because it's before the courts?

MS. PREDHAM:

A. It was just a statement to say that we weren't giving them all the information. It was just to make that clear that we weren't giving them all the information.

CHAYTOR, Q.C.:

Q. But what information is it, did you understand you couldn't give them because it's before the courts?

MS. PREDHAM:

A. Well, we agreed on what information we were giving them, and I guess everything else was what we weren't giving them.

CHAYTOR, Q.C.:

Q. So why was it okay to give the 117 and not okay to give the 317?

MS. PREDHAM:

A. I wasn't part of that decision.

CHAYTOR, Q.C.:

Q. Okay, but you're a part of articulating the position that "we can't give you all the information because it's before the courts."

MS. PREDHAM:

A. Yes.

Page 177

CHAYTOR, Q.C.:
Q. So why can't you give them the 317?
MS. PREDHAM:
A. Like I said, the agreed upon plan when they went in was to give them the 117.
CHAYTOR, Q.C.:
Q. Yes. So why can't you give them the 317?
MS. PREDHAM:
A. Because that was--it was agreed that it was going to be the 117.
CHAYTOR, Q.C.:
Q. Because the matter is before the courts?
MS. PREDHAM:
A. Well, like I said before, I didn't want to give them any information because it was before the courts, but you know, it was decided before we went in that we were going to give them the 117 and that my memory was that no other numbers were given, but--and that was it.
CHAYTOR, Q.C.:
Q. And what else weren't--what other information weren't you giving them because it's before the courts?
MS. PREDHAM:

Page 178

A. I don't think that they were going into the causes of it and getting into that discussion.
CHAYTOR, Q.C.:
Q. Okay, and that's reflected here in Ms. Bonnell's e-mail as well. She says "however, because of the law suit, we are limited in what we can talk about in terms of causative factors."
MS. PREDHAM:
A. And the individual information, they wouldn't talk about any -
CHAYTOR, Q.C.:
Q. People's personal information, yes.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. The causative factors then were not to be spoken of because the matter was before the courts?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you understand that to include anything that you had determined from your review or seen or observed from your review of

Page 179

the lab, as well as anything that Dr. Banerjee or Ms. Wegrynowski would have been able to determine?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And so in terms of what may have happened, nothing, nothing should be said?
MS. PREDHAM:
A. That was my belief.
CHAYTOR, Q.C.:
Q. And that was the decision shared by all in attendance and all who--so that was everybody in attendance, participating in the media briefings agreed with that view?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and did that question get asked? Were they--did reporters ask one way or another what happened?
MS. PREDHAM:
A. I can't remember. I really can't remember if they asked that or not.
CHAYTOR, Q.C.:

Page 180

Q. And what went wrong, you don't recall if they asked that?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And Ms. Bonnell refers to a meeting with Dan. I take it that's Dan Boone?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And are you saying you don't recall attending a meeting with Mr. Boone in which the issue of what could be discussed at the media technical briefings or otherwise disclosed publicly could be--was discussed?
MS. PREDHAM:
A. No, I don't remember.
CHAYTOR, Q.C.:
Q. And did you yourself have discussions with him around that?
MS. PREDHAM:
A. The only discussion I had with him was, I guess, a little bit earlier. He didn't -
MR. SIMMONS:
Q. Excuse me. If I could just interrupt, just

Page 181

for a moment. I don't think there's any problem with disclosing whether there were discussions or not, but I note that with other witnesses, such as Ms. Bonnell, there's been care taken not to infringe on whether there was any advice given around this particular time, and not to stray into solicitor-client privilege here. So there's no problem identifying if there were discussions -

CHAYTOR, Q.C.:

Q. Yes, I think other witnesses have spoken to that though, what their recollections are around that.

MR. SIMMONS:

Q. Yes, but when it's coming to--just as a caution, if it's come to asking whether there was any advice given and what the content of that advice has been, I think that's been respected so far and should continue to be respected here. But the general nature of whether there were any contacts perhaps what, even general areas addressed.

THE COMMISSIONER:

Q. Well, let's find out what the specifics of this are first. What's--where are we going

Page 182

with this to determine whether or not there's any danger of straying into solicitor-client privilege.

CHAYTOR, Q.C.:

Q. Sure, and perhaps my memory on that wasn't as clear. I thought there had been discussion by other witnesses on that issue as to what was discussed in the meeting with Mr. Boone. Perhaps I'll ask it this way then. Do you know whether or not the decision that was made as to what could be disclosed was in keeping with the legal advice provided?

MS. PREDHAM:

A. I don't think we got any legal advice on that. The only discussion was--and I don't know -

CHAYTOR, Q.C.:

Q. I don't know if it's something that -

MS. PREDHAM:

A. I don't know if I can say.

CHAYTOR, Q.C.:

Q. If it is something that you discussed then -

THE COMMISSIONER:

Q. If there's something you're uncertain about, then let's not go down that road, at least until we determine whether or not it might

Page 183

stray into solicitor-client privilege. But what you're saying is that you don't think you got legal advice on it?

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. And so are you saying you didn't discuss with Mr. Boone his views on what could be disclosed publicly?

MS. PREDHAM:

A. I didn't.

CHAYTOR, Q.C.:

Q. And you're not aware that others did?

MS. PREDHAM:

A. Not that I know of. I don't know if they did or not, but I didn't.

CHAYTOR, Q.C.:

Q. Do you think there was a meeting with him that you didn't attend?

MS. PREDHAM:

A. Could have been, but I didn't--you know, I certainly didn't have that discussion with him. The discussion I had with him was about one issue and it's not that.

CHAYTOR, Q.C.:

Page 184

Q. Okay, and your perspective though on this, in terms of any reluctance to give out information of the causative factors or overall numbers, your reluctance was based on your historical position to not discuss matters that were before the Courts?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. What else do you recall happening at the technical briefings? How did it go?

MS. PREDHAM:

A. The first one was a little bit--I can't think of another word, it's not antagonistic, but it was a little bit, you know, more aggressive, I guess, in their questioning. But you know, they went through the--Dr. Denic and Dr. Laing went through their presentation. Dr. Howell introduced it. Dr. Denic and Dr. Laing went through their presentation and then they took questions.

CHAYTOR, Q.C.:

Q. And what did you think was going to happen afterwards, in terms of you finish your media technical briefings. Did you think the media

Page 185

was satisfied that they had this information and that the issue then would not arise again, in terms of the points that couldn't be spoken to?

MS. PREDHAM:

A. Oh no, I mean, as soon as things came forward in court, as it progressed, then it would be, you know, then it would be talked about.

CHAYTOR, Q.C.:

Q. Once the information is released in court?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And were you aware at that time that there was an affidavit to come forward which you ultimately became the person to sign in February '07, and there's some reference that that affidavit was originally supposed to be filed December 15th, 2006. Were you aware that that was in the works at the time, that affidavit?

MS. PREDHAM:

A. No, I think I found out that somebody was asking if it got filed or not, but that was in January, and I certainly found out about the

Page 186

affidavit, but that was towards the end of January, beginning of February.

CHAYTOR, Q.C.:

Q. The reference to ten percent, in the past there had been reference to ten percent. In some answers that you helped prepare and draft to the MUSE, there was reference to this eight to ten percent of patients may--who are being retested may have a change. Did that come up, the idea that we've already been out there in the past talking about a ten percent or thereabout change rate?

MS. PREDHAM:

A. That was only anticipated.

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. Because we had no results then, so that was only what we would anticipate seeing.

CHAYTOR, Q.C.:

Q. Yes, but I'm just wondering, in the decisions and the discussions leading up to the media technical briefing, did that come up again? Because you were conscious in the past of being consistent in the messages that were

Page 187

going out with. So did it come up for discussion again, "well, we've said ten percent in the past. We can't give the numbers now because obviously it's not that"?

MS. PREDHAM:

A. No, I don't recall anything like that.

CHAYTOR, Q.C.:

Q. Do you recall anyone referencing that ten percent when you're trying to make up your mind what can and cannot be disclosed?

MS. PREDHAM:

A. No, I don't recall that at all.

CHAYTOR, Q.C.:

Q. And who, in January 2006 (sic.), asked you if the affidavit had been filed?

MS. PREDHAM:

A. I don't recall. I think there was an e-mail that said apparently we missed some date or something.

CHAYTOR, Q.C.:

Q. A deadline.

MS. PREDHAM:

A. A deadline, and somebody asked about it and I had to check on it, and again, just that's a vague memory.

Page 188

CHAYTOR, Q.C.:

Q. If I could have, please, 1207? And this appears to be an e-mail about one of Dr. Laing's patients that--it's January 25th '07. "This lady called Nancy last week saying that we had called her and told her that we were going to retest her, but she had not heard anything since. On checking into this, the lady was retested and was shown to have a changed ER/PR. She was panelled in February 2006, and a letter was written by Kara Laing as chair of the panel to Kara, the most responsible physician. After an incident with another physician, the entire list," you go on to say, "in September," sorry, "we contacted all physicians who received a letter from the panel to confirm that the patients had been notified. This included all physicians at the Cancer Clinic. After an incident with another patient, the entire list was reviewed with the leadership in the Cancer Care program. This lady was on Dr. Laing's list."

So first of all, in September of 2006, it says "we contacted all physicians who received a letter from the panel to confirm that the

Page 189

patients had been notified." Is that correct?
MS. PREDHAM:
A. We attempt--well, we contacted them all, but we didn't get many results back, and I guess what my--the point I was trying to get across is that we did contact the ones at the Cancer Clinic and went through them and got feedback from those.
CHAYTOR, Q.C.:
Q. So in September 2006, you had made attempts to contact all the physicians?
MS. PREDHAM:
A. Well, we had contacted all the physicians offices, but we didn't hear back from all of them. But that wasn't--I guess I never went into detail there because that wasn't the point of what I was trying to say.
CHAYTOR, Q.C.:
Q. So why are you saying that at all, that--why are you telling Oscar Howell, Pat Pilgrim, Pam Elliott, Leona Barrington that in September you contacted all physicians who received a letter? Why is that being said in this context at all?
MS. PREDHAM:

Page 190

A. I guess just in the preface to say that we did hear back from the Cancer Care program, and that they had contacted all these patients, but this lady was on Dr. Laing's list.
CHAYTOR, Q.C.:
Q. And where is that written, that you heard back from the Cancer Clinic physicians?
MS. PREDHAM:
A. It's not there.
CHAYTOR, Q.C.:
Q. Okay, and wouldn't this--anyone reading this, be of--couldn't this easily be interpreted as saying "well, we contacted all the physicians to confirm the patients had been notified," that piece of work is done, without qualification?
MS. PREDHAM:
A. Well, I guess it would be for someone who wasn't the people that I'm sending it to, because the people I'm sending it to would have known the circumstances at the time and the difficulties that we had.
CHAYTOR, Q.C.:
Q. And Dr. Howell would have known that?
MS. PREDHAM:

Page 191

A. Yes, because he was--he had started by then.
CHAYTOR, Q.C.:
Q. So Dr. Howell, you're saying, would have been well aware that you had to abort your attempt to get confirmation from all the physicians that they had confirmed with their patients and notified their patients?
MS. PREDHAM:
A. Well, we didn't abort it. We attempted it, but we weren't successful in completing it. We didn't--we couldn't get cooperation from the physicians to get it finished.
CHAYTOR, Q.C.:
Q. Yes, and you couldn't make contact with all of the physicians?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. Couldn't make contact or they didn't get back to you?
MS. PREDHAM:
A. I think we made contact with all the--and of course, that was Ms. Parsons that was doing that, but I was aware that we made contact with all the physicians offices, but they

Page 192

didn't get back to us.
THE COMMISSIONER:
Q. Okay.
CHAYTOR, Q.C.:
Q. And Dr. Howell was aware of your difficulties in that respect?
MS. PREDHAM:
A. Oh yes.
CHAYTOR, Q.C.:
Q. You indicate "unfortunately Kara was not now available to meet with this lady and explain why she was missed." Why was she missed?
MS. PREDHAM:
A. I'm not sure.
CHAYTOR, Q.C.:
Q. And did you carry out any investigation to figure out how that could have happened?
MS. PREDHAM:
A. No, I did not.
CHAYTOR, Q.C.:
Q. And how could it be that this person was panelled and almost a year later, February '06, she's panelled and almost a year later she doesn't know her results?
MS. PREDHAM:

Page 193

A. It's very unfortunate.
CHAYTOR, Q.C.:
Q. But there has been no inquiry to determine how that could have happened?
MS. PREDHAM:
A. No. No inquiry by me, I should say.
CHAYTOR, Q.C.:
Q. And do you know whether or not anyone has carried out an inquiry so that that could be covered off?
MS. PREDHAM:
A. You'd have to ask Dr. Howell that, he would have had to follow up with Dr. Laing.
CHAYTOR, Q.C.:
Q. If we could have, please, P-3058? It's an e-mail of January 26th, 2007 and I've moved on into 2007, but just before I do that, I just want to make clear there were--the external reviewers did come back, I didn't cover that off with you in 2006, except probably in a roundabout way. You were aware, of course, they came back.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

Page 194

Q. Dr. Banerjee and Ms. Wegrynowski. Did you receive copies of their reports in 2006, their subsequent reports?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And we understand that was in the spring of 2006 and maybe around May of 2006, the reports came back? Whenever they came back, I take it you got a copy at the time.
MS. PREDHAM:
A. I did, yes.
CHAYTOR, Q.C.:
Q. And you're writing to Sharon Smith, "Here's the latest" and the first e-mail is January 25th, the day before, you got off the phone with, I take it it's Dr. Howell, is it?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "He feels we have to assume that there is another missed person out there and we need to triple check the notifications. Here's the tentative plan. I'll review the panel list with Nancy and we can eliminate those we know

Page 195

for a fact to be contacted, i.e. the ones who have come forwarded in the media and those that have called us and complained, et cetera. Were the Cancer Clinic charts and those seen by Drs. Felix and Kwan, I'll review the charts and ensure there is some documented evidence of follow up. For the rest, I'll call the patient to ensure that they have been contacted. By the way, Dr. Howell was unaware of this latest situation before the media request." And what's this all about?
MS. PREDHAM:
A. Well this was in response to that latest one that got missed, as Dr. Howell said, if there's one out there, then there's going to be more than one. And he wanted to go through a systemic way of identifying if everyone had been communicated with that had a panel letter.
CHAYTOR, Q.C.:
Q. So by this point in time, were you--did you share Dr. Howell's concern, well if there's one missed, there likely are others?
MS. PREDHAM:
A. Yes.

Page 196

CHAYTOR, Q.C.:
Q. Did you have that concern anyhow before this?
MS. PREDHAM:
A. Well yes, I did all fall when we had those, you could see I was concerned, so yes, I had that concern.
CHAYTOR, Q.C.:
Q. And did you do the plan here and go through--did you review the panel list with Nancy? Did you review the Cancer Clinic charts and the charts of Dr. Felix and Kwan?
MS. PREDHAM:
A. No, because I had a family emergency at that time and I was not fully working.
CHAYTOR, Q.C.:
Q. And did anyone else undertake this work while you weren't there?
MS. PREDHAM:
A. No, not at that time.
CHAYTOR, Q.C.:
Q. Was it ever undertaken?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And when was that?

Page 197

MS. PREDHAM:
A. That was this year, in May.
CHAYTOR, Q.C.:
Q. May of 2008?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And why didn't anyone pick up and do it before then?
MS. PREDHAM:
A. I'm not sure.
CHAYTOR, Q.C.:
Q. If we could have, please, P-3059? This looks like it's another ATIPP request from Mr. Quinn?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you're e-mailing to Marian Crowley. The subject line is March 1st, 2005. Why would that be?
MS. PREDHAM:
A. I don't know.
CHAYTOR, Q.C.:
Q. And it appears you're forwarding to her the

Page 198

letter from--or the letter that was sent to Mr. Quinn.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Responding to his ATIPP request, "This is to confirm that on February 15th, 2007, Eastern Health received your request." So this is just the confirmation letter that his request has been received.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And it's a draft letter intended for her signature?
MS. PREDHAM:
A. Yes. Marian had taken over that position for the ATIPP request and I guess at this point in time, we realized that the templates and that were still on my computer.
CHAYTOR, Q.C.:
Q. And were you then involved at all in this response, this ATIPP response to Mr. Quinn?
MS. PREDHAM:
A. Only peripherally.

Page 199

CHAYTOR, Q.C.:
Q. In the same manner in which you are involved in the 2006 request?
MS. PREDHAM:
A. Even less than that. I gave advice to Deanne on searching computers and that at that time, but this time Marian did this all herself.
CHAYTOR, Q.C.:
Q. And Mr. Quinn has referred to the affidavit which was filed in February, 2007. Who made that decision to refer Mr. Quinn to your affidavit?
MS. PREDHAM:
A. In discussion, he was requesting all results of that and I know in a discussion that we had of, I guess the broader group involved in ER/PR, we had a bit of a problem giving, even if we de-identified lab results, de-identified anything that was part of the patient record, to release that and that was our discussion that we were having and as I recall for some reason, Susan and I were talking about it and we were also, I think we were talking about something else with one of the legal counsel at Stewart McKelvey who suggested that and I

Page 200

guess we must have made some comment -
CHAYTOR, Q.C.:
Q. And you might not want to tell me that.
MS. PREDHAM:
A. Oh, well it was just to point them in the direction of the affidavit.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. And see if that met his--because part of the ATIPP is that you have a duty to assist, so he may be satisfied with the information that's in the affidavit and may not need the full detail of all the issues that we had a problem with.
CHAYTOR, Q.C.:
Q. And was that satisfactory to Mr. Quinn?
MS. PREDHAM:
A. No, he went to the Privacy Commissioner.
CHAYTOR, Q.C.:
Q. And if we could look, please, at P-2116? And this is a further e-mail from Marian Crowley to Drs. Cook and Denic and then Dr. Cook to Marian Crowley, April 3rd, "Hi Marian, in speaking to Dr. Denic, I understand he was

Page 201

already talking to you today, as well as speaking to Heather yesterday on this issue." And it's regarding, it appears, ER/PR patient reports. She says, "We had a request from a reporter asking for the actual ER/PR test results of the patients affected with the local results and retest results from Mount Sinai. We denied the release citing that the results were personal information. The reporter has appealed to the Privacy Commissioner who has ordered the reports sent to his office for review. We've been down this road before. We are legally obligated to send the results to the Privacy Commissioner's office. We have to provide the reports by next week. I've discussed this with Heather and we need your advice about how these reports can be generated as expeditiously as possible." So I take it that that's just showing that Mr. Quinn was persistent in wanting the information.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. This issue, of course, takes on a fairly high

Page 202

public profile again after Mr. Quinn's story comes out on May 15th, 2007. Were you aware beforehand that that was going to happen, that Mr. Quinn was going to be writing a story?

MS. PREDHAM:

A. My only knowledge of it, I left the Health Sciences and was just--I had a specialist appointment and I was in the parking lot when Ms. Bonnell paged me and she told me that Mr. Quinn had the affidavit and he said that the numbers didn't add up and my first response was that, the math, the numbers do add up, I was thinking math wise, you know, not, you know, what he eventually took from that and I told Ms. Bonnell I couldn't talk to her because I was waiting for the specialist appointment so long, I had to go in, and after that, I went to, I believe it was Regional and Quality Council. Dr. Howell was there and I said, "you heard that Mark Quinn had called about the affidavit." And Dr. Howell said, "yes, and we're not commenting."

CHAYTOR, Q.C.:

Q. So Eastern Health's decision was going to be not to say anything in response?

Page 203

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And how did you--what was your opinion of that? Did you have any issue with that or did you think that was the right course of action?

MS. PREDHAM:

A. I was a bit surprised, but I wasn't part of any discussion about it, then or after.

CHAYTOR, Q.C.:

Q. And if we could look at P-3060 please? And May 16th, 2006, Ms. Crowley write yourself and Ms. Elliott and copies to Mr. Boone that "The Privacy Commissioner's office is moving ahead with the formal review of Mark Quinn's request for the ER/PR results of the patients. Mark is not satisfied with the information in the affidavit and he wants the patient reports." So I take it there was something more that he was looking for than what could be obtained in the affidavit?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And did you understand what it was, what was

Page 204

the detail that Mr Quinn was requesting?

MS. PREDHAM:

A. Well his request was for all original results and all retested results and I do believe that was the--that's my memory of what the request was and he wasn't getting that information from the affidavit.

CHAYTOR, Q.C.:

Q. At the time that the affidavit was filed in Court in February, did you have any concerns at that point in time in having all of the numbers made public?

MS. PREDHAM:

A. No, because that was progressing through the Court, that was--that was the--that was what I expected.

CHAYTOR, Q.C.:

Q. And was there any discussion at that point in time that, well this is the same information that we weren't prepared to make public just a couple of months ago?

MS. PREDHAM:

A. At that time, I didn't have any discussion with anybody about that.

CHAYTOR, Q.C.:

Page 205

Q. And if we could have, please, P-0704? And this is from Marian Crowley to a number of people, including yourself and Louise Jones, Pam Elliott, Rick Singleton and Pat Pilgrim and it's July 6th, 2007. "Hi all, just to clarify" -

MS. PREDHAM:

A. I think you need to read the -

CHAYTOR, Q.C.:

Q. Okay, read the first one?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So it's an e-mail, it originates from Rick Singleton to Louise Jones, July 5th. "Hi Louise, while I think that last Friday at the Steering Committee on confidentiality, Marian Crowley happened to mention that the Privacy Commissioner's recommended release of health records, names blocked of patients involved in ER/PR. She then went on to mention that she consulted Richard Newman of HIC of the Ethics of such a release. He advised that he saw no problem with it and made the analogy to an unanimous chart reviews as part of research.

Page 206

A few concerns came to my mind, why would she consult on the ethics outside our own structure? Why would she consult with someone who is not an ethicist and the comparison of CBC chart access and researchers is somewhat deficient." What--were you present when Mr. Crowley had made this inquiry of Mr. Newman?

MS. PREDHAM:

A. Yes. And I think she referenced that at that top e-mail.

CHAYTOR, Q.C.:

Q. Yes, and what do you recall about that? What was that all about?

MS. PREDHAM:

A. Well we were at a privacy conference, actually, and we were talking about this ATIPP request, it was shortly after the request came in and both of us had a problem, although there was no, I guess, you know, you go for years working under the Hospitals Act and you had very limited access, external access to a person's health record and now we have this ATIPP legislation and there wasn't any clear cut that would prevent anybody from asking for, for a group of people, information that's

Page 207

on a patient's chart and it just didn't seem right. And we were discussing this and we happened to come across Dr. Newman at this conference or workshop and we just said like, from a research perspective, it wasn't an ethics consultation at all, it was from--from a research perspective, if this request had come into HIC, would you require consent or what would you require? And he told us that he didn't--we couldn't use that as a reason to refuse disclosure, he didn't feel there was anything--he didn't think there was anything stopping us from releasing it.

CHAYTOR, Q.C.:

Q. And then the next day, July 6th, 2007, Ms. Crowley writes, "Just to clarify, at the time that we were preparing to respond to the ATIPP request for release of the ER/PR patients' results, Heather and I were discussing all of the possible exceptions to disclosure of such information. One of the scenarios we discussed was whether the info requested could be classified as health research where we knew there would be rigorous HIC expectations. We ran into Richard Newman at the workshop and

Page 208

had a chat with him about it because there was no hypotheses, et cetera, Richard felt we couldn't use that reason to refuse disclosure. We were not looking at this as an ethics consultation. I have personally been involved in several ethical consults with Rick's great team, but when it comes to access to information legislation, ethics is unfortunately not one of the exceptions in the legislation." And so, I'm just trying to think, so the idea of trying to refuse the disclosure to Mr. Quinn as somehow being classified as health research?

MS. PREDHAM:

A. Well, I mean, it wasn't--it wasn't looking as a reason to refuse it, it just didn't seem right. If you were going to do research tomorrow on ER/PR or anything, you would have to do a proposal to HIC. HIC would have to review it and come up with whether or not you'd need consent or anything and just go through that process. But here we were faced with someone with an ATIPP request looking for information and it didn't seem to have any of that scrutiny level on it. So it was just a

Page 209

disconnect.
CHAYTOR, Q.C.:
Q. But did you ever think that the ER/PR review was ever health research?
MS. PREDHAM:
A. No, no, no, it was just the ability for someone off the street to access information from a patient's chart. It was just--we hadn't thought about it before. It was irrelevant of ER/PR, what our thinking was. It could have been anything that somebody would have called. If anybody wanted to know the blood sugar results of all men from age 40 to 50 that were conducted within the past month at the Health Sciences Centre, I don't know, it just seems like an odd thing that you would give out from an ATIPP request.
CHAYTOR, Q.C.:
Q. If we could have, please, P-3064?
THE COMMISSIONER:
Q. Ms. Chaytor, we'll take our luncheon break when you're ready.
CHAYTOR, Q.C.:
Q. And this is an e-mail between yourself and Ms. Parsons and she's advising--take you to the

Page 210

bottom here. It's from a patient, "I have been a patient at the Cancer Centre, I'm in the group that had ER/PR testing in 1999. My testing came back negative and I did not receive Tamoxifen. I've never been informed if my test results changed. Certainly there will be some effort to contact women in my situation or are we all expected to call into our oncologists separately." And this is May 15th, 2007. Nancy says, "Thank you for contacting us." And she then lets you know and you say "Thank you, Nancy, for your prompt attention. I appreciate getting the result today on my voice mail. I think patients would appreciate a letter in the mail about the testing and your numbers so we can get their test results." So I take it then at this point in time, you're keenly aware that not all patients had been contacted?
MS. PREDHAM:
A. Oh yes.
CHAYTOR, Q.C.:
Q. And not only would you be hearing that in the middle of May--in the media, you in fact are receiving communication directly from patients

Page 211

to that effect?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Did you provide assurances to anyone in May of 2007 that all patients had in fact been contacted?
MS. PREDHAM:
A. I don't recall doing that.
CHAYTOR, Q.C.:
Q. And would you have done that in light of this?
MS. PREDHAM:
A. No, I can't--like I said, for anything with ER/PR, I never said anything was a black and white done issue.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. We'll meet at 2:25.
(ADJOURNED FOR LUNCH)
THE COMMISSIONER:
Q. Please be seated. Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Good afternoon. If I could have, please, P-0106? And this is an e-mail of May 16th, 2007

Page 212

to Mr. Tilley, Dr. Howell and Ms. Bonnell from yourself. And it's re: "ER/PR testing media coverage. Hi all, there's part of me that totally agrees and feels that we should be out on roof tops clarifying this point"--and I'll take you down here, it's an opinion of board member Bill Boyd, who is a lawyer. And he has some concerns, he says, "Thanks for the heads up, George. I was confronted today with the story and questions from colleagues. I heard the comments from the Minister during the supper hour. He must say more than Eastern Health was advised by lawyers to not disclose information, that sounds very bad and makes it appear that we deliberately misled. We must respond, in my view, to the allegations that we misled the media and the public in our previous disclosures, I think we can do so without prejudicing the legal case for the defence." And you will see that it originated from Mr. Tilley sending an e-mail to the Board of Trustee members explaining how the 117 was released and then the 317 being referenced in the affidavit. And your response is, "There's part of me that totally agrees and feels that

Page 213

we should be out on the roof tops clarifying this point. I admit I only heard part of the coverage. I had to turn off Lorraine Michaels and I couldn't bear to watch Peter Dawe on "Out of the Fog". The other part of me is thinking we're only going to give them more fodder and that whatever we say will fan the fires and it would be better to hold the "no comment" line. I'll call Dan this a.m. I got a voice mail from his last night. He was at a pre-hearing meeting with the judge re: the certification and the judge believes that Ches's case is not developed enough to be heard and wants to postpone it until September. The difficult part of the message to hear is that I think Dan said that Ches still wants to proceed. I guess the key point of clarification is that all the patients who need to know knows. It's the general public and the media that doesn't have the details and that is because it's before the Courts." And first of all, what was your issue, Ms. Predham, with trying to watch the media coverage with Ms. Lorraine Michaels and Mr. Peter Dawe?

Page 214

MS. PREDHAM:

A. Well I'm glad you asked me about that e-mail, it was certainly not anything to do with Ms. Michaels or Mr. Dawe, it was just the fact that the media--it was just the media coverage and I just reference the two of those, that it was--I guess it was gone off in a total direction in which I didn't expect and I couldn't believe had occurred and I just found it difficult to listen to.

CHAYTOR, Q.C.:

Q. Okay, so why is that at this point in time, how is it you couldn't believe it had taken the turn of events or the direction that it had gone at this point?

MS. PREDHAM:

A. I think the media was saying that we were covering up and, you know, those types of issues and I guess it was just--it just seemed to be spiralling at that time. But it was certainly nothing about Ms. Michaels or Mr. Dawe at all, I just happened to be listening to them, they were being interviewed and I just, you know, I had to turn it off. It was just the way the story was unfolding, nothing to do with them personally.

Page 215

CHAYTOR, Q.C.:

Q. And what was it about the story, how it was unfolding that was so disturbing to you?

MS. PREDHAM:

A. Well it was the fact that we were covering up or we were trying to hide things or that we had tried to mislead people, that part of the story.

CHAYTOR, Q.C.:

Q. And the other part of me, you're saying is thinking "we're only going to give them more fodder in whatever we say will fan the fires." Give more fodder to who?

MS. PREDHAM:

A. I guess and again, this was a--this is one of those e-mails that, you know, if I had waited ten more minutes, I probably wouldn't have sent and I wouldn't have sent it like it was. It was just--I just reacted and I was probably just, again, a little bit too sensitive at the moment and should have went and got a cup of coffee before I sent the e-mail, but really I was only thinking that the media were aware at the time in December that we weren't telling

Page 216

them all the information, but now it looks like they felt that we were hiding things. But they were aware back in December that we didn't tell them everything.

CHAYTOR, Q.C.:

Q. Even though they were asking the questions or certain questions repeatedly looking for the information.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So how did you think it would unfold when they did receive all the information? Did you expect that the reaction would be any different than what it in fact was?

MS. PREDHAM:

A. I really, with that spring and everything that was going on with me, I really hadn't put too much thought into it of how that would unfold.

CHAYTOR, Q.C.:

Q. Yes, so by this point in time you are surprised, you can't believe how the turn of direction and what's happened.

MS. PREDHAM:

A. Yes.

Page 217

CHAYTOR, Q.C.:
Q. So I guess you weren't, you couldn't understand how they could even think that they had been misled?
MS. PREDHAM:
A. I was surprised, I, you know, it was very clear to me in December and I guess that's what I was thinking, it was very clear in December that they knew they didn't have all the information, yet, you know, here it was, it was like we were trying to mislead them when, you know.
CHAYTOR, Q.C.:
Q. Was it because they were given partial information which would have left a certain impression and now that they had all the information, they could see that it was a different picture?
MS. PREDHAM:
A. Oh, well obviously that's what it was, but like I said, I was reacting here. I was just reacting that morning.
CHAYTOR, Q.C.:
Q. So once you had time to have that further cup of coffee and reflect on it a little more, you

Page 218

could probably understand their point?
MS. PREDHAM:
A. Well probably in May 2007, it might have been, you know, a couple of days later, I might have appreciated differently.
CHAYTOR, Q.C.:
Q. A few cups of coffee later.
MS. PREDHAM:
A. Yes, I would have appreciated their point.
CHAYTOR, Q.C.:
Q. Yes, okay. And so the them, in terms of who you're going to give more fodder to, do you mean the media?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And "whatever we say will fan the fires" and so are you saying here that--you go on to say it's better to hold the "no comment" line.
MS. PREDHAM:
A. No, I was totally torn, I wasn't adding anything to the conversation because a part of me said yes, tell them everything, and a part of me was saying, you know, there wasn't any point.

Page 219

CHAYTOR, Q.C.:
Q. And you phoned Mr. Boone and what would be your purpose in phoning Mr. Boone at this point?
MS. PREDHAM:
A. I don't know. It looks like I was giving an update on the class action lawsuit.
CHAYTOR, Q.C.:
Q. And would you be seeking advice as to whether or not you should go out and say anything further at this point from Mr. Boone?
MS. PREDHAM:
A. No, it doesn't look like it, it looks like-- and I don't believe if--can you just scroll down for a moment?
CHAYTOR, Q.C.:
Q. Sure.
MS. PREDHAM:
A. I don't believe I was asked to do that. I wasn't asked to do anything.
CHAYTOR, Q.C.:
Q. You just forwarded it on--you weren't asked to do anything.
MS. PREDHAM:
A. Yeah.

Page 220

CHAYTOR, Q.C.:
Q. Now who wrote this, "H. Predham, question what this means"?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And you're not asked to do anything in particular, so do you know the purpose whether or not you were seeking advice from Mr. Boone as to whether or not Eastern Health should be out saying anything further in the middle of May, 2007?
MS. PREDHAM:
A. No, I think the only reason I was calling him is because he sent me, he left me a voice mail which was very hard to understand and I was going to clarify that.
CHAYTOR, Q.C.:
Q. You finish this e-mail by saying, "I guess the key point of clarification is that all the patients who need to know, knows. It's the general public and the media that doesn't have all the details and that is because it's before the Court." Ms. Predham, could you say with any certainty that all the patients who

Page 221

need to know, knew at that point?
MS. PREDHAM:
A. Oh no, and at this point, you know, I don't believe anybody would go off based on this e-mail, I guess the point I was trying to get across was that the patients were communicated with and yes, we knew there were patients that didn't get communicated with, but the bulk of them had been communicated with. But it was the media that didn't have all the details.
CHAYTOR, Q.C.:
Q. But is that what this says? This is not--this is saying "The key point of clarification"--so the key point of clarification, are you advocating going out and saying that, making a public statement that all patients who need to know, know?
MS. PREDHAM:
A. Well I wouldn't say that, like I said, this was a very quick response and what the point is is that we weren't hiding results from patients.
CHAYTOR, Q.C.:
Q. Now, Ms. Predham, by saying this or writing this to Mr. Tilley on May 16th, 2007, aren't

Page 222

you telling him that all the patients who need to know knows? You're not saying, Mr. Tilley, the bulk of patients know, there may be some that we're hearing from, including the patient that contacted us yesterday, you're saying that, telling Mr. Tilley in writing in this e-mail that all the patients who need to know, know.
MS. PREDHAM:
A. Ms. Chaytor, I would never expect that a CEO or a VP of Medical Services would take a comment in an e-mail such as that as a fact and move forward with it.
CHAYTOR, Q.C.:
Q. Who was the person responsible within Eastern Health for patient contact?
MS. PREDHAM:
A. Myself.
CHAYTOR, Q.C.:
Q. So if Mr. Tilley is hearing this as a key point of clarification from the person responsible for patient contact, that all the patients who need to know knows, you wouldn't expect him to rely upon that?
MS. PREDHAM:

Page 223

A. Not when everything I said before that was that we were having difficulties with communication. If--if he had read that and was going forward with that fact, he would have to say what has happened, you know, since--to make sure that everybody know.
CHAYTOR, Q.C.:
Q. And when is the last time prior to May 16th, 2007, you had any communication with Mr. Tilley as to the status of patient contact?
MS. PREDHAM:
A. I'm not sure, but if anybody asked me about patient contact, I never ever said that everybody knew.
CHAYTOR, Q.C.:
Q. Except in this e-mail?
MS. PREDHAM:
A. Except in this e-mail, which I admit I did quickly, and should have taken time to write it out properly.
CHAYTOR, Q.C.:
Q. And this is at a point in time where whether all the patients know is a fairly hot topic?
MS. PREDHAM:
A. Yes.

Page 224

CHAYTOR, Q.C.:
Q. If we could have, please, P-3065. This is an e-mail, May 18th, to Susan Bonnell, "As promised, I'll be there in about five minutes", and you've attached the interrogatory questions document and affidavit document, and you'll see your affidavit is attached here, as well as the answers to interrogatories. I believe you did two answers to interrogatories.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And this is the answers to the March 30th, 2007. Why are you forwarding this on to Ms. Bonnell on May 18th, 2007?
MS. PREDHAM:
A. I don't remember, but I would assume that she would like to know any documents that are in the court that are public documents.
CHAYTOR, Q.C.:
Q. And you were headed out to a meeting with her, you were going to be there in fifteen minutes, I think the e-mail said?
MS. PREDHAM:

Page 225

A. Yes.
CHAYTOR, Q.C.:
Q. So was there a meeting then of a group of people on May 18th?
MS. PREDHAM:
A. I don't recall, but there were several meetings at the time, but I don't recall, in particular.
CHAYTOR, Q.C.:
Q. And you'll see these answers were given. This particular copy is not signed, but -
MS. PREDHAM:
A. No, that must have been the last version I got.
CHAYTOR, Q.C.:
Q. Okay. We have a version at 1852, please, and you'll see that this version is signed, and I believe it's dated May 10th, 2007.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. I'll just take you to answer to question 10, as to paragraph 29--so this was asking, I take it, for clarification on certain answers that you gave in your affidavit in February. "As

Page 226

to paragraph 29, what controls were run in all instances", and you respond, "Technical controls were run in all instances. Technical controls are the inclusion of confirmed positive control patient tissue samples". Again, Ms. Predham, what would have been your source of information on that?
MS. PREDHAM:
A. Mr. Gulliver.
CHAYTOR, Q.C.:
Q. And at the time of answering this, would you have been aware that technical negative controls were not run?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you would have been aware of what Dr. Banerjee found in terms of issues with controls, and lack of internal controls, for example?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And answer 11, "What is the hospital policy on documentation of controls and on retention of

Page 227

documentation", and you write, "There is no written hospital or lab policy on the documentation of controls and the retention of such documentation. As part of the lab's policy, the technologists would enter the date, time, and number of tests run and number of controls run into the Meditech system. By 2001, with computer upgrades the technologists included more particulars regarding the type of test run. The pathologists would then sign out the slides from the lab and produce a lab report. The report should refer to both the technical and internal controls run". What was your source of information in answering this interrogatory.
MS. PREDHAM:
A. Mr. Gulliver.
CHAYTOR, Q.C.:
Q. And what were the--this reference to the lab's policy, you've indicated up here there's no written policy, and what do you mean by, "as part of the lab's policy"?
MS. PREDHAM:
A. It was--should probably say practice rather than policy.

Page 228

CHAYTOR, Q.C.:
Q. And then question number 13, "Does the documentation--you'll see 12 says, "What were the controls used during the analytic phase from paraffin section to the staining machine antigen retrieval", and you just refer back to 10 and 11 as your answers, and 13 is, "Does the documentation show the controls were working in all documented cases", and you write, "Not all pathologists referred to the technical and internal controls in their reports. I estimate that 50 percent of all cases, the pathologist referred to the technical controls in his or her report". Where did you get that estimate of 50 percent?
MS. PREDHAM:
A. Mr. Gulliver.
CHAYTOR, Q.C.:
Q. And what was the source of his information?
MS. PREDHAM:
A. He had reviewed all the pathology reports at the beginning of this process.
CHAYTOR, Q.C.:
Q. And why does the answer--so you're referring to technical and internal controls, so meaning

Page 229

the external controls, I take it, external positive controls?
MS. PREDHAM:
A. The technical, that's how it's defined up above.
CHAYTOR, Q.C.:
Q. Well, it refers to documentation show that controls were working.
MS. PREDHAM:
A. The previous answer, it said the technical control was a positive control.
CHAYTOR, Q.C.:
Q. I'm sorry?
MS. PREDHAM:
A. In a previous answer that you read out -
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. It said that the technical controls are the confirmed positive.
CHAYTOR, Q.C.:
Q. Right here, yes.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

Page 230

Q. "Are the inclusion of confirmed positive control", that's right. Were you aware of any other documentation--it says, "Does the documentation show the controls were working in all documented cases". When signing these answers in May of 2007, were you aware of any other documentation that may have suggested that controls were not working in all documented cases?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. For example, the fact that Dr. Banerjee had found and written in his report that internal controls were absent in certain cases that he reviewed?
MS. PREDHAM:
A. They were--they were absent in certain cases.
CHAYTOR, Q.C.:
Q. Yes, and the existence of his report is documentation to show that controls may not have worked in all cases. I take it you didn't drawn that--you didn't think about Dr. Banerjee's report and whether or not that's a document suggesting that controls may not have

Page 231

worked in all cases?
MS. PREDHAM:
A. No, I didn't--I didn't make that connection. I was thinking more the pathology reports.
CHAYTOR, Q.C.:
Q. Did anyone besides Mr. Gulliver assist you in the answers to these interrogatories?
MS. PREDHAM:
A. I don't believe. I think Mr. Gulliver was the main source of information.
CHAYTOR, Q.C.:
Q. If I could have, please, P-1263. This is an e-mail, May 31st, 2007, "In relation to recent developments, I'm going to need information from a claim's perspective asap, and you're going to need a complete set of all the minutes of the surgical pathology review committee, was there any similar committee in existence before this; if so, will need those minutes as well. I also need a good description of the other antibodies listed in the April 4th '03 memo, how many tests have been run using these antibodies, when did we start and stop. I guess what I need is a complete description of all IHC tests and

Page 232

dates, hat concerns have we been having in these areas". So why on May 31st, 2007, did this become an issue and that you now needed information around these points?
MS. PREDHAM:
A. I think all three Dr. Ejeckam memos were released that day; if not that day, it must have been the day before, but I think it was that day and I hadn't seen--I was provided with a copy of the April 4th memo, and I hadn't seen that one before.
CHAYTOR, Q.C.:
Q. And did you receive answers to the questions that you posed?
MS. PREDHAM:
A. I believe I did.
CHAYTOR, Q.C.:
Q. And who provided you with those answers?
MS. PREDHAM:
A. I think it was Mr. Gulliver and Dr. Cook.
CHAYTOR, Q.C.:
Q. So you were able to get--for example, "was there a similar committee in existence before surgical pathology review committee".
MS. PREDHAM:

Page 233

A. I did get the answer, but there wasn't one.
CHAYTOR, Q.C.:
Q. There wasn't, and "how many tests were run using the other antibodies, when they started and stopped", all of those dates were, and the information that was provided to you?
MS. PREDHAM:
A. I can't recall it right now, but I would assume that--I know I had discussions with them after, and I assume I would have had those answers.
THE COMMISSIONER:
Q. So when in this communication one speaks of the antibodies, you're referring to the other antibodies referred to in the Ejeckam memos?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. Not the broad range of IHC testing?
MS. PREDHAM:
A. No, just the ones that are in that memo.
THE COMMISSIONER:
Q. Thank you.
CHAYTOR, Q.C.:
Q. If we could have, please, 472, and I'll just

Page 234

take you to the third page of this first. This is an e-mail exchange that begins with Mr. Thompson, Robert Thompson, to Mr. Tilley, on June 7th, 2007, re; patient contact. "We keep on hearing through the media about patients who say they were not contacted in 2005 about their retest, yet your media material is clear that all retest patients were contacted in October, 2005. How do we reconcile this? A short quick reply will be appreciated as this may arise in the House in an hour", and Ms. Predham, were you also hearing that in the media at that time that there were patients who were saying they were never contacted?
MS. PREDHAM:
A. I must have been. I can't remember that now.
CHAYTOR, Q.C.:
Q. Were you aware that Eastern Health's media material suggested otherwise?
MS. PREDHAM:
A. I certainly didn't pick it up at the time.
CHAYTOR, Q.C.:
Q. And Mr. Tilley forwards on to yourself and others, "Can I get a quick note on this as

Page 235

quickly as possible", and then you respond to the group, including Mr. Tilley, "In October, 2005, all patients that were identified at that time as part of the retesting were contacted by our department. These were calls to inform them that they had been identified as ER negative and will be retested". Ms. Predham, is that correct, in October, 2005, were you able to contact all the patients who had been identified?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. So why did you tell that to Mr. Tilley?
MS. PREDHAM:
A. That was an--that was incorrect at the time.
CHAYTOR, Q.C.:
Q. Do you know why you would have told him that?
MS. PREDHAM:
A. No, I don't, I just made a mistake.
CHAYTOR, Q.C.:
Q. "At the same time, ads were put in the paper, media interviews were held, the patient relations number was put in the paper, and patients were told if they had questions or

Page 236

were not contacted by us to please call us. Between our list and the calls we have received, we felt we had a comprehensive list of all those scheduled to be retested. However, during the past few years we have gotten an occasional call from someone who did not make the original list. There have been a variety of reasons. I must note that we still get calls from people who say they weren't called, but who were always ER positive and not part of the retesting. When the results came back, the patients who were confirmed negative were notified by the particular region, while the patients whose results were changed, were notified by letter through their physician. I hope this clarifies". In terms of stating that the patients whose results were changed were notified by letter through their physicians, did you know in June of 2007 whether or not that, in fact, was the case?
MS. PREDHAM:
A. I could have said that a bit more clearly, that it wasn't--all patients weren't contacted.
CHAYTOR, Q.C.:

Page 237

Q. The plan was that patients would be -
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. - contacted in that manner, but whether or not they had been, you did not know for sure?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Because your efforts to try and contact all the physicians, that effort had never been completed?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then Mr.--that gets forwarded on to Mr. Thompson and Mr. Thompson replies, "George, the return e-mail has unnerved us. Let me explain" and he goes on with a fairly lengthy e-mail which starts with "in December 2006, Eastern Health told the media that in October 2005 patient relations representatives telephoned all individuals whose specimens were sent away for retesting. On May 18th, 2007, Eastern Health repeated this message in

Page 238

the media."
So Ms. Predham, in December 2006, when Eastern Health indicated that all individuals had been--whose specimens had been sent away for retesting had been contacted, at that time, did you pick up on it and express any concern that that may not be an accurate statement?
MS. PREDHAM:
A. I didn't pick up on it.
CHAYTOR, Q.C.:
Q. And again, when that was being repeated in May of 2007, it didn't occur to you then?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. If we could have, please, P-1268? This is a copy of the ad, "a Message to the Public" and were you provided a copy of this at the time?
MS. PREDHAM:
A. I don't think so.
CHAYTOR, Q.C.:
Q. You don't believe you received a copy?
MS. PREDHAM:
A. I can't remember. I may have, but I can't

Page 239

remember.
CHAYTOR, Q.C.:
Q. And do you recall seeing it then in the media?
MS. PREDHAM:
A. I saw it in the paper.
CHAYTOR, Q.C.:
Q. And it says, in bold, "we have always been upfront and open with our patients. An impression has been left with the public that patients affected by the ER/PR review were not contacted or given their own health information. This is not true. Our first priority is and always has been quality patient care. That's why in 2005 when these issues came to our attention, we acted immediately to put safeguards in place. We called all patients whose samples were being retested. We informed all patients and their doctors of their individual test results."
And Ms. Predham, when you did see this, did those assertions cause you any concern?
MS. PREDHAM:
A. I didn't pick up on it.
CHAYTOR, Q.C.:
Q. So I take it you didn't bring it to the

Page 240

attention of anyone that that in fact was not the case?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. If I could have, please, P-1273? This is from yourself to Mr. Tilley and Pam Elliott. "We've added our thoughts in blue below" and that won't come out here. "I'm here if you need to clarify anything. The number of patients increased from 424 to 835 in a month, then it kept going." And what are you trying to say there by mentioning the increase in patients within a period of one month?
MS. PREDHAM:
A. Well, I think that I had a discussion with Mr. Thompson in between that and he was under the impression, from our media releases, that all patients, all 939 were contacted in October 2005. So I guess I was just saying--I was just reiterating that at that time in October 2005, we weren't aware of everybody at that time.
CHAYTOR, Q.C.:
Q. If we could look at 1272, please? So before

Page 241

we leave this one then--sorry, Registrar. Mr. Thompson is saying that "the key question is whether Eastern Health's statements that all patients were contacted in October 2005 is accurate. The short answer is that every patient who they had identified for retesting by October 2005 was contacted by telephone at that time." But is that statement correct?

MS. PREDHAM:

A. No. It should have been that every patient-- it was attempted to contact every patient at that time.

CHAYTOR, Q.C.:

Q. Even the ones--there were patients that you knew about that you still weren't able to contact?

MS. PREDHAM:

A. Yes. Very few, but we couldn't get them.

CHAYTOR, Q.C.:

Q. And if we could look then at 1272? Did you take that up with anyone and try to correct that statement that Mr. Thompson was under the impression of, the one that I just pointed you to? Did you mention that to anyone "oh, that's still not correct. That's not -

Page 242

MS. PREDHAM:

A. There was--as you can imagine, this was a very intense time and I didn't pick that up until much later.

CHAYTOR, Q.C.:

Q. And this is an e-mail same date, between Mr. Thompson and Mr. Tilley, and actually, I think this is the same, and there was another portion in it. In the bottom, he says "this is a summary of today's conversation between Heather, you and me." So this is, I take it you've had a discussion with -

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. - Mr. Tilley and Mr. Thompson on this date. "Would you please let me know whether it properly captures the facts. I will call you." And there is that fact that you're saying you didn't take it up with him about every patient because of what's happening in this time period, and "in conclusion, we are informed by Eastern Health that all people who had been identified for retests by October 2005 were called in October 2005, except for

Page 243

some people whose results were already back from Mount Sinai. Some more people"--and I take it that because they had already been -

MS. PREDHAM:

A. Informed.

CHAYTOR, Q.C.:

Q. Right, or were in the process of being informed. "Some more people though we told, it was a small number, were identified after October 2005 and may not have been called." So the idea that everyone you knew of in October 2005 having been called in October 2005, I take it that's not accurate either?

MS. PREDHAM:

A. No, and the focus of our conversation was, as Mr. Thompson felt the 939 or the patients that were alive of those had been called. I didn't pick up until after the fact that, you know, we had attempted to contact everybody, but didn't get in there. The whole thing was trying to explain that we didn't know everybody in October 2005.

CHAYTOR, Q.C.:

Q. P-1957, please, Registrar? This is a copy of Dr. Banerjee's report with a Post-it on it,

Page 244

and it says "July 25th, 2007, from Heather, for your perusal" and who is DP?

MS. PREDHAM:

A. Debbie Parsons.

CHAYTOR, Q.C.:

Q. Okay, and this is copy three of four, and who, on July 25th, 2007, or thereabouts, did you provide a copy of Dr. Banerjee's report to?

MS. PREDHAM:

A. I think it was Pam Elliott.

CHAYTOR, Q.C.:

Q. Okay, and why?

MS. PREDHAM:

A. Because she was referenced on the--I'm pretty sure on the report or something that Dr. Williams had there that the copy was for me and her as well, and she had not gotten a copy.

CHAYTOR, Q.C.:

Q. And how did that come up in July of 2007?

MS. PREDHAM:

A. I think when we were going through things and discussing it, she saw that her name was copied. It was for Heather Predham/Pam Elliott on it and that she hadn't gotten a

Page 245

copy.
CHAYTOR, Q.C.:
Q. And 1420, please? And this is a letter of September 19th, 2007 to Ms. Marian Crowley and it was signed by a number of physicians. This originated, we understand, out of the letter that was sent to patients with respect to the class action, and patients had to be--there was a Court order that letters be sent out.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And patients be notified. What was your involvement in the letter that went out to patients?
MS. PREDHAM:
A. I had minimal involvement because I was on holidays those two weeks. Ms. Crowley did contact me. I knew there was one going out, like in the future, but I didn't realize the time line. Ms. Crowley did call me at home during that period of time to tell me that they were notified that we had to provide the names and addresses at that time to the law firm, and that they were going to send out a

Page 246

letter, and the Court order stated that the notification of the class action law suit would be in the papers, but that people who had gone from ER negative to ER positive were required by the Court to receive a letter, and Marian called me to try to identify how to--how was she going to identify who those patients would be, easily.
I did check with legal counsel at the time, just to get the content of the letter, of what would be in that, what type of letter it would be, and my understanding, and both Mrs. Crowley's understanding is the letter would be fairly innocuous. It would just be "this is a Court--we are required by the Court order to notify you of this class action law suit. Please find the order attached" or something on that line. So my feeling was that all the patients on the panel list would cover off that conversion. At least she'd have a good bulk of them and we could get that out before the date.
CHAYTOR, Q.C.:
Q. And which panel list is that?
MS. PREDHAM:

Page 247

A. All the patients that were panelled, all the people.
CHAYTOR, Q.C.:
Q. Every patient that was panelled?
MS. PREDHAM:
A. Yes. So that's what Mrs. Crowley did, got the names and the addresses for those patients, but found out, I think it was the Wednesday before the Friday it had to be in the mail, that Eastern Health had to send out the letter, and she did not get the letter until Thursday 3:30-4:00. The letter had to be out on Friday and, you know, they spent the day trying to--as we mentioned earlier about the logistics of actually getting a letter out and she actually had to go to the post office at 4:30, convince the man at the post office to stay late and charged it all on her credit card to get the registered letters out by that day.
CHAYTOR, Q.C.:
Q. Okay, and the content of the letter and what the oncologists are taking issue with here is that there was erroneous information in the letter, that it referred to those individuals

Page 248

whose breast cancer screening results converted.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And did anyone notice--did you or Ms.--did you even see the letter before it went out?
MS. PREDHAM:
A. No, I didn't, no.
CHAYTOR, Q.C.:
Q. And so did anyone else notice that--before the letter was sent, that it was erroneous in referring to breast cancer screening?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Were there any inquiries made as to whether or not anything in the letter could be changed?
MS. PREDHAM:
A. There was, and Ms. Crowley was under the understanding that this was a Court approved letter and that she couldn't change anything.
CHAYTOR, Q.C.:
Q. And who gave her that understanding?
MS. PREDHAM:

Page 249

A. Legal counsel, our legal counsel.
CHAYTOR, Q.C.:
Q. And did you have any other discussions with anyone else in terms of coordinating who, for example, would get the letter?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Or otherwise have any other dealings with respect to this?
MS. PREDHAM:
A. To the issue or to the -
CHAYTOR, Q.C.:
Q. To the letter going out to the patients with this statement that it concerned breast cancer screening?
MS. PREDHAM:
A. No, that was my only contact.
CHAYTOR, Q.C.:
Q. And if we could have, please, P-1427? And this is a follow up to October 1st meeting. It's October 4th '07 from yourself to a bunch of people. "As promised, the last meeting for discussion. I'm circulating two options for a possible letter for communicating the results

Page 250

of the deceased" and you've done two options. So I take it, at this point in time, there's still a plan that there's going to be letters go to the families of the deceased patients?
MS. PREDHAM:
A. I was trying to move the decision along. So I decided if I'd at least have something concrete that we could talk about, at least that would make people consider what we're doing. Because we hadn't come up with a decision yet.
CHAYTOR, Q.C.:
Q. And basically, what was the difference in your two options that you were proposing?
MS. PREDHAM:
A. One, I think, was telling them the results, the straight out, because that was--some people felt we should just disclose the information, which I didn't agree with, and others--the other one was just to notify that the results were available if you'd like to have them.
CHAYTOR, Q.C.:
Q. Okay, and if we could have, please, P-3076? And Ms. Pilgrim is responding to you the same

Page 251

day, "I also prefer the first option. The question you ask is very interesting. I will consider that we use the same line we always do, you know the one that is, or we could talk to the Cancer Centre to have them take over this time," and I think your question that you had asked "thank you for your responses so far, but don't forget to consider options as to who is going to sign this letter and who is going to talk to the patients whose oncologist is no longer practising here?" What did you understand Ms. Pilgrim to be telling you, "I will consider we use the same line we always do...you know which one that is."
MS. PREDHAM:
A. I can't think of what that would be right now. If I didn't understand it, I would have called her.
CHAYTOR, Q.C.:
Q. You have no idea what that refers to?
MS. PREDHAM:
A. Right now, I don't.
CHAYTOR, Q.C.:
Q. If we could have, please, P-2692? And you send out this e-mail to people in the lab.

Page 252

"Nancy is getting numerous calls from the families of the deceased who are waiting for results. She is off today and I answered two of the calls and they are upset about the time they are waiting, so any word? Any time line?" And this is October 5th, 2007. So at this point in time, you're receiving and the Quality department is receiving frequent calls from families of the deceased patients?
MS. PREDHAM:
A. Yes. I think the specimens went away in July. I may be mistaken, but I think they did, and as you can see, by October, we hadn't gotten anything back.
CHAYTOR, Q.C.:
Q. And P-3077, please? This is an e-mail from Ms. Pilgrim to Terry Gulliver and copied to you. It's October 23rd, 2007. "Terry, I need to talk to you about the NLCHI list. In going over the list with Heather, there appears to be information that we could have provided that we did not." What's that referring to?
MS. PREDHAM:
A. This is, I guess, results that we could have shared, I think. The most of going through

Page 253

the NLCHI list was--where they were--they had questions, so they were trying to compile their own list and anything that they couldn't clearly reconcile, they would come back with the questions for us to clarify on.

CHAYTOR, Q.C.:

Q. Is this information though that could have been provided to NLCHI that wasn't provided or wasn't provided to whom?

MS. PREDHAM:

A. Oh, it may be that. I just -

CHAYTOR, Q.C.:

Q. Who did you understand it was? And I don't know if that's what it is, but -

MS. PREDHAM:

A. I would have understood it at the time, and my--all the rest of them is about patients, certain patients and which ones that we knew and the different numbers. So it was that type of thing, and but maybe it is. Maybe it is some information that he would have had that we hadn't given to NLCHI.

CHAYTOR, Q.C.:

Q. And do you know what the answer was as to why it hadn't been provided?

Page 254

MS. PREDHAM:

A. I can't remember.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-3078? And this is an e-mail from you to Ms. Pilgrim and Mr. Gulliver, October 24th. "Here's a synopsis of what came out of this morning's meeting. Page me if you need to talk about it. Patients that have been identified as not having been retested previously at Mount Sinai and whose specimens have been sent, either in September or October," and you've listed nine people. "As of right now, these are the only patients that would have to be contacted. We need to confirm that we are calling all of these patients and we also need a carefully worded script as to what exactly we are going to say to explain about the late contact. We also need a decision if we will or will not call the patients who have been on Tamoxifen." Ms. Predham, why do you need a carefully worded script as to exactly what you're going to say to explain the late contact?

MS. PREDHAM:

A. Well, I just wanted to make sure, you know,

Page 255

what were we saying to people when we called them up to say that they were missed in our first review.

CHAYTOR, Q.C.:

Q. And why not just tell them what happened?

MS. PREDHAM:

A. Oh, that's what we did.

CHAYTOR, Q.C.:

Q. And was there a script ever drafted?

MS. PREDHAM:

A. I don't think so.

CHAYTOR, Q.C.:

Q. And what reason was given to the patients as to why it was so late that they are being identified and tested?

MS. PREDHAM:

A. Well, it took us a while to figure out why people were missed. There was a variety of different reasons. I didn't give them a reason at that time. I told them that when we went through the list, we thought we had everybody and we have now discovered that your results--your specimen was not retested.

CHAYTOR, Q.C.:

Q. And why would you need a decision if you will

Page 256

or will not contact the patients who have been on Tamoxifen?

MS. PREDHAM:

A. It must have come up in discussions and I just wanted to make sure that it was not anything that was going to--before I called people, I needed to make sure that that was not anything that was--we were going to do. We were going to stay with the same plan.

CHAYTOR, Q.C.:

Q. Yes, because the vast majority of patients who'd been retested, the plan had always been, regardless if they were on Tamoxifen or not, they were contacted and told.

MS. PREDHAM:

A. Yes, but -

CHAYTOR, Q.C.:

Q. So was it -

MS. PREDHAM:

A. - somewhere along the way, it must have come up again, and I just wanted to make sure before I called anybody.

CHAYTOR, Q.C.:

Q. Was there somebody suggesting or contemplating that these patients, these nine patients would

Page 257

be treated any differently than the other patients who had been contacted much earlier?

MS. PREDHAM:

A. I don't recall specifically, but there must have been some question in my mind that there was that consideration by--or a suggestion made and I just wanted to make sure.

CHAYTOR, Q.C.:

Q. If we could have--then were you involved in contacting these people?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. If we could have, please, P-2875? And this is a fairly lengthy--it's November 3rd now and you're writing this to Louise Jones, Pat Pilgrim and others and it's a final update and you give a list of--what is this and what are you doing here?

MS. PREDHAM:

A. Contacting those individuals on the previous one that we had identified had not been retested.

CHAYTOR, Q.C.:

Q. Okay, and so this is the result of your

Page 258

efforts in that regard?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and if we could, I think it's page three of this document. There's a patient here, and I believe this is Dr. Laing's name. "This is Dr. Laing's patient and she feels that she should not be contacted. Louise suggested a quick ethical discussion on the circumstances. I'll try to do that later today."

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. What was the circumstances around that patient?

MS. PREDHAM:

A. I really don't know how to -

CHAYTOR, Q.C.:

Q. Without -

MS. PREDHAM:

A. It's such a unique situation, I don't know how to describe it without identifying the patient, but -

CHAYTOR, Q.C.:

Page 259

Q. Is there any issue in terms of, for example, the patient's competency?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and did an ethical consult take place?

MS. PREDHAM:

A. I think Louise contacted Dr. Singleton. We went ahead and contacted the patient.

CHAYTOR, Q.C.:

Q. And if we could have 1538, please? This is the same reference to that patient, I believe. Okay, and if we could have, please--I just want to make sure that, in fact, it was Dr. Laing's.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. I was questioning my memory on that.

MS. PREDHAM:

A. Oh, I remember.

CHAYTOR, Q.C.:

Q. Okay, sorry. If we could have, please, P-3439? And this is an e-mail from Ms. Pilgrim to yourself, amongst others, about the weak

Page 260

positive review, and what do you know about this issue and how it came up at this point in time and what the ultimate decision was made in terms of whether or not to review the weak positives?

MS. PREDHAM:

A. I wasn't, other than being copied on this e-mail and maybe another one, I wasn't involved in this. I do know it came out of testimony from the Inquiry about a particular patient who was beyond our parameters who did not get Tamoxifen.

CHAYTOR, Q.C.:

Q. Okay, and P-3445, please? I'm into my last book. That's a good sign.

MS. PREDHAM:

A. Oh, good.

CHAYTOR, Q.C.:

Q. Just going to take you to the last page then of this document, or page three anyhow, sorry. I think this will give us the sense of what's going on here.

MS. PREDHAM:

A. It was a very complicated issue.

CHAYTOR, Q.C.:

Page 261

Q. Okay. So you do remember about this issue?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. Well then, perhaps you could just tell us then, this is in June of 2008, and what you recall about the circumstances of this particular patient?
MS. PREDHAM:
A. I think she wrote to Ms. Jones, had some concerns, and in investigating it then, of course it came forward--investigating that, we discovered that she did meet the criteria but not had been identified for retesting, and--can I just -
CHAYTOR, Q.C.:
Q. Yes, please, go ahead.
MS. PREDHAM:
A. But there were--it was hard to track the time line of what happened. She had already spoken to Nancy and she did get retested, but the communication was very unclear, and I believe Ms. Smith ultimately followed up with her. This was my preliminary review of it and Ms. Laidley had more information to add to that.

Page 262

CHAYTOR, Q.C.:
Q. Okay, and I think if we go to page one, we'll see that Ms. Laidley does a bit of a chronology of what she's able to piece together. She's reviewed the chart.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And pathology reports, and she spoke with pathology in Carbonear, and she goes through the fact that the patient had a biopsy and a partial mastectomy and then ER/PR at that time was ER negative, PR 20 to 25 positive. She comes down in number eight, "in December of 2003, had a biopsy done of chest wall with diagnosis of recurrence of infiltrating ductal carcinoma. And then January 2004, referred to Cancer Clinic and was seen by Dr. McCarthy. In speaking with the patient, she decided to request a repeat of ER/PR. Repeat was done which showed ER positive, 60 to 70 and PR positive 50 to 60." So I take it, Ms. Predham, there was a conversion in 2004 with respect to this patient?
MS. PREDHAM:

Page 263

A. Yes.
CHAYTOR, Q.C.:
Q. And was there an incident report or an occurrence report filled out in 2004 regarding this?
MS. PREDHAM:
A. No, and I don't think that anyone identified it at the time. I don't think anybody identified the changed results at the time.
CHAYTOR, Q.C.:
Q. You don't think that was picked up by Dr. McCarthy at the time?
MS. PREDHAM:
A. No, because if I remember rightly, and I think it's referred to in Ms. Smith's letter, I believe Dr. McCarthy went off on maternity leave before the results came back.
CHAYTOR, Q.C.:
Q. And the next physician taking over her care didn't pick up on it?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And then in November 2005--and I take it nor did the pathologist who would have entered the

Page 264

addendum on her pathology report?
MS. PREDHAM:
A. Yes, it would have been done through Carbonear and nobody picked it up there.
CHAYTOR, Q.C.:
Q. And on November, then November, the OPIS notes indicate the patient was asking about her ER and PR and Dr. Zulfiqar could not find them on the computer. No results are available in PCI because they went back to Carbonear for reporting. It states he would request repeat to those levels. And then she has a recurrence in January 2007, and the OPIS notes refer the results of ER/PR from the initial diagnosis and not to the retesting in 2004, and this patient is not in the database and was not retested when retesting of ER negative patients was set up. And why was it that she wasn't retested when the overall retesting was taking place.
MS. PREDHAM:
A. She didn't get identified through Carbonear.
CHAYTOR, Q.C.:
Q. And as you succinctly write, "There are multiple--multitude of issues here".

Page 265

MS. PREDHAM:
A. Multitude of issues.
CHAYTOR, Q.C.:
Q. Multitude of issues. If I could have, please, P-2633 and P-2634. Sorry, you only do one at a time, don't you. I'm sorry. 2633 is good. I'm really trying to rush now.
PIKE, Q.C.:
Q. Multitasking.
CHAYTOR, Q.C.:
Q. Getting good at that. This is physician panel meeting then, June 5th, 2008, and I take it you're back to doing minutes at this point?
MS. PREDHAM:
A. I'm not on that panel.
CHAYTOR, Q.C.:
Q. You're not on this panel.
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Whoever is on it -
MS. PREDHAM:
A. Ms. Smith took my -
CHAYTOR, Q.C.:
Q. Ms. Gregory is now doing the -

Page 266

MS. PREDHAM:
A. Yes, and Ms. Smith is taking my position.
CHAYTOR, Q.C.:
Q. And why is that, why aren't you sitting on the panel any more?
MS. PREDHAM:
A. Well, it was evident as it progressed, and I think I mentioned this earlier, that someone from the Cancer Clinic would have been best on that panel because it was support from a clinical--you know, support from a patient--primarily a cancer clinic patient situation, so Ms. Smith was not in that position at that time, but she was now.
CHAYTOR, Q.C.:
Q. And do you any longer have any contact with the patients on this issue?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. For example, coming out of this now, whatever decisions are made by any patients that are being panelled or continued in through 2008 to be identified, you weren't involved in the contacting of those patients?

Page 267

MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And why was that decision made?
MS. PREDHAM:
A. Well, we had one of our staff, Ms. Laidley, was working with the cancer clinic, so between herself and Ms. Smith, they were doing all the patient contact.
CHAYTOR, Q.C.:
Q. If we could have, please, P-3462. This is an e-mail from Dianne Smith to yourself, and who again is Dianne Smith?
MS. PREDHAM:
A. Ms. Pilgrim's administrative assistant.
CHAYTOR, Q.C.:
Q. She quotes James Joyce.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "Pat would like to talk to you in the morning about the following; Janet Henley-Andrews called this afternoon with the following questions. One, was she ever panelled; two, if she was, was a panel letter sent to her

Page 268

doctor, the name of the doctor/doctors panel letter was sent to", and her contact information, and this was sent to you, and were you able to provide the answers to those questions?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And was Ms. Henley-Andrews ever panelled?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And why not?
MS. PREDHAM:
A. When the information--she had contacted Nancy in, I guess, October, 2005, and requested testing, and--because she had not had an original ER/PR done. At that time, Dr. Cook agreed to send her off for testing and we brought the results to a panel meeting in November. Dr. Felix was her surgeon and her treating physician, and there was some discussion at the panel--I think this was the first time I heard the discussion about DCIS, and it was agreed that she didn't meet the

Page 269

criteria because she didn't have any original results done, and I was of the impression that Dr. Felix was contacting her with those results.

CHAYTOR, Q.C.:

Q. And was Dr. Felix present at the time that that was discussed?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So even though her name came up, you didn't understand that you would have any involvement in contacting her, you understood it was tasked to Dr. Felix?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And was there anything put in the minutes arising out of that panel meeting to indicate that?

MS. PREDHAM:

A. I don't think so because she wasn't--she didn't meet the criteria of being panelled.

CHAYTOR, Q.C.:

Q. We've also seen a previous exhibit in the

Page 270

Commission that information went back to the government. Mr. Thompson had written a letter, and Ms. Henley-Andrews happened to be one of the patients that was being inquired of, and the information that went back said that she was, in fact, contacted or her results given at a date which couldn't be the accurate date. You're aware of that?

MS. PREDHAM:

A. Oh, yes.

CHAYTOR, Q.C.:

Q. Okay, and how did that happen?

MS. PREDHAM:

A. That was--that was my typo. I don't know how I put in September instead of November, but when the letter got over to the Centre for Health Information, I got a call asking me was I sure, and obviously I realized I had made a mistake.

CHAYTOR, Q.C.:

Q. In any event, though, she wasn't provided her results in November?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Page 271

Q. So the information you were providing was assuming that Dr. Felix had followed up and given the information in November, 2005?

MS. PREDHAM:

A. Yes, it was an assumption.

CHAYTOR, Q.C.:

Q. Those are all my questions. Thank you very much. I realize it's been quite a long time for you. Thank you.

THE COMMISSIONER:

Q. Thank you, Ms. Chaytor. Mr. Pritchard.

MR. PRITCHARD:

Q. Commissioner, I don't have any questions for this witness. Thank you for your evidence, Ms. Predham.

THE COMMISSIONER:

Q. Mr. Browne.

BROWNE, Q.C.:

Q. No questions for the witness. Thank you very much, Ms. Predham.

THE COMMISSIONER:

Q. Mr. Pritchett.

MS. HEATHER PREDHAM--EXAMINATION BY MR. BLAIR PRITCHETT

MR. PRITCHETT:

Q. Good afternoon, Ms. Predham. My name is Blair

Page 272

Pritchett. I'm here on behalf of the Western, Central, and Grenfell Health Authorities. I just have a few questions for you today. I want to take you back to--I think it was Saturday's evidence. I know you've been here a while, but I think it was on Saturday. Ms. Chaytor was talking to you about Trish Wegrynowski's exit interview. Do you recall that discussion somewhat?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And a particular point I wanted to discuss with you was I believe something in your notes about considering a disclaimer on reports from referral labs. Do you recall that issue coming up at that time?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And from my own notes, I recall Ms. Chaytor asking you that--speaking to you about the concept that basically people who were referring specimens in to Eastern Health would need to or should be told if there were

Page 273

fixation problems that caused a compromised result going back. In other words, if there was something about the sample coming in that might affect the result going out.

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And does that accord with your understanding as well, that that came up?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And I believe Ms. Chaytor went on to ask you from your own position involved in quality and risk management, would that stick out in your mind during that discussion, and I believe you said that would strike you as an important issue at that point?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And as I take it, the upshot of this discussion that you had with Ms. Wegrynowski was that you need to be advising referral sources of problems if you're going to be

Page 274

reporting something back or sending a sample back to them?

MS. PREDHAM:

A. That, as well as making it clear that if there were problems there that they were aware of, that it could influence the test. So it's a two sided thing, that we're doing the test, but we can't control what's happening in your site, and, I guess, as well if there's identification of issues, you have to communicate that back.

MR. PRITCHETT:

Q. Yes. So you want to make sure that you're properly communicating your own institutions ability to do what you're undertaking to do?

MS. PREDHAM:

A. Exactly.

MR. PRITCHETT:

Q. And by the same token, from a patient safety perspective, if you see an issue, you want to make sure that the referring institution is made aware of that?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Page 275

Q. And that would affect not only the individual patient in a particular case, but also patients on a go forward basis as more cases are being referred?

MS. PREDHAM:

A. Oh, definitely.

MR. PRITCHETT:

Q. And the idea being if there is some sort of consistent problem, flagging it early and often, if unfortunately that is the case, would hopefully raise the antenna of the people sending you the samples?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. And again, I guess, from that discussion, I take it that in your world, the view would be if you get a report or a sample come back from an institution and that's unqualified or unequivocal in what it's saying, that effectively you take it at face value? You know, if you get a report -

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Page 276

Q. From Eastern Health that says this is ER positive or ER negative or what have you, you take it for what it says unless there's reason to doubt the validity of the conclusion?

MS. PREDHAM:

A. Yes, that's fair.

MR. PRITCHETT:

Q. And the same would apply to a sample, for instance, in this case a slide going back, that if you're not being told there may be a problem with it, you're going to assume there's no problem with the end of the process that they just handled?

MS. PREDHAM:

A. Yes.

MR. PRITCHETT:

Q. When you had that discussion with Ms. Wegrynowski and this point came up, did you contact any counterparts in Western, Central, of Grenfell areas about this issue, about this concern?

MS. PREDHAM:

A. No, I didn't, but I thought Dr. Cook was taking it seriously and was going to look into that.

Page 277

MR. PRITCHETT:
Q. So leaving that meeting, that was the impression you were left with?
MS. PREDHAM:
A. Yes.
MR. PRITCHETT:
Q. But were you ever specifically made aware of that communication being made to any of the other authorities throughout the province?
MS. PREDHAM:
A. No.
MR. PRITCHETT:
Q. Thank you. Those are my questions.
THE COMMISSIONER:
Q. Thank you. Ms. Newbury, I would normally call the afternoon break about ten minutes time. It's your call, would you refer to start and I'll interrupt you in ten minutes or would you prefer to take the break before.
MS. NEWBURY:
Q. I'll start.
MS. HEATHER PREDHAM--EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good afternoon, Ms. Predham. My name is Jennifer Newbury, and I represent the Canadian

Page 278

Cancer Society. I have a few questions for you this afternoon, starting with, I guess, a discussion about the various policies that have been in place in Eastern Health and its predecessor organizations, in particular, Health Care Corporation of St. John's in your case, and I just want to speak to this a bit more generally, but if you want to see any of the policies, we can certainly pull those up. There are critical occurrence and incident review policies, occurrence reporting policies, and adverse events. I think you described them as guidelines.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And -
MS. PREDHAM:
A. Not the adverse events. Disclosure guidelines.
MS. NEWBURY:
Q. Disclose guidelines, okay.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:

Page 279

Q. And I understood that it was referred to as adverse events for the Health Care Corporation of St. John's?
MS. PREDHAM:
A. Adverse events would be--I think would be Eastern Health's terminology.
MS. NEWBURY:
Q. Okay. Just, I guess, to clarify that, perhaps we could bring up P-0056, please.
MS. PREDHAM:
A. Actually, you're right, it's disclosure of adverse events.
MS. NEWBURY:
Q. Okay, Eastern Health Guidelines, okay.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And we'll bring them up, anyway. They'll be there just for your reference, and subsequently--I guess, those three times of policies were in place between 1997 and 2004, and in 2005 Eastern Health--2005 and subsequent, some other policies came into effect, disclosure of adverse events, occurrence reporting, and a sentinel events

Page 280

policy?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. So they deal generally with the same topics, as I understand it, but the wording and some of the content may have changed?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Okay. I'm just wondering what your view is as to the applicability of these policies or the guidelines to the ER/PR problems subsequent to 2005?
MS. PREDHAM:
A. Well, the ER/PR problem was always seen as a sentinel event.
MS. NEWBURY:
Q. Okay.
MS. PREDHAM:
A. The problem with it, you know, in putting it into a policy like that, any of those policies, it wasn't black and white because we had never seen anything this large or this complicated before.

Page 281

MS. NEWBURY:
Q. Okay. So was there doubt as to whether or not Eastern Health would have to follow--I guess the policy that was in place at the time was that of Health Care Corporation of St. John's, and that would be, I assume, the critical occurrence incident review policy?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Was there any doubt as to whether or not Eastern Health was obligated to follow that particular policy?
MS. PREDHAM:
A. Oh, no, there was no question that way. It was just that this was a very unusual occurrence.
MS. NEWBURY:
Q. So it wasn't whether or not it should apply, it was perhaps the mechanics of how do we go about applying it?
MS. PREDHAM:
A. Yes, that's fair.
MS. NEWBURY:
Q. And is that because of the number of patients

Page 282

who were actually involved or caught up in the whole issue?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And would you agree that the absence of a multi-patient policy or a policy that clearly spells out how we deal as an organization with such a large event when there's so many patients involved, really is that an issue of convenience for the organization that, well, we don't have the ability to conveniently refer to a policy that says you can do one report that applies to, say, 500 patients?
MS. PREDHAM:
A. No, it--I guess, as we developed the policies, we really hadn't focused in on multi-patient--you know, one or two patients probably, but nothing of this magnitude, and to even have or develop a policy or process on how we were going to deal with that -
MS. NEWBURY:
Q. Uh-hm.
MS. PREDHAM:
A. Requires some different thinking, and we had--

Page 283

we have done, actually, a table top exercise with a scenario and how we would do that to try to figure out, okay, if this happened again, if something similar of this magnitude happened again, what would be the logistics to make it--you know, so we wouldn't go down, we wouldn't have the delays, we wouldn't have the problems and the questions that we had this time, how would we get it to flow better.
MS. NEWBURY:
Q. Okay. So would that really be an issue of enabling the organization to respond more efficiently to the problem and more promptly perhaps to the problem?
MS. PREDHAM:
A. Oh, definitely.
MS. NEWBURY:
Q. Okay, and would you agree that the default would be in the absence of such a policy which lays it out and enables the organization to respond, you know, efficiently, as efficiently and as promptly as possible, that the default would be that you apply the policy for the patients on an individual basis?
MS. PREDHAM:

Page 284

A. Oh, yes, and that was always--the intent was that we do that. It was just questions arose that we didn't quickly encounter them, and the workload as well, and circumstances that we were all in, you know, didn't allow for that timely resolution of issues.
MS. NEWBURY:
Q. So it wasn't ever a situation in your mind that the organization could say, well, we don't happen to have a policy that deals with this situation because there are so many patients, so we don't really have a policy to go by -
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. And we'll just, you know, do it on an ad hoc basis?
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. And in responding to a similar situation today, do I understand your evidence correctly that you would feel that the sentinel event policy would govern this type of situation?

Page 285

MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And again you still would have to try to sort out how do we deal with the fact that there's so many patients, and how can we deal with this as efficiently as possible?
MS. PREDHAM:
A. Exactly, yes.
MS. NEWBURY:
Q. I just wanted to ask you about the interaction between policies that might be in place on a department or program basis versus what have been described as corporate-wide policies, such as those that I've just referred to, and in particular there's evidence about--from a couple of witnesses now about the corrective actions for IHC occurrences, which is a policy applicable to the pathology program.
MS. PREDHAM:
A. Okay.
MS. NEWBURY:
Q. Are you familiar with that particular policy?
MS. PREDHAM:
A. No.

Page 286

MS. NEWBURY:
Q. Okay, perhaps I can bring that up. It's P-2157 and this is a very large document, so it will take a minute or so to bring that up. Perhaps I'll give you a little bit of background while that exhibit is being is brought up. Dr. Morris-Larkin had actually referred to this in her evidence and I think they were entered through an earlier witness. These are policies that she understands to be now applicable in the pathology department to respond, I think her evidence was that it's basically an internal occurrence reporting in the lab and it allows the lab to provide direct feedback and address the issues in a more timely and more direct fashion. Now the exact exhibit is on page 177 of that. So this is--I think there's actually three pages there and if you want to scroll down through that, Ms. Predham, and just familiarize yourself with the document.
MS. PREDHAM:
A. Okay, so this is their internal, when it's a quality issue that they're finding with the stain and that and they report that and this

Page 287

is how they keep track of any issues that they had.
MS. NEWBURY:
Q. Yes, that's my understanding from her evidence as well, and it's a fairly general policy, I think if you look at it there.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And I was wondering how does this policy fit in with the corporate wide policies and in particular in a situation if you have something that might be considered to be an occurrence and they do actually refer to that language "occurrence" in this policy, how does that impact, I guess, if it does at all upon the corporate wide policies about occurrence reporting?
MS. PREDHAM:
A. Well it fits in quite well because this is something internal to the lab, so this is meant to track information that they pick up in their day to day, as it progresses through that. So this would be something that the, like and I think the example that Ms. Chaytor

Page 288

showed me, that the report isn't signed out and the report released outside, at that point it would be an occurrence, but this is something internal that is identified as an issue and is dealt with at that time and is a way to trend that. And I think I gave an example of the pharmacy that has a very extensive one, to double check before it leaves, if the person doing the double check picks it up, an internal report is done, but if it leaves past that person and is discovered then, then an occurrence report, a corporate wide occurrence report is done.
MS. NEWBURY:
Q. And it was my understanding when you were giving the evidence about the double check system for the pharmacy, is that that's something that was, I guess, approved or the quality department had some input into that type of a program to make sure that it met the, I guess the criteria or the objectives of quality programs.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:

Page 289

Q. Before that was implemented.
MS. PREDHAM:
A. Well not so much that, I mean, they had a discussion on, I guess it was when do you fill out a occurrence report? What do we need to fill out an occurrence report for? They had this process in place and they were typing that up to do the same kind of review, so that they could look at the types of things that are being caught before they come out of pharmacy to learn is there anything that we can do on the front end to fix these? So it wasn't that they were getting our approval, they were just getting out feedback on, you know, as this process goes through.
MS. NEWBURY:
Q. Okay. And did you provide similar feedback to the pathology department on this policy?
MS. PREDHAM:
A. I didn't, no.
MS. NEWBURY:
Q. You didn't, okay, and do you know if anyone else in your department -
MS. PREDHAM:
A. I'm not sure, Ms. Laidley is linked with the

Page 290

lab. They do have Ms. Wade works in the lab now as a quality person and we do link with her.
MS. NEWBURY:
Q. Right, uh-hm.
MS. PREDHAM:
A. So somebody may have had interaction with her.
MS. NEWBURY:
Q. Okay, and are there ever situations that the corrective actions and the policies of the department or the program would replace what goes on in terms of the corporate wide policies? Is there ever a dual reporting scheme going on?
MS. PREDHAM:
A. There may be, I can't think of anything that would cover that off, you know, I can't think--there's usually, what has happened is that there's a decision, you know, by the program that these are the types of things that we need to keep track of and as part of this, like a quality review, they catch it first and then they fix it and that's what it's designed to do, that's part of their quality control program. And then anything beyond that, would

Page 291

be an occurrence, but I don't think that there's a disagreement--I can't think of anything right now.
MS. NEWBURY:
Q. I'm just wondering if there might reach a certain level of seriousness or perhaps, you know, if a problem is happening, happening repeatedly, would there be any obligation to pass along that information in accordance with the occurrence policies for the corporate wide -
MS. PREDHAM:
A. There may be, depending on the circumstances, I mean, there's always a possibility that there could be.
MS. NEWBURY:
Q. Right, okay, and you don't know of any sort of regular or quarterly or annual reports that must be provided from a particular program as to how these polices are working, you know, here are the statistics that we have?
MS. PREDHAM:
A. They have to report to the portfolio committees of each of their portfolios, so the lab would be reporting to Dr. Howell's

Page 292

portfolio committee.
MS. NEWBURY:
Q. Right.
MS. PREDHAM:
A. So in that, they would have to report on their indicators.
MS. NEWBURY:
Q. Okay.
MS. PREDHAM:
A. So I would anticipate that one of their indicators and I haven't seen that, but one of their indicators would be, you know, quality--whatever, correction action log, forms completed, number of actions taken or something on that line that they could keep track of there.
MS. NEWBURY:
Q. So would you anticipate that the report might include sort of the numbers or the types of problems involved and that if the quality department or anyone to whom the program reports has any concerns, that they can delve into that a bit further?
MS. PREDHAM:
A. Yes, each portfolio committee has a

Page 293

representative from our department on them. So there would be someone there who would see these reports.

THE COMMISSIONER:

Q. It's about time for that break, wherever it's convenient for you, I don't -

MS. NEWBURY:

Q. No, this is a good spot.

THE COMMISSIONER:

Q. All right then, we'll take the afternoon break, but before I do while I have counsel in the room, I wanted to give you a heads up on Monday. As you probably noticed where the evidence for one of our witnesses is scheduled for Monday is via video conferencing, it turns out when we were doing the schedule, we did not anticipate the fact that the time changes in England are different than they are in Canada, so the good news is that Monday we plan to start at 10:30; the bad news is we'll end the day an hour later. So, you can adjust your plans accordingly. We'll take the afternoon break.

(RECESS)

THE COMMISSIONER:

Page 294

Q. Please be seated. Ms. Newbury.

MS. NEWBURY:

Q. Thank you. Commissioner, there are two exhibits that I'd ask to enter, C-0275 and C-0276.

THE COMMISSIONER:

Q. C-0275?

REGISTRAR:

Q. No, there's a C-0276 and there a P-03 -

THE COMMISSIONER:

Q. The two numbers I have are C-0276 -

CHAYTOR, Q.C.:

Q. No, Mr. Crosbie has the other exhibit, he was going to enter it.

THE COMMISSIONER:

Q. Okay.

CHAYTOR, Q.C.

Q. There is another exhibit, C-0275. Has that already been -

REGISTRAR:

Q. That's already been entered.

MS. NEWBURY:

Q. Oh, okay.

CHAYTOR, Q.C.:

Q. That's the one we were asking about.

Page 295

REGISTRAR:

Q. (Inaudible).

THE COMMISSIONER:

Q. Well, while we're at it, Mr. Crosbie, have you requested an exhibit 3468?

CROSBIE, Q.C.:

Q. I have.

THE COMMISSIONER:

Q. I will enter that at the same time. So, we you won't need to make a request later. Thank you.

MS. NEWBURY:

Q. Thank you.

EXHIBITS C-0276 AND P-3468 MARKED AND ENTERED.

MS. NEWBURY:

Q. Ms. Predham, you gave evidence a few days ago, I can't recall which day, that each program and department has been encouraged to identify occurrences in their area themselves, so, what's important to them, it's not necessarily something in the routine of their work as an occurrence. And I think what you were talking about is to try to identify in advance, the types of things that might constitute an occurrence. So, that when that situation

Page 296

arises, the program is familiar with how to respond.

MS. PREDHAM:

A. Well, the staff would have to know that they have to report, if this happens, they need to report an occurrence, fill out an occurrence report. So, that's the key thing, is that this is what the program would like to see identified as occurrences.

MS. NEWBURY:

Q. So, basically it's an identification issue, what constitutes an occurrence.

MS. PREDHAM:

A. Exactly.

MS. NEWBURY:

Q. And was that exercise ever carried out with the laboratory medicine program.

MS. PREDHAM:

A. Yes, it would have been over the years. It's an ongoing thing. It would have been more formally started back in '97, but it would have progressed over the time, you know, when they filled out occurrences.

MS. NEWBURY:

Q. Okay, but would there be sort of a list of

Page 297

examples; these are the type of things that would constitute an occurrence and if this happens, perhaps you can fill out a report.

MS. PREDHAM:

A. The programs, each one did it different, differently. Some areas did that and some areas didn't. They just did it verbally and said look, this is the type of thing we'd like to have an occurrence on, the manager kept track of that.

MS. NEWBURY:

Q. Okay. It's not something that's documented necessarily.

MS. PREDHAM:

A. I wouldn't even begin to know. If it is, I wouldn't know where to look for it.

MS. NEWBURY:

Q. Okay, thank you. And when discussing the quality tool, I think you referred to it as a failure modes and effects analysis.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. You mentioned that there's a process of sitting down with the people involved in a

Page 298

program, in particular, implementing a new process to try to identify particular issues or problems that might arise and presumably to try to guard against those types of problems.

MS. PREDHAM:

A. Exactly.

MS. NEWBURY:

Q. And try to develop a process that won't attract too many problems.

MS. PREDHAM:

A. Well, you're anticipating things that can go wrong and trying to put the things in place beforehand to prevent those things.

MS. NEWBURY:

Q. Okay. So, you try to visualize how this might go and where the potential pitfalls. And I believe it was your evidence that that type of a tool wasn't used when the ER/PR was switched to the IHC method because that wasn't in vogue, I guess, at the time.

MS. PREDHAM:

A. Right.

MS. NEWBURY:

Q. It wasn't a tool readily known in the quality industry. Was this something that was ever

Page 299

done subsequently, just to go back, I guess, it's not ideal to do it after the process has been implemented, but was there ever an attempt to go back and look at that, retrospectively, to see where the potential pitfalls here, what can we do to change our process.

MS. PREDHAM:

A. Not that I'm aware of.

MS. NEWBURY:

Q. Okay. And based on your evidence about identification by departments as to what constitutes an occurrence, I assume that it would be important for members of the program to readily be able to identify an occurrence as such.

MS. PREDHAM:

A. Oh, definitely.

MS. NEWBURY:

Q. Okay. So, it's not just a matter of following the procedures, they have to know this is an occurrence, we need to file a report.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Page 300

Q. And you can have all the elaborate policies in the world, but if people don't recognize this to be an occurrence, then they're not going to be of much benefit to the program.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And it seems, just from a number of witnesses giving examples about occurrences, that an event such as mislabelling, whether it's mislabelling of a specimen or mislabelling of a drug, seems to be a readily identifiable occurrence. And would you agree with that?

MS. PREDHAM:

A. Yes, I would.

MS. NEWBURY:

Q. Okay. And I'm not, I guess, I didn't get the same impression from the evidence that a changed laboratory test result attracts the same sort of automatic recognition that this is an occurrence. Would you agree with that proposition?

MS. PREDHAM:

A. At this point in time, I'd say it depends on the area of the lab, if we're just talking

Page 301

about the lab, we do get occurrences about changed results from certain parts of the lab.

MS. NEWBURY:

Q. Okay. And what parts of the lab would you say fall into that category?

MS. PREDHAM:

A. I think it would be biochemistry, but I might have the total incorrect name. I haven't gone through occurrences from the lab in quite a while, but I do know I have seen results that have been reported and then subsequently changed on occurrence reports, but telling you which part of the lab, you know, I think biochemistry. That's what's popped in my head that I've seen them.

MS. NEWBURY:

Q. Okay. And perhaps some of the influencing factors as to whether or not a particular program or department or person working in the area recognizes something to be an occurrence, it might depend on whether or not a physician was first informed of the initial lab results that were ultimately changed.

MS. PREDHAM:

A. Well, that would be a critical part because

Page 302

again, if it was something that was caught before it left the area, it may be seen as, you know, with the double checks in it, it may be seen as part of that process.

MS. NEWBURY:

Q. Okay.

MS. PREDHAM:

A. But if it was released, signed out, you know, the potential for someone to act on it and then discover that it was incorrect, that would be an occurrence.

MS. NEWBURY:

Q. Okay. But can you say that if a physician was not informed of the first set of results, that that would definitely not constitute an occurrence or is that still a grey area?

MS. PREDHAM:

A. I think you would have to look at the circumstances there. I wouldn't want to say black or white.

MS. NEWBURY:

Q. And whether or not a change in result might impact the type of treatment that a patient would get, whether it was communicated to the patient or the treating physician or not,

Page 303

would that be a factor influencing whether a department or program might consider something to be an occurrence or not?

MS. PREDHAM:

A. If the lab, you know, you take another part of the lab released blood work results and then later found it to be incorrect, whether or not there was treatment or whatever, I guess they would know the importance of the type of test, but any kind of test can influence treatment.

MS. NEWBURY:

Q. Right.

MS. PREDHAM:

A. So, you know, I wouldn't want him differentiating because of that because you wouldn't know every circumstance that it would be that important. So any kind of change, like a release that had the potential to be acted upon, would be an occurrence.

MS. NEWBURY:

Q. What about a change that's not released but could have had a very significant impact upon patient treatment?

MS. PREDHAM:

A. Well that would be something that would come

Page 304

up in this program and they'd have to do that. You know, there may be and you know, totally speculative here, but there may be certain things that are, you know, I guess to use the example when we look at medication occurrences, if we have high alert drugs, so we have six categories where we identify high alert drugs, so if we had any type of occurrence with those, it gets a higher level of scrutiny than it does with the other medications. So, you know, parts of the lab may have that as part of their QA process.

MS. NEWBURY:

Q. And is that something that perhaps might be advantageous to sit down in advance to try to, I guess get down to the details with a particular program as to whether or not something would constitute an occurrence, whether for their own internal laboratory purposes or for the corporate wide application of policies?

MS. PREDHAM:

A. Oh definitely and, you know, occurrence reporting is a very challenging area because you have frontline staff who are, you know,

Page 305

taking the time, they have identified something and then they have to be able to recognize that as an occurrence and then identify the need to fill out an occurrence report, but also they have to see that there's a purpose of doing this, that there's going to be some benefit at the end of the day. And a lot of that comes through education, but also to relate these are things that happened, these are things that have happened because you've reported them, and you know, how important it is to get them to realize that and that's a challenge that's well documented in quality literature and one of the key things that, with our electronic occurrence reporting system is, you know, well a couple of the key things, one is the ease of doing that. It's also to have prompts of some kind in the taxonomy for that area that these are the things that your area is reporting, so that if you had any question, you'd be able to go in and there would be prompts there that say these are the types of things that you're looking at, but also getting that feedback that somebody has gotten this, we've gotten it

Page 306

quickly, because those are all the problems that we experience with the paper reporting system. So, because of the benefits of that electronic occurrence reporting system, that's why we use it as a tool to change the culture because we have to have the culture, everybody has to see the impact on patient safety. So we're using the occurrence reporting system as a tool to influence the culture of the organization.

MS. NEWBURY:

Q. And one of the advantages of the electronic occurrence reporting system is that it does provide a bit more information as to what would be considered an occurrence or what wouldn't be considered an occurrence?

MS. PREDHAM:

A. Yes, and it's easily changeable, you know, with the paper system when you have it done, to even change that piece of paper and, you know, you can't adapt it for an area as easily as you can an electronic one and the software that we've purchased, you know, once they identify their area or whatever they're going from, they can limit their search of what

Page 307

they're doing, so more detail can be in there that there could be help--you know, prompts there to help them through that as well.

MS. NEWBURY:

Q. Okay, and perhaps another couple of factors that might influence whether or not a program sees something as an occurrence or not would be the passage of time between an initial test and a retest, whether it was a day or an hour or a year.

MS. PREDHAM:

A. Well the ability to identify trends like that is very important as well.

MS. NEWBURY:

Q. And also the reasons for the retest, whether someone did it because a specimen was dropped on the floor or whether there was another broader concern about quality.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And would you agree that the more analysis that's done of these types of factors in advance, the more readily people might be availing of the various occurrence reporting

Page 308

policies?

MS. PREDHAM:

A. Oh, once you know what's there and once you can tell people the type of things that you learn from that and it's all, it's all in that frontline staff who see that in identifying that it's important that I tell people about this.

MS. NEWBURY:

Q. And in terms of the department, now it has its own policy for occurrence, the corrective action occurrences, how will that--will that be done on an electronic basis as well or will that department get the same advantages of the electronic occurrence reporting system if they now adopt their own internal system that they might use more frequently than the corporate wide systems?

MS. PREDHAM:

A. Right now, we're only in the early stages of implementing our big system and the ability to sub -

MS. NEWBURY:

Q. Until a thousand.

MS. PREDHAM:

Page 309

A. Yeah, hasn't been addressed yet.
MS. NEWBURY:
Q. And is that something that you think might be worth looking into?
MS. PREDHAM:
A. I could be, you know, we'd have to work with the areas doing that.
MS. NEWBURY:
Q. Ms. Predham, perhaps it will be safe to say from your evidence that in the summer of 2005, you and other members of the group responding to the ER/PR problem were dealing with some complex issues?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And that not all members of the group would be well versed in all aspects or all topics of that particular area.
MS. PREDHAM:
A. Absolutely not.
MS. NEWBURY:
Q. So you, yourself, were learning about ER/PR for the first time.
MS. PREDHAM:

Page 310

A. Yes.
MS. NEWBURY:
Q. And so the techs might be learning information that they hadn't known before about what oncologists do or vice versa.
MS. PREDHAM:
A. Exactly.
MS. NEWBURY:
Q. And in addition to the complexity of the issues, there's actually a lot of information being obtained from various sources, not just within Eastern Health, but from Mount Sinai, Sloan-Kettering.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Mount Sinai about time lines and retesting and from Sloan-Kettering about the whole issue about lobular cancer and what's expected in terms of positivity. Would you agree that given the complexity of the information and the quantity of information involved, as well as your observation that people didn't attend all of the meetings all of the time, that that might lend itself to mis-communication or

Page 311

perhaps some messages not being communicated at all to people who ought to know, and that it would have been perhaps beneficial to have a more comprehensive system for documenting all key information?
MS. PREDHAM:
A. Oh definitely.
MS. NEWBURY:
Q. Okay, and several instances, I believe you, in your own handwritten notes when you were trying to keep pace with all of that information at various meetings, some of your notes you had incomplete sentences, perhaps that's reflecting the challenge that you had of trying to keep up with what was being said.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And you gave an example, I think a significant example where there was a disagreement between you and Mr. Gulliver or a misunderstanding between you and Mr. Gulliver as to what information you had initially understood pertaining to the Ventana equipment and your initial understanding that it was ten times

Page 312

more sensitive, verses his later clarification or denial that he said it and he insisted that it was really a matter of the Ventana equipment being more consistent.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Do you think it would have been beneficial when relying upon people for key information to obtain that information in writing?
MS. PREDHAM:
A. Yes, or actually you know, over the years when I've been involved in this, I, not that I don't take people's word for things, but I like to have things verified and it never--at that time, I didn't realize I hadn't actually gotten anything that said, you know, that about the Ventana.
MS. NEWBURY:
Q. And it may not necessarily be an issue of taking someone at their word.
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. Whether it was a slip of the tongue or, you

Page 313

know -
MS. PREDHAM:
A. Exactly.
MS. NEWBURY:
Q. - what you actually remembered or heard if you were listening to a lot of other complex information at the time.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And perhaps people take more care when they write something down that they think is going to be relied upon in any significant manner by others.
MS. PREDHAM:
A. And even having formal minutes that could be reviewed by the group, that would be beneficial because at least then everybody knows what everybody is aware of.
MS. NEWBURY:
Q. And they would know if something was attributed to them, they can say, no, I didn't say that, this is what I -
MS. PREDHAM:
A. Exactly.

Page 314

MS. NEWBURY:
Q. If I said it, I apologize, this is what I had intended to say or, you know, someone misunderstood it, taking down the minutes.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. At least then that would give the advantage of everyone being aware of all of the same information.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And would you agree that this would apply when information is obtained from external sources, whether it's Mount Sinai or Sloan-Kettering or the regional health authorities, for that matter.
MS. PREDHAM:
A. Oh definitely, even when we went across the country with our audit, for that matter, you know, we spoke to somebody very informally, I guess if you want that, and asked some questions, it would have been beneficial to get that in writing.

Page 315

MS. NEWBURY:
Q. Okay, thank you. Exhibit P-0067 please? Ms. Predham, this was a letter that you received, I believe in early July or mid July, 2005. It's a letter from Dr. Cook to Dr. Williams and on page 3 of the report, there are several recommendations there from Dr. Cook as to what should be done in the immunoperoxidase testing. And were you surprised by the recommendations that Dr. Cook was making at this time?
MS. PREDHAM:
A. I don't think I was that surprised, I was more concerned by the earlier part of the letter and I don't recall, you know, I can remember--the one memory I do have when I read them was that I was under the impression that external proficiency testing was being done and it was being done in other parts of pathology, but I didn't differentiate between the two parts.
MS. NEWBURY:
Q. Right.
MS. PREDHAM:
A. But other than that, I was more concerned with the rest of the letter.

Page 316

MS. NEWBURY:
Q. With the content of the letter, okay. So recommendation one there talks about the monitoring--establishing a monitoring program immediately and that relates to the external proficiency testing, is that the recommendation relating to that?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And what about the recommendation No. 3, which recommends training of the technologists in a major immuno referral lab that has well established quality control and troubleshooting programs, did that surprise you in the sense that perhaps it might suggest that the training beforehand may not have been sufficient?
MS. PREDHAM:
A. I didn't pick that up at the time.
MS. NEWBURY:
Q. Okay, so you weren't reading too much into these recommendations at the time?
MS. PREDHAM:
A. No, my focus was more on the letter and that,

Page 317

you know, I didn't have to worry about it yet, but -

MS. NEWBURY:

Q. More of that later on, I guess. Exhibit P-2949 please? And this is the letter containing a draft letter to patients which didn't get sent out earlier and you gave some evidence about this last week and in particular on the first paragraph where it states, "Due to improved technology and the discovery of inconsistent results, Eastern Health has begun retesting a select group of patients"--et cetera. And it was your evidence that you were hoping at this time that you would be able to attribute inconsistent results due to the improved technology.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. Would you agree that for Eastern Health to be able to attribute inconsistent results to new technology that it would essentially have to say something to the effect that the lab did the best it could with the technology that it

Page 318

had until 2004, but it wasn't until 2004 when improved technology was obtained by the lab that it was then in a position to produce more accurate and reliable ER/PR test results.

MS. PREDHAM:

A. I don't think I would have said anything like that as such, the thought at the time that we were hoping was that it was improved technology and now we've got a, you know, a more intense or more sensitive system which is doing the results better.

MS. NEWBURY:

Q. But in light of, I guess, the information that you had--at this point I think it was primarily Dr. Cook's earlier letter that got into the specifics.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And the recommendations there, even if new technology was available as of 2004 when it was implemented in the lab, would you have thought, looking at Dr. Cook's letter generally and the recommendations that the lab was doing the best it could with the older

Page 319

version of the technology?

MS. PREDHAM:

A. No, but I don't think I really absorbed at that time those recommendations and the implications for that at that time.

MS. NEWBURY:

Q. Sure, okay. Now when--I guess shortly after this letter was drafted at one of the meetings, Mr. Gulliver had clarified to you that the Ventana machine was not ten times more sensitive than the DAKO equipment, but rather the Ventana system was just more consistent than DAKO, and you indicated that you were a little preoccupied in the balance of that meeting -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. Just thinking about the implications of that clarification. At that point in time, did that, I guess, reduce any hope that you might have had that you could attribute the inconsistent results to the older technology or was that another strike against being able to say that?

Page 320

MS. PREDHAM:

A. I guess it was another strike, but it was also--I think that there was something with the consistency of the Ventana which would provide better results.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So that was a part there, but it was just the fact that, I guess, in my mind I was thinking CT scan, MRI, like that type of progression of technology, and that was--I had to take that out of the picture.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So then I had to rethink the information that I had and kind of try to re-centre then around that without that part.

MS. NEWBURY:

Q. When you did the quality review of the IHC laboratory in early August, 2005, and learned at that time that the types of documents that you had expected didn't exist, that the key quality assurance activities that was being

Page 321

used was the technologist reliance upon feedback form pathologists -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And when you later learned that the technologists had concerns about communication that they had with the pathologists -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And I believe you later learned that the pathologists weren't aware that they were the key quality assurance tool.

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. When you learned all of that, did that further dash any hopes that you would have of being able to rely upon the implementation of new improved technology to explain the inconsistent results?

MS. PREDHAM:

A. It was a factor, but it was getting smaller all the time.

Page 322

MS. NEWBURY:

Q. Okay. And in light of those types of problems that you learned in the lab in your review, as well as the information from Mr. Gulliver about the Ventana equipment and the fact that it was just more consistent rather than more sensitive, as well as Dr. Cook's letter and his recommendations from mid May or late May, 2005, at that point in time how realistic do you think it would have been to expect that you could essentially say that the lab was doing the best they could with the older technology?

MS. PREDHAM:

A. Well, we couldn't really say that because we couldn't prove that. Even if we were doing the best we could, even if we followed everything perfectly and did everything, we had no proof that we did. So there were enough questions that when we asked, you know, why this or why that, there was enough questions and doubt there that you couldn't say that.

MS. NEWBURY:

Q. In your experience and your various roles in

Page 323

quality over the years, if you--if there isn't a proof of all of these types of procedures in place, the documentation that you might have expected, the quality assurance programs in place, how realistic is it that they were doing everything the way they should have been?

MS. PREDHAM:

A. I've had experience over the time that people do that without the lack of documentation, and I gave a--I told about another incident that we had where we thought there was a cross contamination and we were able to do an observation on it. There was little or no documentation, which was one of the suggestions that we had, and there were a few small breaks in practice that could be improved, but nothing really--nothing that really stood out, but the practice was very good and they'd been doing it for a period of time and they were following all the processes as they went through because we could watch them do that, and confirm that, but if we hadn't been able to do that genetic testing on the virus, we would have put it down to we

Page 324

weren't able to do this stuff. We would have, you know, felt that we didn't have any proof there that they were doing that well, but they were still doing a very good job in that, but they didn't have any documentation to support that to--for their accountability of what they were doing.

MS. NEWBURY:

Q. And you indicated that the individuals who were involved in that--that was just one instance, it wasn't a collection of potential problems, it was just one instance of cross contamination?

MS. PREDHAM:

A. Well, it was one instance, but we had several patients involved.

MS. NEWBURY:

Q. And in that instance, were the people involved able to clearly communicate what their procedures and protocols were?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And precise, and there was no room for -

MS. PREDHAM:

Page 325

A. No.
MS. NEWBURY:
Q. Doubt about any detail.
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. And did you get the same assurances when you were discussing doing your review of the lab with the technologists?
MS. PREDHAM:
A. Well, it was a bit difficult because the equipment wasn't there. We couldn't go through the actual process that they were using. I couldn't observe them do that on the old machine.
MS. NEWBURY:
Q. Uh-hm.
MS. PREDHAM:
A. They were quite knowledgeable with the new one, but I didn't have anything about the old one.
MS. NEWBURY:
Q. Was there any thought to attempting to locate another machine just to perhaps ask them how to do it or perhaps get a lab manual to

Page 326

refresh the memory of the technologists?
MS. PREDHAM:
A. No, not at that point.
MS. NEWBURY:
Q. Ms. Predham, you spoke last week about the 80/20 rule and your understanding of its application in the quality field.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And it was your observation that at Eastern Health, 95 percent of the time a problem is due to the way things are done, not the people actually doing it?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And the general rule, I think you stated, was either 80 or 85 percent of the time if they're having a problem, it's due to the way things are done, not the people actually doing it?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And that's a fundamental philosophy behind

Page 327

quality improvement?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And would you say that the way things are done would typically involve a number of factors?
MS. PREDHAM:
A. Oh, definitely, and also the way things are done also includes the supports the organization has put in around it.
MS. NEWBURY:
Q. Uh-hm.
MS. PREDHAM:
A. So if somebody is doing a procedure and they're doing a procedure by wrote (phonetic), time to time, what reminders, what parameters, what double checks are in place, if there's known areas where you can make a mistake, so that's part of the way that things are done, what supports are there by the organization to prevent errors.
MS. NEWBURY:
Q. Okay, and it wouldn't be a matter of just pointing to one particular step that was missed along the way?

Page 328

MS. PREDHAM:
A. I mean, it could be. Given the circumstances, it could be there may be one step.
MS. NEWBURY:
Q. But in your experience, would it be typically more than one step?
MS. PREDHAM:
A. Typically--well, take the swiss cheese model, that there's a multitude of factors, and unfortunately with that model, it only takes one to stop something.
MS. NEWBURY:
Q. Sure. So it is your experience then that it's more of a swiss cheese -
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Occurrence or observation that you make up to 95 percent of the time?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And -
THE COMMISSIONER:
Q. Sorry to interrupt, but there's something I'm

Page 329

not getting, so we might as well resolve it now. When you say 95 percent is due to the way things are done, and then you went on to add about institutional supports, then you are attributing to the cause of a problem, the absence of features which would catch the problem?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. So it's not only was a, b, c, d, e, done correctly because if it's done correctly, there is no problem.

MS. PREDHAM:

A. Right.

THE COMMISSIONER:

Q. But it's whether or not there are in place other features which enable you to determine whether a, b, c, d, and e were done correctly?

MS. PREDHAM:

A. Yes. One of the premises of the whole patient safety movement is that you have to understand that people will make mistakes, and especially in complex environments like a hospital, they're more likely to make mistakes. So the

Page 330

organization has an onus then to put in those double checks to catch known mistakes, and the other component of it is that if something does go wrong, what is the recovery processes in place. So if something happens, and something goes wrong, how do people react and do they know how to react. So if the discover that there's--you know, which is like occurrence reporting or like quality control, but it may be a bit more specific in certain areas.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. If they discover something happened, how do they quickly recover from that.

MS. NEWBURY:

Q. So it's a response to the problem to hopefully mitigate or avoid potential damages?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And over what period of time did you make the observations that Eastern Health 95 percent of the time it's the way things are done?

Page 331

MS. PREDHAM:

A. That would be from '96 on up. I know when I finally saw the swiss cheese model, it resonated with me because I had seen it happen, I had seen it occur numerous times before I had seen the model.

MS. NEWBURY:

Q. So you didn't need a big description as to what that meant?

MS. PREDHAM:

A. No.

MS. NEWBURY:

Q. And in handling disclosure over the years when problems arise, has it been your observation that patients are not interested in hearing the detail about problems when they are due to the way things are done?

MS. PREDHAM:

A. I don't know if they're not interested. Some people are interested in a great level of detail, and some people just want a general gist of what happened, some people want someone to blame.

MS. NEWBURY:

Q. Uh-hm.

Page 332

MS. PREDHAM:

A. And they want us to blame somebody, and sometimes they perfectly understand that everybody is human and mistakes happen.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So it's very, very different. I'd say each time it's been different.

MS. NEWBURY:

Q. And I guess I asked the question because it was your evidence, I think, over the last couple of days that when advising patients, particularly those that were confirmed negatives, of the results of the retesting, and addressing the issue of the cause of the problem, the patients were not--they were really only interested in finding out the one cause of the problem, and if there wasn't only one cause, they were not particularly interested in finding more of the detail?

MS. PREDHAM:

A. They didn't ask me the specific detail.

MS. NEWBURY:

Q. Okay, and is that consistent with your

Page 333

experience over the years since 1996, that when you have these sort of more systemic type problems that occur, in 95 percent of the time that patients are equally not interested, or that's your understanding that they don't pressure the questions?

MS. PREDHAM:

A. Sometimes. You know, I've had--I've disclosed information to one lady about her father who died, and she didn't want to know the circumstances that led to the ultimate circumstance that led to his death, she just wanted to know about that circumstance, the actual final thing. I guess, the final hole in the swiss cheese, and--but she had no interest in the rest of it.

MS. NEWBURY:

Q. Okay.

MS. PREDHAM:

A. But I had another one who wanted to know every detail along the steps, what contributed to it, what happened, what--you know.

MS. NEWBURY:

Q. So over the years then in other reports to patients or disclosure of problems to

Page 334

patients, you've had a variety of experiences with the patients?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. But you can't say the same for the disclosure that you've been making regarding the ER/PR problem, that there hasn't been the same variety of interest?

MS. PREDHAM:

A. Well, no, but I also--it's a different circumstance because I wasn't--in all the ones that I've been involved before, there's been a very serious adverse outcome, you know, there's been a death or a debilitation, or something on that level, and I guess maybe that makes it a little bit different than, you know, I was telling people that the results--these were your results, and these are your results now. So it may be a different level.

MS. NEWBURY:

Q. So you're attributing it to the fact that you were in a position that you were telling patients that they've been confirmed negative?

MS. PREDHAM:

Page 335

A. Yes, and I really hadn't thought about it before now, but maybe that's a contributing factor.

MS. NEWBURY:

Q. And you were in some other meetings, though. I think you attended at least one meeting with patients where that wasn't the case?

MS. PREDHAM:

A. No, Ms. Parsons did.

MS. NEWBURY:

Q. Okay, thank you. Ms. Predham, do you perceive it to be a good thing that 95 percent of the time the problem is due to the way things are done as opposed to a particular individual being a cause of a problem?

MS. PREDHAM:

A. I don't think that's a good thing. I think that's--you know, if it was the other way around and we had bad people working for us, that may be easier to deal with because you could deal with the bad person and then move on. It makes it more complex when it's a system issue.

MS. NEWBURY:

Q. Because you have more holes to patch up?

Page 336

MS. PREDHAM:

A. Yes, and it's harder to get a handle on as well.

MS. NEWBURY:

Q. Okay, and has it ever been considered that the way things are done are sometimes due to choices by individuals working in the system?

MS. PREDHAM:

A. Well, that's one of the--when you're investigating these, there's various tools that you can get that you go through to help you determine if it is an individual issue or if it's a system issue.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. And of those, you know, you'd look at a substitution test. So would somebody with the same education, the same practical experience, in the same circumstance make the same decisions. That type of thing.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So, you know, yes, it could be--it could be a

Page 337

decision thing, but that doesn't mean that it's an individual thing, it may be just the circumstances.

MS. NEWBURY:

Q. Right, it might have been a reasonable decision, but one that was not -

MS. PREDHAM:

A. And it could be related to--you know, say, there was a policy change and the organization didn't do a good job in educating about the policy change.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So the staff member made a wrong decision based on lack of knowledge.

MS. NEWBURY:

Q. Uh-hm.

MS. PREDHAM:

A. So then that's--you know, that's the type of thing.

MS. NEWBURY:

Q. Yeah, not to say that all decisions that might be the fault of an individual choice or action somehow is a terrible thing necessarily.

Page 338

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. It's just it may be, like you said, due to the level of education or what might have perhaps been known in the health care industry at the time?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. But would you agree that the way things are done basically arise from a variety of decisions made by individuals or the organization? You could have a process that was put in place after an intensive failure modes and effects analysis session, or you could at the other extreme have a process put in place that was the result of very little time, effort, or resources on developing and documenting, for example, standard operating procedures?

MS. PREDHAM:

A. Uh-hm.

MS. NEWBURY:

Q. So there's a whole gamut there of, you know,

Page 339

why things are done in a particular way -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. By an organization, and some might have been, you know, with great effort to hopefully avoid any problems, but unsuccessful?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And others might have been as a result of very little effort to avoid and guard against particular types of problems?

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. And in retrospect and hindsight looking at all that has happened over the last few years, do you still really believe that patients were only interested in finding out just one cause of the problems for ER/PR testing and they would not be interested in more detail?

MS. PREDHAM:

A. No, no, and I don't think -

MS. NEWBURY:

Page 340

Q. Sorry, I must have misunderstood.

MS. PREDHAM:

A. Sorry, if I gave that impression.

MS. NEWBURY:

Q. Okay.

MS. PREDHAM:

A. But I do know that several asked me specifically, you know, what happened, and when I went into discussion that there was a multitude of things, or that it appears to be a multitude of things, you know, they weren't really pushing on, well, what are they, they didn't specifically ask me what they were.

MS. NEWBURY:

Q. And did you ever consider that a patient or family hearing that sort of an explanation might be deterred from pursuing the matter further or perhaps didn't have enough context in which to press for more information?

MS. PREDHAM:

A. No, it didn't occur to me.

MS. NEWBURY:

Q. And in light of, I guess, a couple of circumstances that have, I guess, come to light since your communications with patients,

Page 341

first of all we have the ethics consultation report, Mr. Singleton. Perhaps I could bring that up just for your reference, P-0783, please, and you were shown this, I believe, yesterday, and in his report he has stated here by the cursor, "There were no mistakes or technical errors at the root of this problem", and notwithstanding Mr. Singleton's direct communication with several individuals who had knowledge of the particular problem, he still, I guess, left that session and drew a conclusion which he wrote in the report that there were no mistakes or technical errors there, and we also have evidence of Joan Dawe, and I'm not sure if you're familiar with her evidence, that--again she learned about the problem first in September of 2005 at a meeting, and I think that was following a presentation--a verbal presentation from Dr. Williams that lasted about an hour. Are you familiar with how she learned of the ER/PR problem?

MS. PREDHAM:

A. Through this process.

MS. NEWBURY:

Page 342

Q. Okay, and she had subsequent updates as well about the problem, but she was under the impression, for a considerable period of time, that new technology was a major contributing factor to the circumstances surrounding the testing and she expressed some disappointment about not having been advised, at least at a high level, about the general nature of the quality and organizational issues described by Dr. Banerjee and Ms. Wegrynowski in their external review reports, and I'm just wondering, given that Mr. Singleton and Ms. Dawe had lengthy careers affiliated with the health care industry and direct access to knowledgeable persons within Eastern Health and in fact, had direct communication with them on these particular issues, were apparently themselves not able to ask the appropriate questions to elicit a better understanding of what caused the ER/PR problem, and in light of that information, in hindsight, do you think that perhaps the patients might have also been in the same position that they just may not have known which questions to ask to elicit more detailed information?

MS. PREDHAM:

A. They certainly could have.

MS. NEWBURY:

Q. Okay, and would you think that a patient would be in any better position than either Mr. Singleton or Ms. Dawe to elicit that information?

MS. PREDHAM:

A. No, but now every patient that we spoke to, we left our name and number if they had any questions, and some did call back and ask questions. But you know, you're right. I mean, it was--we identified that it was a phone call out of the blue, you know, and telling them this information and it was there. I know, in reviewing documents, that I had made the plan to write them after. That had been a discussion of a plan, but again, the way that we did this caused problems and caused things to be overlooked and that was one of the things that got overlooked.

MS. NEWBURY:

Q. Did you ever advise a patient on the issue of causation that you were aware of several factors that could have contributed to their particular problem or that contributed to the problems generally and come out and offered to share that information with the patients?

MS. PREDHAM:

A. I don't think I would have worded it that way.

MS. NEWBURY:

Q. Ms. Predham, on the role of Nancy Parsons as a patient relations officer and a patient contact, do you think it would have been appropriate for Ms. Parsons to advise patients whose results had changed, and she was aware of the change, that the retest results were back from Mount Sinai, a panel would be reviewing her file to see if any changes of treatment were necessary or just to simply advise them that a panel review would be necessary or a physician review would be necessary and that a physician would ultimately be in touch with her?

MS. PREDHAM:

A. Maybe. At the time when we talked about it and I sought direction, there was no recommendation to change it to anything else and it was--and that's the way it was

Page 343

Page 344

Page 345

responded to.
MS. NEWBURY:
Q. So you understood that Ms. Parsons was telling such patients who called that she didn't have any information to give them?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And were you aware that some oncologists, upon receiving a panel letter for which there was no treatment change recommended, that some of those would not immediately communicate this information to the patient, but rather would wait until the next regular appointment to make this communication?
MS. PREDHAM:
A. I think we discovered that in the verification process.
MS. NEWBURY:
Q. And when was that?
MS. PREDHAM:
A. That was in 2008, but I also had that one incident in 2006, the fall of 2006, I think.
MS. NEWBURY:
Q. Okay, and we've had evidence here that this

Page 346

was Dr. Siddiqui's approach in handling those cases.
MS. PREDHAM:
A. Oh, no, I was not aware of that.
MS. NEWBURY:
Q. Okay, and Dr. McCarthy actually testified that this approach was given at the direction of Dr. Laing, and perhaps it would be helpful to bring up her evidence, September 19th, page 391.
THE COMMISSIONER:
Q. While that's coming up, you said that, in response to a question by, I think, Ms. Newbury, regarding Nancy Parsons and her method of dealing with inquiries, you said you sought direction?
MS. PREDHAM:
A. Yes. Well, we had this concern when patients called. Now, I mean, as far as I understood, there was not a lot. There was only, you know, a few patients that called that actually the results were back and she was put in that position.
THE COMMISSIONER:
Q. Um-hm.

Page 347

MS. PREDHAM:
A. And it was--you know, it was very concerning, especially to Ms. Parsons, because she had to speak to them. So she asked--so we asked Dr. Williams and Dr. Laing if they could, you know, what would be the best way to approach that and they just said, well, you know, do that, get them panelled as quickly as possible.
THE COMMISSIONER:
Q. So it was the advice of Dr. Laing and Dr. Williams to continue the method which has been described to us by Ms. Parsons?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. And put them on the list for panelling as quickly as you could?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. All right, thank you.
MS. NEWBURY:
Q. Now on page 391, I'm going to read this out. The question that I asked Dr. McCarthy, "I'm

Page 348

just wondering, upon receipt of the panel letters, what was your practice with the different types of letters? And I understand some might have recommended a treatment change. Some may have recommended no change of treatment. Others, you may have already dealt with, and in each of those situations, how did you handle the situation when you received the panel letter?" And Dr. McCarthy replied, "well, Dr. Laing gave us, the oncologists, specific recommendations. If there was a treatment change, you were to contact the patient as soon as possible and advise the patient of the treatment change. If there was no treatment change, so to give you the example of ER"--and I think this might be confused here, "ER positive 90 percent, where they already got Tamoxifen, now they were 30 and 90. She felt and agreed that the next available clinic appointment would be adequate to explain that to the patient, since the treatment did not change."
And then I questioned Dr. McCarthy "okay, and I understand from earlier evidence from Dr. Siddiqui that the appointments typically

Page 349

for a patient who was being followed would be perhaps every six months and it might alternate between a radiation oncologist and a medical oncologist" and Dr. McCarthy replies "or even yearly."

And then I questioned her again "or even yearly, okay, and in some cases, where there was no recommended change of treatment, was it your understanding that if they didn't have an appointment for three months down the road or eight months down the road, that the information would be relayed to that patient at that next appointment?" and her answer was yes. And my question, "and was that your understanding to be the protocol according to Dr. Laing?" Her answer was yes.

And on the next page, "was that relayed to you in a meeting or was there any written record of that?" Dr. McCarthy replied, "there was no written. We discussed this during the panel itself, and as well, we discussed it at our oncology meetings after rounds so that the other oncologists would be in the loop." And then I questioned her "so it was your understanding that your colleagues all would

Page 350

have understood that to be the direction of all?" and her answer was yes.

And on the next page, 395, in the right-hand column, I questioned her again. "I guess the concern or the question that I have now-- is now would a patient whose results had changed, albeit there would be no recommended change of treatment, how would these patients know or first learn that there would be no change of treatment for them?" and Dr. McCarthy replied "at their next clinic visit." My question "was there any concern that there are a lot of patients out there who are anxious to get the information and they might be, you know, quite worried about knowing what impact the ER/PR retesting would have upon them?" and Dr. McCarthy replied "any patients who called in who inquired, who wanted to speak with us, we dealt with those. We spoke with them. We met with them at their request."

Then I asked, "but they would not necessarily know, you know, where the process was, whether or not the results were available at that time." And Dr. McCarthy replied

Page 351

"well, there was a hotline that they would call and Ms. Parsons would advise them of that." And then I asked "was there ever any discussion about adopting another approach in terms of those patients who had a change in result but no change of treatment?" and her reply was "not that I recall."

So it would appear that Dr. McCarthy thought that a patient who is particularly anxious might call the hotline and given some indication that there was a change of treatment and perhaps they could call the physician and make an appointment and get the changes there.

MS. PREDHAM:

A. Well, in that circumstance, they would have already been panelled.

MS. NEWBURY:

Q. Right.

MS. PREDHAM:

A. I think Ms. Parsons was referring only to people whose results came back and they had not been panelled yet.

MS. NEWBURY:

Q. But I think Dr. McCarthy there, the focus of

Page 352

the question was what about the anxiety of those patients who know generally, from the media, that there is a retesting program taking place. They're anxiously awaiting for their results. Those patients are panelled, but some of those patients do not have a recommended treatment change. Now the oncologists, according to what Dr. McCarthy is saying, and consistent with what Dr. Siddiqui had adopted as his approach, would be only those patients who had a change of treatment would be contacted immediately. Others might have to wait for six months or perhaps even a year before they would be told "yes, there was a change of your results, but there was no change of treatment," and the only other possibility that Dr. McCarthy would have as to how they might otherwise learn of their results earlier would be if they happen to call the oncologist and set up an appointment, in which case they would accommodate that patient's request. But of course, the concern I pointed out to her was how would they know when to call. Do they call weekly? Do they call monthly? They have no idea where they

Page 353

are in the system. And the other possibility that she suggested is that they could call the hotline and perhaps find out a bit more information as to whether or not the results are back, but of course, according to Nancy Parsons, they would not be told. They would not even be told that their results are available and that a panel would be looking at it.

MS. PREDHAM:

A. Well, in that circumstance, the fact that the oncologists were told to wait for the next clinic visit, I'm very surprised at, and during the verification process, it didn't strike me that there were a lot of people who were waiting--you know, who were told with a discrepancy time by the oncologists. But Ms. Parsons' concern and the situation that we were talking about were solely the people whose results were back and had not been panelled. That's the only ones that she had that concern with saying that. The ones that were panelled, she would--if they had not known and they were panelled, then Ms. Parsons would just say "I'll have to check into it"

Page 354

and then would track down the physician as Dr. McCarthy said, and arrange an appointment time to meet with them. The only ones that I'm aware that Ms. Parsons ever said that there was "nothing new to tell you" were the ones whose results had converted and they had not been panelled yet.

MS. NEWBURY:

Q. Okay. So your understanding that she would make some efforts to contact the physician if, in fact, she was aware that the patient had been panelled?

MS. PREDHAM:

A. Oh yes, definitely.

MS. NEWBURY:

Q. And how would Ms. Parsons know--what sort of time frame was there for Ms. Parsons learning about the fact that panelling had taken place?

MS. PREDHAM:

A. Well, you know, if she had--she had a list of all the patients there, but also I was only down the hall for her to ask and we talked about patients who called in numerous times.

MS. NEWBURY:

Q. And so were you ever aware that this was

Page 355

actually the approach that had been adopted, almost as an official approach, for the oncologists certainly in the Cancer Clinic program?

MS. PREDHAM:

A. No, I'm very surprised actually and after all the charts that I've reviewed, I'm still very surprised. It didn't strike me when I went through that there was a lot of patients in that area of no recommendations that had to wait--that, you know, I do--I can even visualize, and of course, I'm tired and I'm going through my memory here, but I've seen evidence of Dr. McCarthy calling patients, you know, to tell them the news on the phone.

MS. NEWBURY:

Q. Sure. But it certainly seemed to be an approach of Dr. Siddiqui and one that was consistent with direction given by Dr. Laing. So unless the patient happened to be proactive and know when to call and perhaps either call the oncologist directly or perhaps call Nancy Parsons and rely upon her to track down the information, there might very well be patients out there who are waiting for the call

Page 356

patiently and not taking the steps themselves to make a call.

MS. PREDHAM:

A. Oh, certainly.

MS. NEWBURY:

Q. And might go for months without knowing the results.

MS. PREDHAM:

A. Certainly, but I was never aware of that, that that was a practice.

MS. NEWBURY:

Q. And given that it was the oncologists, in the summer of 2005, who had expressed such concern about anxiety for patients about knowing that retesting is taking place but not yet having the results, would it--I mean, does that surprise you because it's now the oncologists who had adopted this approach of simply putting panel letters in the file for those for whom no treatment change was recommended and wait maybe three months or six months or 10 or 11 months?

MS. PREDHAM:

A. Oh yes. You know, obviously from the e-mails that we saw today, I was aware of one lady who

Page 357

was going back for her annual appointment and then was informed of the results, but I was thinking that was more the unusual event, rather than the routine.

MS. NEWBURY:

Q. Ms. Predham, are you able to indicate now what the current number of retro converters are, retro converters as you understand that description?

MS. PREDHAM:

A. From a clinical point of view?

MS. NEWBURY:

Q. From whatever point of view you understand, I guess. Whatever you understand a retro conversion to include.

MS. PREDHAM:

A. The ones that were taken off Tamoxifen, I would say would be four. But from a retro converter from a true lab perspective on what really is a false positive, in other words, I don't have any idea what the number is.

MS. NEWBURY:

Q. Okay, and do you know if anyone in Eastern Health has any idea what that total number is?

MS. PREDHAM:

Page 358

A. I know the analysis is underway and I just have a general sense that they are looking at that and answering those questions now. I don't know where they are in progression of that. I'm not involved.

MS. NEWBURY:

Q. And can you name the individuals that are involved in that analysis?

MS. PREDHAM:

A. That would be Mr. Wayne Miller and Ms. Pilgrim, and I guess, as well Dr. Denic and Mr. Gulliver.

MS. NEWBURY:

Q. Okay. Now three of those witnesses, Dr. Denic and Ms. Pilgrim and Mr. Gulliver, have all given evidence since September, early September I believe Dr. Denic gave his evidence, and they weren't able to provide any data at that time. So does that mean that the analysis has only taken place since their evidence?

MS. PREDHAM:

A. I'm not really sure. I do know that it's underway. Of course, when the Centre for Health Information came in and were updating

Page 359

the database and everything, it was we'd wait until then, and I do know that Mr. Miller was meeting with different people trying to get the questions that they had, specific questions to get the data for them. So that was undergoing--that was underway definitely the summer, and I do know--I thought that Dr. Denic told me that he had some results back on some of the questions that he had asked.

MS. NEWBURY:

Q. Okay. Ms. Predham, are you aware--certainly my understanding that ER positive results were not included in the NLCHI database. Do you have any understanding what might have been included there?

MS. PREDHAM:

A. They had an overall database. Their request from the Department of Health was to create a database of all patients who were retested at Mount Sinai. So--and this is my understanding and I'm sure they're going to be on later the week anyway.

MS. NEWBURY:

Q. Yes.

MS. PREDHAM:

Page 360

A. But the analysis part that was conducted were only on those that met the criteria of ER 30, ER 10 and retested. So there are patients in there who are positive that didn't meet the criteria, that are in the database but they weren't analyzed in a--they were excluded from the analysis.

MS. NEWBURY:

Q. Okay. So do you know if the NLCHI database would include a patient that was ER 30, PR 40 and converted to zero/zero?

MS. PREDHAM:

A. It could, I don't know, it could.

MS. NEWBURY:

Q. And you were shown a couple of lists that you understood to be a picture in time of retro converters and perhaps I could bring up the longer list first, P-2642, please. And this is one dated May 17, 2006 and you provided it to Dr. Denic and that was based on information from Dr. Cook. And did you understand this to have been a comprehensive list of retro converters to that date?

MS. PREDHAM:

A. Yes.

Page 361

MS. NEWBURY:
Q. Okay. And this still includes patients for whom there ultimately was no change of treatment because they might have initially been considered negative.
MS. PREDHAM:
A. Right.
MS. NEWBURY:
Q. Okay.
MS. PREDHAM:
A. Correct.
MS. NEWBURY:
Q. And for the purposes of the shorter list, if a patient had been considered and treated as negative from the outset, that they would be taken off the list.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. They would no longer be considered a retro converter for that purpose.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And do you know whether or not this list would

Page 362

reflect all of the results for retro conversions for patients who are deceased or known to be deceased at that time?
MS. PREDHAM:
A. I don't know. I know that there's one patient there who is deceased, but I don't know if that's including all of them. From the re-tests I have no idea.
MS. NEWBURY:
Q. Now, a couple of months later--if I could bring up P-0103 please. Ms. Pilgrim sends an e-mail you and Sharon Smith identifying four cases of retro converters who are living and one deceased patient's husband has been calling. This is--I'll show you now the second page. Are you familiar with that e-mail?
MS. PREDHAM:
A. I'd have to look at it again.
MS. NEWBURY:
Q. You can scroll down through it, the e-mail that I'm referring to is the one on page two.
MS. PREDHAM:
A. I can scroll down?
MS. NEWBURY:

Page 363

Q. Yes. So, there's the longer e-mail that I'm referring to.
MS. PREDHAM:
A. Okay.
MS. NEWBURY:
Q. So, that identifies the retro converters.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Now, this is subsequent to those two earlier lists that you provided to Dr. Denic.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. So, by that time it seems that the list is wheedled down and is that based on excluding patients for whom there was no change of treatment?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And would it also exclude patients who were known to be deceased?
MS. PREDHAM:
A. Yes.

Page 364

MS. NEWBURY:
Q. Okay. And is it your view that to do a true analysis of retro converters, you would have to include patients who are deceased?
MS. PREDHAM:
A. Oh yes.
MS. NEWBURY:
Q. And patients who did not require change of treatment.
MS. PREDHAM:
A. Oh, you'd have to take the treatment side out of it to get a full -
MS. NEWBURY:
Q. Yes, and it's your understanding as well that an ER negative/PR positive patient who converts to ER and PR negative would also be considered a retro conversion.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. If I could bring up Exhibit C-0276, please? Ms. Predham, you can scroll through this. It's a series of 9 letters, panel letters, that I've located from documents that were provided from you, from your files and these

Page 365

are the only nine that I was able to find, again, subject to my own ability to identify that. That would constitute or possibly constitute retro conversions. Would you have any reason to believe that there are more than 9 such panel letters?

MS. PREDHAM:

A. Oh, I wouldn't be able to tell you.

MS. NEWBURY:

Q. Oh, okay, just off top of your--I'm just wondering, does the number -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. - strike you as being low or -

MS. PREDHAM:

A. No.

MS. NEWBURY:

Q. And Ms. Predham, there's one panel letter that is not reflected in either of your lists at P-1373 or P-2642 and that's at page 3 of this exhibit. And the patient there was diagnosed with breast cancer in 2004. She was initially 40 estrogen or ER, zero for PR and a repeat report from Mount Sinai, she was five and

Page 366

zero. And also second specimen from a mastectomy was reported and it went from 10 ER, zero PR to zero and zero upon retesting. And the recommendation of the panel which met on February 16, 2006 that this patient is considered to be hormone negative and recommend that the patient's name not be given further hormonal treatment for her metastatic breast cancer.

Now, first of all, would that, based on the information that you see there which I guess is fairly limited, would that be a retro conversion in your view?

MS. PREDHAM:

A. I don't know. It depends on the--I don't know, I wouldn't be able to comment on it to tell you the truth until I saw the name and really, you know, the decisions about the--I facilitated decisions about the retro converters, but it was clinicians that made the ultimately decision. So, I don't know.

MS. NEWBURY:

Q. Mr. Coffey, has the patient's name; that might be of some assistance. Obviously without divulging -

Page 367

MS. PREDHAM:

A. Yes, okay, yes.

MS. NEWBURY:

Q. I'm not sure if that's of any assistance to you, Ms. Predham.

MS. PREDHAM:

A. There was something--there's some other thing that was an issue there and it was something to do with the second specimen. And I remember, based on her name, that there was something unusual with this situation.

MS. NEWBURY:

Q. Okay. And are you able to tell from this letter and from being prompted by Mr. Coffey with the patients name, whether or not this patient had actually received any hormonal therapy? I think the third paragraph there is a little ambiguous as to whether or not she -

MS. PREDHAM:

A. I can't remember, but I remember there was something, the whole situation was not a--oh, thank you. I think it's an indication from there, maybe the unusual thing was, was that she was treated with Tamoxifen, but for a short period of time and was taken off it

Page 368

before she was panelled.

MS. NEWBURY:

Q. Okay.

MS. PREDHAM:

A. And that may be the unusual thing about it.

MS. NEWBURY:

Q. Okay. But certainly the fact that she may have been treated initially with Tamoxifen, would that, in your understanding of things, put her in the category of a retro conversion?

MS. PREDHAM:

A. Oh, certainly, in our criteria, she could have been included in that.

MS. NEWBURY:

Q. Okay. And, of course, that's retro conversion as being used here -

MS. PREDHAM:

A. From a treatment -

MS. NEWBURY:

Q. When you look at a category of four -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. - which is what I think is still being used up until Ms. Pilgrim's evidence -

Page 369

MS. PREDHAM:
A. Yes.
MS. PREDHAM:
A. - that's because that they've taken out the deceased and they've taken out patients for whom there was no change or treatment because they were initially negative -
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. - Treated was negative.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. But this would not be in that category.
MS. PREDHAM:
A. There was, you know, again, it may have been-- she wasn't included in that category, no.
MS. NEWBURY:
Q. And do you think she should have been in the category four?
MS. PREDHAM:
A. From here and from what I remember, she could have been.
MS. NEWBURY:

Page 370

Q. Okay.
MS. PREDHAM:
A. But there is a memory that was something complicated about this case and I can't remember what that is.
MS. NEWBURY:
Q. Ms. Predham, there are a number of what would appear to be retro conversions based certainly on the clinical side of things, keeping in mind that many people who have testified so far have referred to a 10 percent cutoff, that are apparent when looking at some data that was provided to Mark Quinn at Exhibit P-0720-- if we could bring that up please--that are not reflected on either of the two lists of retro converters that were provided to Dr. Denic -
MS. PREDHAM:
A. Oh, okay.
MS. NEWBURY:
Q. - in May of 2006. I just wanted to show those to you so that you're familiar with it before I ask you questions. And these are the, I think, the category of PR retro conversions because the ERs were initially negative or less than, say, 10, but the PRs were

Page 371

considered to be positive and upon retesting at Sinai, several of the examples went 0, 0, one went to 2, 0. And perhaps I'll show you just to familiarize yourself with that. Line 20 of the data, negative 75, 2, 0. And you have some doubts, I think from your earlier evidence, as to whether that would be from a technical point of view, a retro conversion.
MS. PREDHAM:
A. Well, no, I mean, the thing from a technical point of view that I would have considered that the lab would be very interested in is that something would have 75 percent PR and then go down to 0. The case with this person, of course, is that that's two specimens for the same person and that may be why it wasn't picked up, because she was panelled or panelled, I presumed, based on the other results.
MS. NEWBURY:
Q. But the fact that, from a technical perspective, and perhaps the labs interest in this, the fact that that could have happened on a specimen, whether or not there were other specimens for that patient, that might have

Page 372

had consistent results upon retesting, the fact that that could happen, do you think that that would be of interest to the lab?
MS. PREDHAM:
A. Oh, definitely. The--you know, the other, it would require investigation, of course, any of this would require investigation just from my limited knowledge of listening to them.
MS. NEWBURY:
Q. Uh-hm.
MS. PREDHAM:
A. Because I know, as I mentioned earlier, that there was some discussion at the panel table early on about needle core biopsies and how it could change something, you know, from pathology and could affect the results.
MS. NEWBURY:
Q. Okay.
MS. PREDHAM:
A. So, you know, the source specimen and all this would have to be considered in part of that analysis.
MS. NEWBURY:
Q. And you have no idea whether that situation I just showed you, line 20, was needle core

Page 373

biopsy or not?
MS. PREDHAM:
A. Absolutely not, no, I don't.
MS. NEWBURY:
Q. That's something that would require investigation?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And line 61, there are apparently three samples for a particular patient. One of those three, it had 0 ER, 50/60 PR, and upon retesting, it came out to be zero/zero, and you note that the other two for that particular patient, number 61, they were all negatives?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. So in that case there, it might have actually had an implication for the particular patient?
MS. PREDHAM:
A. Oh, definitely, and as part of the lab, would be very concerned about this, but they'd also have to start and get the original slides

Page 374

reread because, of course, the first person that we thought was a retro convertor was actually a misread slide.
MS. NEWBURY:
Q. Right.
MS. PREDHAM:
A. So they'd have to verify that and move on. so it requires detailed analysis, but the lab would be looking at something different than the clinicians would be looking at.
MS. NEWBURY:
Q. They might have slightly broader concerns than a clinician?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And on that point that you just raised about the fact that the first one that you looked at was actually a misinterpretation of a slide, and it probably should have been read as negative all along -
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Would that warrant a description other than

Page 375

retro conversion for that particular specimen?
MS. PREDHAM:
A. She wasn't considered a retro convertor.
MS. NEWBURY:
Q. She wasn't.
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. And from a patient's perspective, do you think it would matter to the patient whether or not the change result from positive to a negative was due to misinterpretation of background staining versus false nuclear staining? Do you think that would matter to the patient?
MS. PREDHAM:
A. No.
MS. NEWBURY:
Q. And would it matter, I guess, to the lab in terms of the numbers of such categories that it responds to? I mean, is it any less of a problem for the lab if they have all, say, 25 or whatever number there might be, that were due to background staining, is that less of a problem for the lab?
MS. PREDHAM:

Page 376

A. A different problem.
MS. NEWBURY:
Q. Different, okay, and perhaps it might influence how the lab would approach the investigation or the response to the problem?
MS. PREDHAM:
A. Exactly.
MS. NEWBURY:
Q. And just for communication purposes, given that some of this information is being relayed to the public or to the Department of Health, for example, do you think it might warrant further explanation rather than just saying that this is not considered a retro conversion.
MS. PREDHAM:
A. In hindsight, possibly.
MS. NEWBURY:
Q. Just a couple more to show you on the category of PR retro conversions, for lack of a better term. 142--the ones that I'm showing you, by the way, are ones that I couldn't locate on either of those lists of Dr. Denic in May of 2006. Here for line 142, we have less than 5 for ER, less than 25 for PR, going to

Page 377

zero/zero.
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Now, of course, if that were 1998, it might have been treated as clinically negative from the outset.
MS. PREDHAM:
A. But again then from a lab perspective, it does need to be investigated.
MS. NEWBURY:
Q. Right, because -
MS. PREDHAM:
A. And, of course, the person may be deceased and, you know -
MS. NEWBURY:
Q. Right, so it may not have been panelled, but it still would be a concern for the lab?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. And line 436--I just want to show you because there are quite a few that do not get picked up on your lists or in the panel letters. 436, you have less than 10 for ER, 60 for PR,

Page 378

and then down to zero/zero for ER and PR upon retesting. Line 717, again just one specimen there, negative ER, greater than 60 for PR, going to zero/zero upon retesting?
MS. PREDHAM:
A. Yes.
MS. NEWBURY:
Q. Line 767, there are several samples there for the patient, two actually, and the second, negative ER 40-50 PR, going to zero/zero upon retesting, and it may not--I'm not even sure what the X's mean there.
MS. PREDHAM:
A. I think, if I recall rightly, that that would have been two blocks of the same specimen, as opposed to two specimens.
MS. NEWBURY:
Q. Okay, and line 827, we have one specimen there, negative ER, 60-70 PR, going to zero and zero, and I won't take you through all of them, but there were also conversions 10 ER, 10 PR going to zero/zero and I have located those at lines 132, 239, 413 and 804. So there's four in that category, according to Mr.--the data given to Mr. Quinn, and on

Page 379

Exhibit P-2642, if I could bring that up, please, it does acknowledge one that fits that description.
MS. PREDHAM:
A. Okay, and the others may be those that are deceased.
MS. NEWBURY:
Q. Right, okay. So here, it does acknowledge and it indicates that that was panelled, 10/10, zero/zero, and there's also another category, you can see here down for the second Gander one, the cursor is there, there's a category of less than ten for ER and less than ten for PR and zero and zero, and again that case was panelled and confirmed to be negative, and looking at Mark Quinn's data that was given to him, there were actually a total of eight that fit that category. So there were seven others that fit this description that it doesn't appear that they were panelled, and perhaps it may not be as much of a concern from a clinical perspective if it's below the ten percent cut off, if indeed that's what was used consistently by oncologists. But would you agree that that would be of concern from a

Page 380

technical perspective for the lab?
MS. PREDHAM:
A. Oh definitely.
MS. NEWBURY:
Q. Okay, and if I can go back to Exhibit 0720, please? And there are also a couple of, I guess, stronger ER/PR conversions, 778. So this is a 10 to 20 ER, a 40 to 50 PR and that converts to zero/zero, and I couldn't find that on either of the lists, and there's some weaker ER conversions. Looking first at line 615.
MS. PREDHAM:
A. And this just highlights how important that analysis be done on this, as opposed to looking at the panel results.
MS. NEWBURY:
Q. Right, okay, and so there are two actually with this example, lines 615 and 68, where the results went from 20 ER to zero. You see line 615, there's one example, 20 to zero to zero/zero upon retesting, and again, I couldn't locate those on either of the two lists that were given to Dr. Denic. And despite all that, I think it's still the

Page 381

evidence that there were four retro conversions and again it's your understanding that this is because there was no treatment change, and perhaps these were deceased patients and not panelled.

MS. PREDHAM:

A. Um-hm.

MS. NEWBURY:

Q. And it was Dr. Denic's evidence that he'd reviewed four of the retro conversions, but there hadn't been a more extensive review, I don't believe, of retro--of the conversions. I think the focus was on those that had -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. - had a treatment change and were still living patients. Now the final number of patients in this list given to Mark Quinn, if we look down right at the very bottom, and assuming this is accurate, 887 patients. Now it's my understanding that the NLCHI database, even though it might have excluded some ER positives, I'm not--I guess we'll have to wait and get the evidence on that, but the NLCHI

Page 382

database is now over 1,000 patients that were retested. Is that consistent with your understanding?

MS. PREDHAM:

A. For the life of me, I can't remember how many are in their database.

MS. NEWBURY:

Q. That's fine, but in any event, it seems that there are -

MS. PREDHAM:

A. Yes.

MS. NEWBURY:

Q. - certainly more that have come to light since then. So perhaps there are more retro conversions as well, and I take it from your evidence that you would agree that a further analysis of this would be appropriate?

MS. PREDHAM:

A. Oh definitely. It has to be done.

MS. NEWBURY:

Q. And is there any reason why that wasn't done before?

MS. PREDHAM:

A. Well, like I said, the timing of when it would have been addressed would have been, you know,

Page 383

the winter or the spring of 2007. We also had to make the decision about retesting all of the deceased that hadn't been retested, and you know, I wasn't able to do it, and then of course, it got addressed again in May, June and then the Centre for Health Information was coming in. So it was decided to wait until they did their exercise and then we'd use their data.

MS. NEWBURY:

Q. Ms. Predham, I just wanted to ask you if you could clarify something about panel letters relating to some of the people on the longer list at P-2642, please, and line two of this, the patient was five ER, 25 PR and converted to zero/zero and it indicates the patient was panelled and there's no recommendation, considered negative. I couldn't locate a panel letter, and perhaps I don't have all of them, but I couldn't locate one that related to that particular patient and I'm wondering how that patient might have been advised of the recommendation or conclusions of the panel.

MS. PREDHAM:

Page 384

A. It's not clear. I can't remember doing up this list and whether it was myself and Kara, when we went through that, you know, that I wrote this in the side, oh that person, we discussed that person at panel and there's--you know, this person was confirmed negative. There was no recommendation. If the person was confirmed negative and no letter was written, we would have notified that person from Quality.

MS. NEWBURY:

Q. Okay, and so you would put that person's name and information on a list and give it to Nancy Parsons and she would make the call?

MS. PREDHAM:

A. Or I may have called. It would depend on the circumstances.

MS. NEWBURY:

Q. Oh, okay, and would they be told that there was actually a change of their results?

MS. PREDHAM:

A. Most likely we would have said that, you know, these were your original results, and in 1998 when we reviewed your chart, you were considered negative, and now your results are

Page 385

zero/zero, and you know, we may have given that, in that level of detail, depending on the circumstances of the phone call.

MS. NEWBURY:

Q. Okay, and would other members of the Quality department have been in the same situation to discuss, you know, and answer questions on that particular point? It's a little different than the patient that was considered--you know, had zero/zero from the beginning and confirmed to be zero/zero.

MS. PREDHAM:

A. Yes, but we did have--you know, over that period of time, we did have ones that were not probably so dramatic as that, but we did have ones that were probably two and something and came back as zero/zero.

MS. NEWBURY:

Q. Okay, and there are several other--if you look down through that line six, seven and eight, they all are noted to be scheduled for review, but I couldn't locate any panel letters. Now one of them is a little curious because it's negative, negative going to zero, zero. That's in line seven, I believe. No, six.

Page 386

MS. PREDHAM:

A. That may have been the same person there. See where the bold lines are?

MS. NEWBURY:

Q. Um-hm.

MS. PREDHAM:

A. That may be the same, two specimens of the same person.

MS. NEWBURY:

Q. Okay.

MS. PREDHAM:

A. I'm not sure.

MS. NEWBURY:

Q. And also lines 9, 11, 12, 14, 16, these were all patients who were panelled but for whom there were no letters that I could locate.

MS. PREDHAM:

A. Okay.

MS. NEWBURY:

Q. And you're comfortable though that these patients would have all been contacted by now certainly?

MS. PREDHAM:

A. Definitely by now. After the review that we've done with the Centre for Health

Page 387

Information, they would find any gaps that we would have in that.

MS. NEWBURY:

Q. Thank you very much, Ms. Predham. Those are all the questions I have for you.

MS. PREDHAM:

A. Thank you.

THE COMMISSIONER:

Q. I understand the consensus of the room is that we press on. Mr. Simmons, I'll look at you. It's your witness.

MR. SIMMONS:

Q. All depends of course on how Ms. Predham is feeling.

THE COMMISSIONER:

Q. It's one of those -

MR. SIMMONS:

Q. And (inaudible).

THE COMMISSIONER:

Q. - one of those things where it's a real dilemma.

MS. PREDHAM:

A. A catch 22.

THE COMMISSIONER:

Q. How tired are you versus having to come back

Page 388

again another day.

MS. PREDHAM:

A. Not that I don't like seeing all your faces, but I'd rather press on today.

THE COMMISSIONER:

Q. Yes, we'll take that one with a grain, Ms. Predham. So we'll press on?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Mr. Crosbie?

CROSBIE, Q.C.:

Q. Thank you. I was going to avail of the high level of technology that we've all become used to here. I just want to raise the podium. Perhaps I'll just lift it up. That's the technology I meant there, this sturdy cardboard box. Thank you. I'm estimating about 40 minutes, by the way.

THE COMMISSIONER:

Q. All right.

MS. HEATHER PREDHAM--EXAMINATION BY CHESLEY CROSBIE, Q.C.

CROSBIE, Q.C.:

Q. I'd like to discuss with you, Ms. Predham, first of all, the issue of quality and risk.

Page 389

Your job title speaks to responsibilities in both areas, quality and risk, right?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. I guess, in my mind, and perhaps others, quality would seem to be focused on processes and systems that prevent adverse events. Does that seem reasonable?

MS. PREDHAM:

A. Well, I define quality as broader than that. It would be looking at processes and events that could--could increase patient satisfaction, could increase timeliness of treatment, so not just limited to adverse events.

CROSBIE, Q.C.:

Q. Not limited to safety, but satisfaction with the--with the overall contact or experience of the health care system?

MS. PREDHAM:

A. Satisfaction, utilization, efficiency, all those issues. Quality would be the broad umbrella of that. Safety would be one component, but it would be a broad umbrella.

Page 390

CROSBIE, Q.C.:

Q. Risk would be focused on dealing with situations that arise after an adverse event has occurred, would that be fair?

MS. PREDHAM:

A. No, again I think that's the--that's the reactive side of risk management, but the proactive side of risk management is to anticipate and determine what those issues can be that would cause an adverse event, and stop it before it happens.

CROSBIE, Q.C.:

Q. If--but you acknowledge that risk and risk management has an after the event component, which is important?

MS. PREDHAM:

A. Oh, definitely.

CROSBIE, Q.C.:

Q. And that includes managing situations where legal recriminations are in the offing?

MS. PREDHAM:

A. Could be.

CROSBIE, Q.C.:

Q. In your job, you don't report to the insurer on quality issues generally, do you?

Page 391

MS. PREDHAM:

A. No. I wouldn't say that I would report on quality issues. It would have to be--it would have to have some kind of implication that would be reportable, that a potential claim would arise.

CROSBIE, Q.C.:

Q. But you do report to them on risk issues?

MS. PREDHAM:

A. I would report to them on risk issues that have happened, not on the proactive side of my job. I would report on the reactive side.

CROSBIE, Q.C.:

Q. And risk issues that have happened would include potential litigation, as well as actual?

MS. PREDHAM:

A. Well, a potential claim is important to identify, and part of--not the purpose of occurrence reporting, but one of the benefits, I guess, of occurrence reporting is that you're aware of things before you actually get litigation.

CROSBIE, Q.C.:

Q. No doubt. I believe you told the Commissioner

Page 392

that you have to follow instructions of the insurer regarding liability questions or risk losing coverage?

MS. PREDHAM:

A. I don't think I put it that way. I think we would--if I did say that, on thinking about it now, I wouldn't put it that way. I'd put that we would have to consider it, and we'd also take--you know, as the claim progressed, we would have to, you know, follow requests of the insurer and provide documents and policies and that.

CROSBIE, Q.C.:

Q. Well, I gather loss of coverage is a background issue?

MS. PREDHAM:

A. It would be a concern. I've never come across an issue that we actually had loss of coverage, but it would be a concern.

CROSBIE, Q.C.:

Q. You believe--you believed in this ER/PR situation that you had to take the insurer's instructions on disclosure to patients on what to disclose and how to disclose it?

MS. PREDHAM:

Page 393

A. No, I don't think that was an issue. I don't think we took what we had to disclose and how to disclose it. We've disclosed in lots of issues regarding various statements of claim, and we've disclosed in that without instruction from an insurer. We've told them what we're going to say. If we're putting something in writing, we might run the letter by them, but we don't take direction on what we're going to say.

CROSBIE, Q.C.:

Q. There are views, however, through Mr. Boone were certainly sought?

MS. PREDHAM:

A. Oh, yes.

CROSBIE, Q.C.:

Q. Could we go to Document P-0287, page two, please. While she's doing that, this is an executive meeting, June 13th, 2007, which is of course after certification was granted at the end of May, 2007, and I realize that you were not present there, but you do have interactions with HIROC, the insurer. You see Item 1.6, "CEO meeting with minister and deputy minister".

Page 394

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. And it goes on to say, "CEO is scheduled to meet with the Deputy Minister of Health, Board chairs, and CEO's, on June 14th, 2007, and requested input on key messages", and amongst those bullet items we can see education is the first one, "To distinguish between errors versus variation in medical treatment". The second bullet is, "Move to a just culture", and the fourth one is, "HIROC's concern with full disclosure and the impact on insurability". The item about full disclosure seems to be linked to "just culture", and also the errors.

MS. PREDHAM:

A. I would not be able to pass any comment on that. I wasn't at that meeting. I certainly don't know what the issue is there.

CROSBIE, Q.C.:

Q. May I suggest one reading is that this is a statement that if Eastern Health made full disclosure of errors, it could lose insurance coverage?

Page 395

MS. PREDHAM:

A. Just to counter that, this was June of 2007, and I don't know why that would be an issue at that time.

CROSBIE, Q.C.:

Q. You can't help us out any further about what that means?

MS. PREDHAM:

A. No. Mr. Tilley was a member of the board of HIROC and maybe it was something that he learned through that route. I don't know.

CROSBIE, Q.C.:

Q. Yes, he told us he was a member of the HIROC board at a certain point in time.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Now on the question of an ethics consult, in 2005, did it occur to you or was it discussed in your presence that an ethics consult on disclosure should be sought?

MS. PREDHAM:

A. Unfortunately not. It would have been quite beneficial and it would have been a very good exercise to go through and help us go through

Page 396

this.

CROSBIE, Q.C.:

Q. What if you did seek ethics advice, and the advice was to make full disclosure in writing, and HIROC was against that, what would happen?

MS. PREDHAM:

A. Well, I don't know, but that's a very, you know, imaginary thing. HIROC wasn't against disclosure in writing, the oncologists were opposed to that at that time. I don't know what would happen at that time. There would be all feedback and a decision would have to be made.

CROSBIE, Q.C.:

Q. We have seen input from Mr. Boone stating a position that a letter should not go out for fear of creating a cause of action. Do you recall that?

MS. PREDHAM:

A. That was in October of '05?

CROSBIE, Q.C.:

Q. I believe it was, yes.

MS. PREDHAM:

A. I thought the feedback was communication at that time, not necessarily a letter.

Page 397

CROSBIE, Q.C.:
Q. Is it possible, Ms. Predham, that the reason nobody at Eastern Health--bring it back a step. To those of us not embroiled in the day to day management of this, I guess, crisis situation, you'd agree that it could be described as a crisis back in 2005 -
MS. PREDHAM:
A. Oh, I'd agree with that.
CROSBIE, Q.C.:
Q. To those of us not snarled up in the crisis, it seems like an obvious avenue to follow to seek an ethics consult about how to handle the situation.
MS. PREDHAM:
A. Well, looking back, Mr. Crosbie, I have to agree it would be an obvious thing to look back it, and we didn't do it, and I can't explain why we didn't do it.
CROSBIE, Q.C.:
Q. Could it be that the reason nobody at Eastern Health asked for an ethics consult in 2005 is that they did not want to be put in a situation of conflicted loyalty and potentially lose insurance coverage?

Page 398

MS. PREDHAM:
A. Absolutely not.
CROSBIE, Q.C.:
Q. That it was better not to get the ethics advice?
MS. PREDHAM:
A. Absolutely not.
CROSBIE, Q.C.:
Q. The question--we've heard your description of the meeting where a decision was made on sending a letter or not sending a letter to patients, and you described how Dr. Williams banged his fist on the table and that sticks in your memory?
MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. And said "call them".
MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. And your interpretation was that he was getting frustrated with the delays in formulating a letter and the logistics of getting a letter out to patients?

Page 399

MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. Some of us remain mystified by why it is that a letter could be such a logistical problem?
MS. PREDHAM:
A. I can only tell you what I remember, and I can only tell you that I know that Dr. Williams was frustrated with the discussion that was ongoing at that time, and, you know, put an end to it by saying "call them".
CROSBIE, Q.C.:
Q. Why not call them indeed, and send a letter confirming what you've told them?
MS. PREDHAM:
A. We should have done that, and I do believe that in my review in anticipation, I had commented in some document that we were going to do that, but that was something that was overlooked and missed.
CROSBIE, Q.C.:
Q. Just lost in the swirl of events?
MS. PREDHAM:
A. Lost in the swirl.
CROSBIE, Q.C.:

Page 400

Q. I believe your evidence is that the disclosure policy adopted in August, 2005, did not apply to multiple or mass adverse events situations?
MS. PREDHAM:
A. I guess the message I was trying to get across was that when we developed it, we weren't thinking of this type of situation because we hadn't come across anything this large beyond a couple of patients, so we hadn't anticipated this type of situation when we were writing that disclosure policy. The focus of the disclosure policy was individual patients.
CROSBIE, Q.C.:
Q. Indeed. Now you answered some questions from my colleague about this issue, so I may have missed some of the answer, but I may not be the only person suffering from information overload at this point. Just to press ahead with that, did you review the disclosure policies during the course of your involvement in the ER/PR matter to see if you should be conforming to them, or to determine whether or not they were applicable?
MS. PREDHAM:
A. I--we didn't sit down and go through the

Page 401

guidelines at the time and say this is what we were going to do, but, you know, as someone who drafted it, Dr. Williams who commissioned it, all the people, the players in there, were intimately aware of those guidelines. I don't think there was any need that we actually go through that policy. We were aware of the philosophy behind it.

CROSBIE, Q.C.:

Q. Are you aware of anyone who did review the disclosure policies and who stated the result of that review in your presence?

MS. PREDHAM:

A. No, I don't recall that.

CROSBIE, Q.C.:

Q. And stated whether or not the policy applied?

MS. PREDHAM:

A. I don't recall.

CROSBIE, Q.C.:

Q. And I guess there's nothing in writing to evidence that anyone undertook that exercise, is there?

MS. PREDHAM:

A. No.

CROSBIE, Q.C.:

Page 402

Q. Has anyone been tasked to write a disclosure policy that applies to multiple or mass patient situations?

MS. PREDHAM:

A. We're currently in the process, and someone in our department is tasked with drafting out a disclosure policy, a new disclosure policy, and parts of that would be to identify something of this nature, and, I guess, that's the drafting--the group that's looking at it is working through drafting on how to address that.

CROSBIE, Q.C.:

Q. Excellent.

THE COMMISSIONER:

Q. The current one will go, and there will be a new one which will encompass not only what you would describe as one or two patient incidents, but a larger thing, is that what you said?

MS. PREDHAM:

A. Yes. The disclosure guidelines, the one from the old Health Care Corp, was drafted with the mindset of a certain type of incident. When we became Eastern Health, the Canadian Patient

Page 403

Safety Institute guidelines on disclosure were forthcoming, they were in the works. So we put an interim one, which was fundamentally the same policy, in place in anticipation that shortly once those disclosure guidelines came in, we would build on that and utilize that.

CROSBIE, Q.C.:

Q. Do you know if there's a draft in circulation now?

MS. PREDHAM:

A. I'm not sure. I haven't been to work in the past month or so, so I'm not sure. I know it was tasked out and it was starting to look at--the first thing that they would have to do would be to research it, see if there's anything else out there, that kind of thing. So I'm not sure how far they've progressed.

CROSBIE, Q.C.:

Q. Could we have Document 56, please, P-0056, page 18, and that's from the administrative policy manual. It seems to have been signed into effect August 1st, 2005.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Page 404

Q. It is called "Guidelines on Disclosure of Adverse Events", and between this and page 20, I guess, is most of this--feel free to look through with your mouse. Can you explain to us what there is in this which does not apply to multiple or mass adverse events situations?

MS. PREDHAM:

A. I guess there's--there may not be anything that's specific to that, but I guess what I've tried to portray is that the comfort level of--or the perspective of going in this has been that this is solely on a--something has happened, you know the outcome, and you're telling the patient.

CROSBIE, Q.C.:

Q. So that's your answer?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. To change topics, there are instances where patients were not informed of changed test results for many months, as we've seen?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Page 405

Q. You tried to follow up with physicians to verify that they had met with patients, but I'm getting the idea that you weren't happy with the sort of response you got, or you didn't get a satisfactory response back from the physicians?

MS. PREDHAM:

A. Right.

CROSBIE, Q.C.:

Q. Just a questions in my mind, why not use a form which required the responsible physician to check off a box saying that he or she met with the patient and then it had to be returned to somebody responsible for tracking compliance?

MS. PREDHAM:

A. That would be an excellent idea, but we didn't do that, and even when we did the review this time in 2008, we didn't do that either.

CROSBIE, Q.C.:

Q. Was there a reason for it or just wasn't thought of?

MS. PREDHAM:

A. Never thought of it.

CROSBIE, Q.C.:

Page 406

Q. Because then if they don't return the form within a given period of time that you give them to do that, you can presume there's no compliance and the patient has not been informed, and then you can start to bug them?

MS. PREDHAM:

A. Oh, certainly.

CROSBIE, Q.C.:

Q. And you've got a central registry then of what's happened?

MS. PREDHAM:

A. Exactly.

CROSBIE, Q.C.:

Q. Well, maybe next time.

MS. PREDHAM:

A. I will file that away.

CROSBIE, Q.C.:

Q. May we have Document P-0308, page one. Let's see--I'm going to bring you down to the third last paragraph, "Finally, I think we should be aware that we will not be able to notify everyone", and this was sent to Pilgrim, Williams, Bonnell, and reading that, I guess a person could draw the inference that at a high level Eastern Health knew it would not be able

Page 407

to notify everyone from October, 2005?

MS. PREDHAM:

A. I guess you could say that. I had--I had concerns just from our contacts. We had been disclosing the confirmed negative results at this time, so I had realized that we had people that have moved and we had no other contact information, so I was aware of those problems then.

CROSBIE, Q.C.:

Q. A lady by the name of Rosalind Jardine testified here on the third day of the Commission hearings, and I get this information from a review of the transcript which I gather is publicly available, Commissioner.

THE COMMISSIONER:

Q. Yes.

CROSBIE, Q.C.:

Q. Okay, so whatever I'm saying, if it comes from the transcript, is public information.

THE COMMISSIONER:

Q. Yes.

CROSBIE, Q.C.:

Q. That's my understanding.

Page 408

THE COMMISSIONER:

Q. (Inaudible).

CROSBIE, Q.C.:

Q. Thank you.

THE COMMISSIONER:

Q. Any exhibits which would be C exhibits would not be.

CROSBIE, Q.C.:

Q. I understand.

THE COMMISSIONER:

Q. This comes from the transcript. So Mrs. Jardine was diagnosed in 1999 and had a lumpectomy--diagnosed with breast cancer. She had chemotherapy and she had radiation. Her ER was read as zero here and PR 25 to 30, read by Dr. Denic. Dr. Ganguly was equivocal on whether she was a candidate for Tamoxifen, but the medical oncologist--Ganguly, of course, is radiation--was Dr. Laing and she decided that the risks and rewards did not favour Tamoxifen. So she decided or advised, I guess, that Ms. Jardine was not a candidate for that. Unfortunately, she had a recurrence or a metastases was detected in September of 2005, and she received emergency surgery for

Page 409

that. She had her tissue sample read in October, October 27th 2005 by Dr. Mullen at Mount Sinai, and this returned a result of 50 percent ER and 20 percent PR. She was not offered Tamoxifen in 2005 because it was outside the time frame, which I guess is five years that they were working with at that time. She was offered other medications instead, and I can inform the Commissioner that I met with Ms. Jardine within the last two weeks and she's doing well still.

Now what I'm leading around to is the panel recommended no change in treatment for Ms. Jardine because change in treatment had already been implemented by Dr. Laing, who was this lady's treating oncologist. In other words, Dr. Laing didn't wait around for the panel to make a recommendation. She acted as soon as she knew the change in results.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. I guess we can have a look at C-0082, can we, Commissioner?

THE COMMISSIONER:

Page 410

Q. Yes.

CROSBIE, Q.C.:

Q. Thank you, and we can bring this down a little bit here. This letter is dated December 18, 2005, and you can see the second paragraph says more or less what I had just reviewed, that she had been treated by the time of this letter, treated appropriately, therefore there's no recommendation from the panel at this time.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Okay, and is this the--does this look like an official panel letter to you? Is that the form of a panel letter?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. A recommendation letter?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Okay.

MS. PREDHAM:

Page 411

A. The wording in the second paragraph would be--well, would be different, depending on the circumstances. But that's the format.

CROSBIE, Q.C.:

Q. Right. Okay, so what I'm getting around to is, was she counted as one of the statistical number of 117?

MS. PREDHAM:

A. Probably not. I think we had that discussion with Ms. Chaytor and probably not.

CROSBIE, Q.C.:

Q. Okay, and so there would be others in a similar situation?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. But you can't give us a number for how many?

MS. PREDHAM:

A. No. I mean, you know, we probably could figure it out, but no, I can't.

CROSBIE, Q.C.:

Q. But not at the present moment you can't?

MS. PREDHAM:

A. No.

CROSBIE, Q.C.:

Page 412

Q. Okay. Could we have document P-3468, please? This particular document seems to have originated from John Rumboldt.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. And who is that, please?

MS. PREDHAM:

A. He works at Department of Health. I'm not sure what his position is.

CROSBIE, Q.C.:

Q. And there was no date on this. It appears to be an e-mail from you, Heather. Is that right?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. To Mr. Rumboldt?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Undated, but you believe that this was sent on May 24, 2007?

MS. PREDHAM:

A. I think that because I was asked to locate the

Page 413

attachment, and I think it was in May 2007.
CROSBIE, Q.C.:
Q. In fact, I asked Ms. Chaytor if she could inquire of Mr. Simmons what the date was, that he could inquire of you. That goes back to March 18th this year when I asked that, and I got an answer on September 16th that the date of the memo is May 24th, 2007.
MS. PREDHAM:
A. Okay.
CROSBIE, Q.C.:
Q. Is that what you think it is?
MS. PREDHAM:
A. When I was asked to find the attachment, that's--that fits right with what I had to look for.
CROSBIE, Q.C.:
Q. So that's -
MR. SIMMONS:
Q. That's in 3067 (inaudible).
CROSBIE, Q.C.:
Q. 3067. 3067 would be the inquiry.
MR. SIMMONS:
Q. No, it has the answer.
CROSBIE, Q.C.:

Page 414

Q. The answer. Oh, so you mean the question and the answer -
MR. SIMMONS:
Q. The one that you have a copy of is embedded in the lower part of this e-mail, 3067.
CROSBIE, Q.C.:
Q. Oh, I see. So they're both the same day. Is that the idea?
MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. Ms. Predham, the inquiry and the answer was the same day though?
MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. Thank you. So the inquiry is "the Minister is looking for the info by the four RHAs. Do we have that?"
MS. PREDHAM:
A. I think that was a subsequent inquiry. I think that was--when I sent him this one, because it was 9:31 a.m., he came back at 9:40 asking me if there was info by four RHAs.
CROSBIE, Q.C.:

Page 415

Q. Okay. Well, let's go back to 3468? Thanks. Okay, so May 24, 2007, happens to have been a Friday and the last day of argument in the certification hearing. Does that seem about right?
MS. PREDHAM:
A. I can't remember that.
CROSBIE, Q.C.:
Q. Well, the Judge's decision, which was given orally, was on the 27th of May.
MS. PREDHAM:
A. Okay.
CROSBIE, Q.C.:
Q. And so if you count back, that would mean--well, that Friday, we were still arguing. So it would be during the course of the hearing.
MS. PREDHAM:
A. Okay.
CROSBIE, Q.C.:
Q. Okay, so this was a hearing at which Eastern Health placed reliance on the Dr. Gown affidavit, and you're familiar with that affidavit?
MS. PREDHAM:
A. Yes.

Page 416

CROSBIE, Q.C.:
Q. In fact, we could have a quick look at that. P-0375, page two, please? And Eastern Health placed reliance, amongst other things, on this paragraph six which states "the seven year average is 74 percent ER positivity," and you see that?
MS. PREDHAM:
A. Yes.
CROSBIE, Q.C.:
Q. This may be a matter for when the NLCHI witnesses come, but I just note in passing that the reference is not to ER or PR positivity, but just ER. But perhaps that's for tomorrow. At the very moment, Eastern Health was proffering the 74 percent to the Court as a true positivity rate, you were giving advice to someone in the Government who was asking for information on behalf of the Minister of Health. Is that right?
MS. PREDHAM:
A. I was locating a document, that I did not prepare, and providing it to the Minister, to the Department of Health.
CROSBIE, Q.C.:

Page 417

Q. Um-hm. So your answer is this short e-mail with a table or two tables attached to it, and, well, maybe you can just read the first two paragraphs, not the last short sentence but the first two, "here are the statistics" and would you read that?

MS. PREDHAM:

A. "The weak positive category is the clinically negative group. Up to 2000, it was 30 percent and less. After 2000, it was ten percent--up to 2000, it was 30 percent and less. After 2000, it was ten percent and less. In other words, you have to add the negatives and the weak positives together to get the number of clinically negative."

CROSBIE, Q.C.:

Q. Thank you. And then if we can go to the second page, which should be a table, I guess--oops, over shot. Is that your handwriting?

MS. PREDHAM:

A. No.

CROSBIE, Q.C.:

Q. Do you know whose?

MS. PREDHAM:

A. No.

Page 418

CROSBIE, Q.C.:

Q. Okay. This is the exhibit, page two. So there we have a table, and if you can go to page--sorry, go to strong positive percentage. It's about four items down in the left-hand column.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. You see strong positive and percentage.

THE COMMISSIONER:

Q. Are you able to see that there? Would you like us to make it a little larger?

MS. PREDHAM:

A. No, I can see it.

CROSBIE, Q.C.:

Q. And then cross reference that with the column "total DAKO" and you get 59 percent.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Do you see that there?

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Page 419

Q. So what I'm submitting to you, Ms. Predham, is that this document states the positivity rate for 1997 through 2004 is actually 59 percent.

MS. PREDHAM:

A. This isn't my document. This is Mr. Gulliver's document, but this only includes the results from in the Health Care Corp. That doesn't include the results from out of town.

CROSBIE, Q.C.:

Q. And is that an important distinction?

MS. PREDHAM:

A. I just pointed out that it's incomplete data, and I don't know what Dr. Gown based his--who gave information to Dr. Gown and what he based his affidavit on. But I'm only bringing that forward is that I didn't prepare this document and I only provided it to Mr. Rumboldt on his request.

CROSBIE, Q.C.:

Q. Were you aware or did you recognize at the time that there was an incongruity between the 74 percent that was being proffered to the Court through the affidavit of Dr. Gown and the 59 percent in this table?

Page 420

MS. PREDHAM:

A. I don't think I was aware because I don't think I saw Dr. Gown's affidavit until after it was filed in Court.

CROSBIE, Q.C.:

Q. When did you become aware of it?

MS. PREDHAM:

A. Aware of Dr. Gown's affidavit?

CROSBIE, Q.C.:

Q. Um-hm.

MS. PREDHAM:

A. I'm not sure. Somewhere along the way, but I can't remember. I can't remember exactly.

CROSBIE, Q.C.:

Q. Was it soon after the certification application?

MS. PREDHAM:

A. I really can't remember.

CROSBIE, Q.C.:

Q. When you did see it, did you become aware of what I had just referred to as an incongruity?

MS. PREDHAM:

A. I certainly didn't pick it up. I only discovered, in 2008, in fact that these numbers here don't reflect ER positivity,

Page 421

which I always thought they did. They do reflect hormonal positivity. So a combination of ER and PR positivity.

THE COMMISSIONER:

Q. When you say these numbers here, are you talking about that particular document you have in front of you?

MS. PREDHAM:

A. Yes. So when it says--and I guess it's more concerning when it's the ER negative and PR positive, strong positive. They could be into the strong positives, and this is Mr. Gulliver's data and I wasn't aware of that distinction when I had looked at it in previous times. But I only became aware of that in 2008.

CROSBIE, Q.C.:

Q. Okay. So your evidence now is this is based on either or, if there was a positive ER or a positive PR.

MS. PREDHAM:

A. It's a combination, and like I said, Mr. Gulliver would have to speak to that. I always thought it was only ER, but I found out after it was a combination.

Page 422

CROSBIE, Q.C.:

Q. Because Dr. Gown states his 74 percent in relation to ER.

MS. PREDHAM:

A. Yes.

CROSBIE, Q.C.:

Q. Do you know whether counting positive PRs would increase the positivity rate or decrease it?

MS. PREDHAM:

A. I have no idea.

CROSBIE, Q.C.:

Q. I think we'll see that it increases the positivity rate when we hear from the witnesses tomorrow. Last item, and I'm pretty close on the mark of 40 minutes.

THE COMMISSIONER:

Q. You may get the prize, Mr. Crosbie.

CROSBIE, Q.C.:

Q. Do you have any familiarity with the idea that a health care provider might owe a duty to a patient to put the patient's interest ahead of the interest of the health care provider?

MS. PREDHAM:

A. Well, yes. I mean, that's the priority of

Page 423

anybody in health care.

CROSBIE, Q.C.:

Q. That's not a foreign notion to you?

MS. PREDHAM:

A. No.

CROSBIE, Q.C.:

Q. In fact, that's a premise that you work with in your job?

MS. PREDHAM:

A. Exactly.

CROSBIE, Q.C.:

Q. Let's say that there is such a duty. We'll say hypothetically because I don't want to be suggesting legal propositions, which are a matter for argument. Let's say hypothetically that there is such a duty to put the patients interest first. In relation to disclosure, do you see any conflict between your loyalty to HIROC and your loyalty to patients?

MS. PREDHAM:

A. I don't see any conflict there, because HIROC is the insurance provider we have now. If Eastern Health went to tender tomorrow and changed insurance providers, there wouldn't be any loyalty there. We'd just have another

Page 424

insurance provider. And currently right now, we have, depending on the time of claim and occurrence and where it's located, we may deal with up to three different insurance providers.

CROSBIE, Q.C.:

Q. I'm not so much directly or posing the issue in relation to HIROC, as I am to your capacity in which it could be suggested you wear two hats, the quality hat and the risk manager hat. Do you see any inherent conflict between your responsibilities for quality and your responsibilities for risk?

MS. PREDHAM:

A. No, because a risk manager focus is on a safe environment and safety to the patient. The patient is always the focus and there's no--nothing else would override that.

CROSBIE, Q.C.:

Q. Thank you very much.

MS. PREDHAM:

A. You're welcome.

THE COMMISSIONER:

Q. Thank you, Mr. Crosbie. Mr. Simmons?

MS. HEATHER PREDHAM, EXAMINATION BY MR. DANIEL SIMMONS

Page 425

MR. SIMMONS:
Q. Ms. Predham, I know you're happy to see me, but you'll be even happier when you see me leave again.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. So I'll get right to the point as quickly as I can with this. I'd like to go right back to a couple documents that Mr. Crosbie just referred you to and first of all, P-0375, please. That's the affidavit from Dr. Gown that you were referred to and we'll go to paragraph six of that affidavit. The last sentence says "I have been advised that the seven-year average was 74 percent ER positivity." Do you see any definition there or description of what Dr. Gown is determining to be a positive versus a negative result?
MS. PREDHAM:
A. No.
MR. SIMMONS:
Q. Okay. 3468, please, second page? This is the other document Mr. Crosbie showed you and this is the table that you forwarded on to Mr.

Page 426

Rumboldt which you say originated elsewhere, and he referred you to the total number of tests with strong positive percentage, which is the fourth row. If you go farther down, you'll see a row that says "tests reported with positive staining, strong plus weak." It's the second one from the bottom.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. You see that?
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. And if you carry that over to total DAKO, percentage there is 75.8 percent.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Does that seem consistent with Dr. Gown's statement in his affidavit?
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Okay. Now you've been asked a number of

Page 427

questions by a number of people about your role as a risk manager, and you've made the distinction between, I guess, what we'll call claims management and risk management.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. And if I understand correctly, you've said that there is a proactive side to being a risk manager and a reactive side. The management of claims made by people where those claims have to be reported to an insurer, is that the reactive side of the role?
MS. PREDHAM:
A. Yes, it is.
MR. SIMMONS:
Q. Okay, and the proactive side involves doing things which you do where there has been no claim made against the organization and the insurer is not involved -
MS. PREDHAM:
A. Exactly.
MR. SIMMONS:
Q. - in any capacity? Is that right?
MS. PREDHAM:

Page 428

A. Yes.
MR. SIMMONS:
Q. Okay. Can we have P-3369, please? Ms. Predham, this is a document you provided me with and you identified it earlier for Ms. Chaytor as being related to the accreditation program of the Canadian Council on Health Services Accreditation, CCHSA.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. And I believe you told us what time period this came from, and I've forgotten.
MS. PREDHAM:
A. 2005.
MR. SIMMONS:
Q. 2005, so this is a fairly current statement from CCHSA.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. The very beginning there says that there is a CCHSA aim standard which requires that the governing body and managers prevent and manage any risks to the organization. Do you know

Page 429

what an aim standard is? Do you know enough about the accreditation process to give me some idea about that?

MS. PREDHAM:

A. The CCHSA, the format they have, they have standards and it's different, I guess, different levels. The standard is an overall standard and then they have different criteria. I can't remember the terminology right now. And part of the self-assessment below the standard, they would have criteria which you would have to rate yourself, rate the organization against.

MR. SIMMONS:

Q. Uh-hm, okay. And do you understand this section of the CCHSA standards to speak to what's expected of an organization in its risk management function?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. I'm just going to take you right on to page six. There's some questions and answers here and under this third question, it begins with a statement, "Your overall objective is to

Page 430

minimize risk and poor outcomes and thereby minimize liability." So it does speak to minimizing liability, but as a result of minimizing risk and poor outcomes, is that consistent with your understanding of a risk management role in the organization?

MS. PREDHAM:

A. Yes, the focus is always on the patient or client or resident and as a side effect, you're reducing liability.

MR. SIMMONS:

Q. Okay, and on the next page, there's a question, "How does the concept of patient client safety fit into risk management and quality?" And I'm just going to read out the answer there. It says, "CCHSA believes that care cannot be of high quality unless it is safe; therefore, patient safety has always been a main concern for CCHSA. Your organization's risk management and quality management activities work together to improve processes and outcomes and de-minimize risks. From the point of view of accreditation, your organization's self assessment on-site survey, follow up on recommendations and use of

Page 431

indicators provide a great ability to detect, prevent and learn from patient safety issues." How does that fit with your understanding of what the role of risk management is in your organization?

MS. PREDHAM:

A. That fits my understanding.

MR. SIMMONS:

Q. Now I don't see anything in this document that talks about the management of claims at all.

MS. PREDHAM:

A. No.

MR. SIMMONS:

Q. You've told us that there is a provincial organization of sorts among risk managers in health care in Newfoundland and Labrador?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Yes, can you just tell me a little bit of what that's all about?

MS. PREDHAM:

A. Probably in 1998 the Nursing Homes Board Association, the Health Care Board's Association would have a meeting where quality

Page 432

people would get together once a year and talk about different activities, from '96, '97. And in '98, myself and the risk manager from Western determined the need to have a group of risk managers from across the province get together to talk about issues that we were facing and share information of similar projects we were doing, policies that we were doing. So at that time we established a risk management network and we would meet by conference call monthly and at a certain point in time, we became a chapter in the American Association of Health Care Risk Managers and one of the key things that we've done as a group is education for people, and educating staff about root cause analysis, failure mode and affects analysis.

MR. SIMMONS:

Q. Okay, and you've also provided me with a document in relation to that, P-3055 please? Now I understand this to be a promotional brochure for a conference put off by that organization in October of 2001?

MS. PREDHAM:

A. Yes, that was the first one we did and I guess

Page 433

one of the issues that we found was that the education budgets of the health boards were not very robust, so we weren't getting away to any national conferences on risk management. So we asked--well we decided how about if we brought people here? So we organized this organization and the two main people that we had come speak to us was Catherine Tolton. This was right after the cardiac surgery inquest in Winnipeg, so she was the counsel and came to tell us about the situation and what they learned and it was a lot of system errors and also about reporting of occurrences and disclosure to the family were a lot of issues that came out of that. And we also had David U from the Institute for Safe Medication Practice and really this was the first time we heard about their work in the analysis, subsequent analysis of medication occurrences and what you can do with that on a trending level and to increase reporting.

MR. SIMMONS:

Q. Okay. I'm not going to go through this brochure in detail with you, but is it fair to say that the topics that were discussed at

Page 434

this conference were generally related to prevention of occurrences, identification of risk and avoidance of harm, as opposed to anything to do with the management of claims once they're made against the organization?

MS. PREDHAM:

A. Oh definitely.

MR. SIMMONS:

Q. You've been asked many questions about HIROC, the insurer. Am I correct in understanding that HIROC, in addition to providing actual insurance coverage as a commercial insurer would, also provides some tools and assistance from time to time on the prevention side as well.

MS. PREDHAM:

A. Yes, they have a very strong risk management side of their organization. One of the biggest tools they have is RMSAM, we have two things with very similar acronyms, it's Risk Management Self Assessment Module. They base it on actual claims across the country and they look at--they analyze the claims and then look at things that organizations can do a self assessment of risk management strategies

Page 435

to prevent similar claims from happening in their organization.

MR. SIMMONS:

Q. Right, so they would be aware from claims made elsewhere of areas where there is potential for patient harm?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. And use that information to help other member organizations to self assessments in those particular areas?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Has Eastern Health or Health Care Corporation before that participated in those self assessments?

MS. PREDHAM:

A. Yes, we've done several, well the Health Care Corporation did several, the other legacy boards had done, the ones that were linked with HIROC had done them and Eastern Health has just completed one and I think we're in the process now of getting ready for the next

Page 436

one.

MR. SIMMONS:

Q. Okay, and have you been involved in any of those yourself?

MS. PREDHAM:

A. Peripherally. One of the members of our department is the co-ordinator of that project.

MR. SIMMONS:

Q. Right, okay, so although you've been in the risk management role quite a bit, someone else in quality has actually been the person involved in this self assessment sponsored by HIROC?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. And I believe you could also give us an example concerning information provided by HIROC concerning sterilization equipment or incident as another example?

MS. PREDHAM:

A. Back in, I think it might have been 2003 there was a serious incident with sterilization of critical or semi-critical equipment in Ontario

Page 437

and the government of Ontario mandated a full review of all processes in all hospitals in the sterilization of critical and semi-critical equipment. We had, of course, read about this and had planned to do the same thing ourselves, but HIROC had the audit and shared it with all the subscribers in case they, you know, and actually encouraged them to go through that process, so we used that tool to go through that.

MR. SIMMONS:

Q. Okay. So that's another example, is it, of an involvement in identifying potential hazards and dealing with them before any harm materialized from it.

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Now, you've been shown P-0073 before, I'd like to bring it up for just a minute, please. This is from July 19th, 2005, it's your e-mail message to Dr. Williams and others following a conversation you had with HIROC. It concerns, it's at the time at which disclosure is being considered. In the third paragraph there,

Page 438

it's where you say "It's not that they don't want us to disclose, they just don't want us to disclose until we are sure of our facts." Now, my first question is, did HIROC or anyone on its behalf give any direction to you or anyone at Eastern Health at this time concerning the manner of disclosure and whether there should be disclosure or anything concerning the course of action that Eastern Health was to take, any direction?

MS. PREDHAM:

A. No.

MR. SIMMONS:

Q. This appears, from the context of this e-mail message to be that some advice was being given of things to consider.

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Is that a fair way to characterize it?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Between this time and the 10th of August which was when the meeting was held where Dr. Laing,

Page 439

I think Dr. McCarthy were present and there is discussion about whether the organization should wait until results were back before notifying patients. Between this message and that meeting on the 10th of August, can you tell me how much, if any, influence this position communicated to you from HIROC had on the organization delaying giving any notification or making any public announcement in that timeframe?

MS. PREDHAM:

A. The only influence would have been making sure we had the story straight, but really because the situation changed dramatically the next day or we thought it changed probably two days after that, little or no effect.

MR. SIMMONS:

Q. Okay. After the 10th of August, after the oncologists make their position known on disclosure, did this position continue to have any influence at all on the course of action the organization took after that time?

MS. PREDHAM:

A. No.

MR. SIMMONS:

Page 440

Q. I'm going to jump right up to September 30th now. September 30th, you've told us that you were in a meeting with Ms. Bonnell when the call came The Independent concerning an inquiry which led to The Independent story being published on the 2nd of October. You've told us you were meeting with Ms. Bonnell to discuss a letter.

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Form of a letter. You've told us that by that time, the first results from Mount Sinai had been returned a short time before.

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Okay. Now, the letter that you were discussing, who was that letter intended to be directed to?

MS. PREDHAM:

A. The patients who were going to be retested.

MR. SIMMONS:

Q. So it would be going to the patients who would be retested, as opposed to just those whose

Page 441

results had been returned?
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Now that sounds like the type of letter that was being discussed back in July, August of 2005.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. So at that point were you picking up, in essence, from where things had been left off?
MS. PREDHAM:
A. I guess we were re-evaluating the plan.
MR. SIMMONS:
Q. Okay, and was there any consideration being given then by you or Ms. Bonnell to public notice or announcement in addition to preparing letters to go to the patients to notify them that their samples were to be retested?
MS. PREDHAM:
A. Well I guess that was part of the process. It was, you know, we were looking at the plan again, that was always part of the plan,

Page 442

notification of the patients and public disclosure.
MR. SIMMONS:
Q. Okay, but I gather that that process, while it had restarted, had not advanced very far before The Independent story got ahead of it.
MS. PREDHAM:
A. Oh no, this was our first action.
MR. SIMMONS:
Q. Okay. Now I'll bring you right now to P-0092 please? This is the e-mail message from Mr. Boone on the 18th of October, 2005, you've told us that you did not see this message until after your meeting that day with Dr. Williams and others at which the decision was made to phone patients instead of sending a letter, is that correct?
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. You've told us that in your conversation with Mr. Boone, you understood him to be hesitant and my question is what, on the phone, did you understand him to be hesitant about the organization doing?

Page 443

MS. PREDHAM:
A. Hesitant about disclosing.
MR. SIMMONS:
Q. About disclosing. Was the hesitation confined to the sending of a letter or was it more generally about making contact with patients at that time?
MS. PREDHAM:
A. Oh it was hesitancy about contacting patients, not the letter.
MR. SIMMONS:
Q. When you communicated that hesitancy to Dr. Williams, how did you communicate it? What message did you give him?
MS. PREDHAM:
A. I told him that, you know, a brief conversation, that Mr. Boone had expressed hesitancy in communicating with patients and Dr. Williams said it's too late for that now, we're going ahead.
MR. SIMMONS:
Q. Okay, and at that meeting a decision was made to communicate to the patients, not by letter, but by telephone?
MS. PREDHAM:

Page 444

A. Yes.
MR. SIMMONS:
Q. So did the hesitancy that was communicated by your to Dr. Williams, in your view did that have any impact at all on the discussion on the decision that was made at that meeting?
MS. PREDHAM:
A. Oh no, Dr. Williams disregarded it.
MR. SIMMONS:
Q. Now, throughout this whole piece in relation to disclosure to patients, was there ever any direction from the insurer that the organization had to take any particular action or was prohibited from taking any particular action in relation to disclosure?
MS. PREDHAM:
A. No.
MR. SIMMONS:
Q. Were you ever told by anyone, the insurer or on its behalf, that there was going to be any consequences as a result of ignoring any advice from the insurer in relation to disclosure?
MS. PREDHAM:
A. No.

Page 445

MR. SIMMONS:
Q. And in fact, the organization did ignore advice, correct?
MS. PREDHAM:
A. Yes, yes.
MR. SIMMONS:
Q. And were there any consequences as a result of ignoring the advice?
MS. PREDHAM:
A. No, there wasn't.
MR. SIMMONS:
Q. You've been asked a number of questions about external review reports prepared by Dr. Banerjee and Ms. Wegrynowski and when Ms. Chaytor was questioning you, she went through one of the reports and had you identify areas which you considered to be matters of fact and areas which would be matters of opinion.
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Because you had said that factual matters were not caught under the confidentiality that surrounded the reports, but opinions generally were.

Page 446

MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Do you recall that?
MS. PREDHAM:
A. I do.
MR. SIMMONS:
Q. Okay. So first of all then, aside from any legal protections provided by the Evidence Act to those reports, is it correct to say that there is an underlying concern for confidentiality that's grounded in promoting full disclosure by people involved in a peer review and quality assurance process?
MS. PREDHAM:
A. Yes, that's fair.
THE COMMISSIONER:
Q. I'm sorry, would you say that again?
MR. SIMMONS:
Q. The principle behind wanting to promote confidentiality in the peer review and quality assurance process is to promote full disclosure and open discussion by the participants in the process?
MS. PREDHAM:

Page 447

A. Yes.
MR. SIMMONS:
Q. And that's generally accepted within health care, is it?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. The principle behind confidentiality is promotion of full disclosure by the participants in the process. Who are the participants?
MS. PREDHAM:
A. Well it depends on the actual peer review--the quality review. Sometimes it could be the nurses or the team physicians, you'd want them to be able to feel comfortable speaking their mind and that you're not going to go around saying this is what so and so said.
MR. SIMMONS:
Q. So is one of the objectives then that you want people who are interviewed or who give information to the reviewers to be able to speak in confidence to that?
MS. PREDHAM:
A. Yes.

Page 448

MR. SIMMONS:
Q. And is it that you want the people who are speaking to the reviewers to feel free to give their opinions?
MS. PREDHAM:
A. Oh definitely.
MR. SIMMONS:
Q. And do you want the reviewers to feel free to give their opinions as well?
MS. PREDHAM:
A. Yes.
MR. SIMMONS:
Q. Okay. Now, when the review results in a report that contains facts, you've said that those facts are not confidential, those facts can be disclosed, so that if, for example, a review here were to say, there was no check list for the tissue processor, that would be a fact which the organization would be free to disclose, right?
MS. PREDHAM:
A. Certainly.
MR. SIMMONS:
Q. Would you feel that you'd be free to disclose that that was discovered as part of the

Page 449

quality review; in other words, that it came out of the quality review process?

MS. PREDHAM:

A. No, I think we'd prefer to say that it was we don't have this, we don't, you know, this is a fact of the case that this does not exist. We wouldn't say the reviewer has told us this did not exist or this is the information we got out of there.

MR. SIMMONS:

Q. Okay, so by taking that approach, would you be protecting the confidences of the people who participated in the peer review process?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Only a couple more items.

MS. PREDHAM:

A. Thank you.

MR. SIMMONS:

Q. You've mentioned a couple of times that in the spring of '06, you consulted with the health research unit about potential analysis of the test results once they all became available.

MS. PREDHAM:

Page 450

A. Yes.

MR. SIMMONS:

Q. Now can you tell me a little more about why you were consulting, who you spoke with, what you found out, where that went?

MS. PREDHAM:

A. Well all along or throughout this process, Dr. Cook and I had talked numerous times about having to do an analysis of the data and I guess going through the panelling process that became, you know, more evident and when we finished, when we got all the results back, we're going to have to do a full analysis of that.

MR. SIMMONS:

Q. Uh-hm.

MS. PREDHAM:

A. So I went over to the health research unit and met with a biostatistician to give him a broad description of the type of information that we had and the circumstances in which this evolved, very, very board. And when we were going--because I wanted to make sure that we had the information available and in the, you know, in the format that he would need or

Page 451

whatever, and that they would agree to do it. So when we had that discussion, that was the type of things that we covered, the type of information that he would need, anything that would influence the results over the time period, you know, this type of issue.

MR. SIMMONS:

Q. Okay. And what came of that consultation? What were the results of that then?

MS. PREDHAM:

A. Well, he--well it became evident that I needed more concrete information. There was going to be a little bit of--there was going to have to be some decisions made around parameters of change, for instance, so if somebody's results were, you know, originally zero and came back 30, did that mean the same as if they were, you know, PR 60 and came back as PR 90, you know, so what was--what were the significant areas of change. Was it a number? Was it numerically, you know, so five percent was significant, ten percent was significant or less than five was not, or did it matter on, you know, whether it was in the high positives, did that matter if that was a

Page 452

change. So that would be something that we would either have to get from research or from the pathology world.

MR. SIMMONS:

Q. So that was a beginning in considering what could be done about analysis of the information. Now from following on that then, the--if I understand from what you've said, before the process of completing and the collection of the data, dealing with the special cases and so on had to be completed, was there a plan to go back to that kind of approach that you discussed with the health research unit once the retesting data was all collated and prepared?

MS. PREDHAM:

A. Oh yes, it was always a plan to do that.

MR. SIMMONS:

Q. Okay, one final thing I just want to ask you about, a minor point, in Exhibit P-2976 please? I'm doing my best to move along quickly.

MS. PREDHAM:

A. That's good, I appreciate it.

MR. SIMMONS:

Page 453

Q. You were asked about this request from the Muse, the Memorial University Student Newspaper for answers to some questions and this was the version that Ms. Pilgrim sent to you which she described as the final version and you were shown this in question three where it said, "We anticipate that eight to ten percent of those being retested will be affected." And I just want to show you P-0665 please? This is a subsequent e-mail from Dianne Smith whom you've identified as Ms. Pilgrim's assistant, to a Mandy LeRiche, who I believe was the Muse correspondent and it has copies of the answers that actually went to the Muse and in No. 3 it says, "We anticipate that less than ten percent of patients will be affected." Now, did that statement accord more with what you had understood Dr. Williams to be publicly stating up to that time?

MS. PREDHAM:

A. I think it does, you know, it's hard to remember right now, but I think it does.

MR. SIMMONS:

Q. Yes, okay, good. Okay, thank you, Ms. Predham, I don't have anything further for you.

Page 454

MS. PREDHAM:

A. Thank you.

THE COMMISSIONER:

Q. Thank you. Anything arising Ms. Chaytor?

CHAYTOR, Q.C.:

Q. Commissioner, there is a potential question arising; however, it concerns an exhibit that's on hold right now and until we can work that out with counsel for Eastern Health, I don't know that I can ask the question.

THE COMMISSIONER:

Q. Okay. We have these little problems from time to time, Ms. Predham.

MS. PREDHAM:

A. I can imagine.

THE COMMISSIONER:

Q. The basic message is that while I will be telling you thank you very much for your assistance in this matter, there is a possibility that there may be another question at some point in the next week or so and I'm sure counsel will be talking with Mr. Simmons and they will let you know as quickly as possible what the resolution of that is because I have no idea what they're talking about.

Page 455

MS. PREDHAM:

A. Okay.

EXAMINATION BY THE COMMISSIONER

THE COMMISSIONER:

Q. There is one question though arising out of matters raised by Mr. Simmons that I would like you to clarify for me. And that is the business of what you and Ms. Bonnell were doing on that faithful day in September when the call came from The Independent.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And as you described it in answer or perhaps more Mr. Simmons described it and you agreed with his description, that this was sort of a picking up--I'm not sure where I got this idea, whether it was from your evidence or perhaps from Ms. Bonnell who had been here quite some time ago, but my impression was that Ms. Bonnell in particular was most anxious that one get on with this and that actions be taken. So what I'm interested in knowing was, was this the large group deciding it was time to do this or was this you and Ms. Bonnell trying to push it to get something started, to get something done, to get the thing moving again? Or perhaps some third alternative that I haven't thought of.

Page 456

MS. PREDHAM:

A. Well it was, the whole thing, it was like something hanging over your head all summer, you know, no one--we agreed with it when Dr. Laing brought up the issue and so eloquently spoke to it, I could certainly see her point and we went with it, but you just, you know, it didn't sit right. It didn't, you were okay with it, but, you know, it didn't settle and I guess this was Ms. Bonnell's and my first attempt of okay, let's get this started again, let's get together, we'll do that and, you know.

THE COMMISSIONER:

Q. So that was sort of two of the people whom one might say were involved in the group trying to make initial steps, what in your view might be bringing it back on course, is that fair?

MS. PREDHAM:

A. Yes, yes.
THE COMMISSIONER:
Q. Okay, thank you. And that was the only one question you had, Ms. Chaytor?
MS. CHAYTOR:
Q. Yes, that's it.
THE COMMISSIONER:
Q. Well, it is for me, thank you very much. I know it has been a long few days on your part and I very much appreciate your coming. Frankly, I was interested in finally meeting you because so many people said "Ms. Predham will know that" and that's one of the reasons you have been here for such a long period of time. Thank you very much.
MS. PREDHAM:
A. Thank you.
THE COMMISSIONER:
Q. See the rest of you in the morning at 9:30.
Upon conclusion at 6:15 p.m.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 22nd day of October, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.
Dated at St. John's, Newfoundland and Labrador this 22nd day of October, A.D., 2008
Judy Moss

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