COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

September 11, 2008

Appearances:

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

Rolf Pritchard/Jackie Brazil . . . . Her Majesty in Right of NL

Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al

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

Laura Brocklehurst. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

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Q. Commissioner, the next witness is Dr. Denic.
DR. NEBOJSA (NASH) DENIC, SWORN, EXAMINATION BY BERNARD COFFEY, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
DR. DENIC:
A. It's Nebojsa Denic, N-E-B-O-J-S-A, Denic, D-E-N-I-C.
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. And Doctor, while we're on your name, I take it the first name that people know you by is Nash?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay, because we've seen references to it at times, N-A-S-H is the ways it's spelt?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. Doctor, before I get into my questioning, I'd ask the Commissioner, please, Commissioner, there are exhibits, new exhibits, please. Exhibits P-2635 through 2704 inclusive and P-2706 through P-2728 inclusive. In other words, all the way from 2635 through 2728, with the exception of 2705.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-2635 THROUGH 2704
EXHIBITS ENTERED AND MARKED P-2706 THROUGH 2728
COFFEY, Q.C.:
Q. Registrar, would you open, please, Exhibit P-2635? And Doctor, there on the screen in front of you is a curriculum vitae for yourself? That's yours?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And it's relatively current?
DR. DENIC:
A. Relatively current.
COFFEY, Q.C.:
Q. You provided it relatively recently to the

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Commission. Doctor, I'm going to ask you, please, to tell the Commissioner about your educational and professional background, just--you can use this, if you need it, but otherwise, you can just simply go ahead and tell us.
DR. DENIC:
A. Okay, I can just use -
COFFEY, Q.C.:
Q. Sure, you can if you wish.
DR. DENIC:
A. - for reminder.
COFFEY, Q.C.:
Q. Sure.
DR. DENIC:
A. Commissioner, I graduated in Medical School of Belgrade, Belgrade University, or Belgrade, former Yugoslavia, current Serbia, in 1982. After that, I completed the rotation, medical internship and passed a state exam and therefore been fully licensed to practice medicine in former Yugoslavia.
COFFEY, Q.C.:
Q. And that would be in 1983, Doctor?
DR. DENIC:

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A. That's correct. I finished a year of military service. It was mandatory at that time, serving as a physician, in 1984, and in December of 1984, I started my residency training program in forensic medicine at the Institute of Forensic Medicine in Belgrade University of Belgrade. In 1985, I completed the Master of Science in Neurobiology at the University of Belgrade, and in 1988, I finished with my residency training program in forensic medicine, which is three and a half years, and been certified at further examination. So I'm a certified forensic pathology with interest in forensic medicine too. In 1991, I completed a PhD defending a thesis in the field of forensic medicine. I did some additional training in Baltimore in forensic medicine as a sabbatical.
I came to Canada in 1992 at the invitation by the Hospital for Sick Children in the Chief Coroner office, to do research and consulting in pediatric forensic pathology unit, where I stayed for three years.
COFFEY, Q.C.:
Q. That would be in Toronto?

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DR. DENIC:
A. In Toronto.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. And after that, I had been offered the residency training program in anatomical pathology at the Memorial University here in St. John's, which I started it in 1995 and I completed the four years of residency training program in 1999 and I completed the exam in the first attempt and got certified by the Royal College of Physicians and Surgeons and became the fellow of Royal College of Physicians and Surgeons of Canada.
COFFEY, Q.C.:
Q. And that was in 1999, Doctor?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And you're certified in anatomical pathology?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay.

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DR. DENIC:

A. I passed the various exams in order for licensing and my full license was issued by the College of Physicians and Surgeons of Newfoundland and Labrador, at the time it was Medical Board, and my license is in good standing.

In some of my work experiences, while practising in the former Yugoslavia, I was practising at the Institute of Forensic Medicine as assistant professor in forensic medicine and actually ending my career down there as associate professor of forensic medicine, teaching at the three faculties and in two republics at that time. Today it would be two states.

After the completion of the residency training here in Newfoundland, I was offered position with the Health Care Corporation, at that time, and that my job at the St. Clare's Mercy Hospital where I'm still practising as a staff pathologist. My career actually, evolved actually just in terms of the administrative functions that I hold and I've been serving as a treasurer, vice-president

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and the president for the medical staff. I was also president of Newfoundland and Labrador Association of the Pathologists from 2004 to 2007.

I was offered the position of interim clinical chief in 2006, which was March 2006, and I hold that position until May of 2007, when this position was turned into the permanent position as clinical chief of the anatomical pathology program and laboratory medicine program. In April of this year, this position was officially changed to the position of the Chief of Laboratory Medicine for Eastern Health, and this is the position that I currently hold.

COFFEY, Q.C.:

Q. And Doctor, some aspects of your training, I'll be asking you about, but while we're on the topic of administrative positions, okay, Doctor, while you were at St. Clare's, and I take it you began as a staff person at St. Clare's in 1999?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

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Q. At that time, the site chief, there was a site chief and that would have been Dr. Cook?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And at various points afterward, Dr. Cook was not only site chief, but he was also interim clinical chief while Dr. Haegert was away on sabbatical, and then in a period after Dr. Haegert came back, Dr. Cook became clinical chief?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. In fact, you took over from Dr. Cook in 2006?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. While Dr. Cook was site chief at St. Clare's and you were there as a staff person, did you hold any position? Were you assistant site chief or substitute site chief in any way?

DR. DENIC:

A. Yes, in a certain period of time, I think that would be a period maybe 2004, 2005, whenever

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Dr. Cook would take a vacation or he would be away on a conference, he would ask me, you know, just to take on these duties and deal with the issues that may arise during his absence.

COFFEY, Q.C.:

Q. And we'll see some reference to that in a couple of the exhibits, and in terms of those particular times that you had to substitute for--fill in for Dr. Cook in that capacity, I take it they were relatively short periods of time?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Couple of days or a couple of weeks?

DR. DENIC:

A. Couple of days and even a couple of weeks.

COFFEY, Q.C.:

Q. Yes, but that would be about it. Doctor, other than that, I take it the site chief duties were left to Dr. Cook?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

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Q. Doctor, could you tell us, please, in relation to your duties, I just want to clarify this, even as of today, I take it Dr. Cook is still the site chief?

DR. DENIC:

A. Yes, he is.

COFFEY, Q.C.:

Q. He's remained site chief throughout the whole period of time you've been at St. Clare's?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And Doctor, as interim clinical chief and then initially as clinical chief?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Could you tell the Commissioner, please, what your duties were?

DR. DENIC:

A. The duties of the clinical chiefs are defined by bylaw, and the duties are that the clinical chief, along with the program director, they're responsible for the operation and the quality of the lab. That's a general

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statement and that we were accountable to vice-president of Medical Services. As a part of other duties is that clinical chief has to be the member of the medical staff that has to attend the meetings of the clinical chiefs and MACs and get involved in planning of the laboratory medicine operations, along with the program director.

Also, the duties are that clinical chief is involved in recruitment and retention and some of these duties has to be liaised with our discipline chair, since a certain number of our members are the faculty members and that falls under the jurisdiction of the discipline chair. The other duties is that clinical chief has to liaise with other departments and the clinical chiefs and look into the needs of those departments that work the service that we provide. Some roles of the clinical chief are also defining the budget, but that budget should be defined by original, at that time, just program director and the vice-president, that's all.

We have to promote research in our institution and liaise again in that regards

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with the discipline chair. We have to support educational activities, educational activities from the undergrads, post grads and anybody rotating through the program.

So these are the broad-based duties.

COFFEY, Q.C.:

Q. Okay, Doctor, and that was while you were clinical chief, either interim or had the title of clinical chief?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, approximately how much of your time would be devoted to clinical chief's duties, as opposed to a staff pathologist's duties?

DR. DENIC:

A. That would change, you know, but understanding was around 50 percent of the time would be taken by the clinical chief's duties, but that really fluctuates and it's difficult to define and sometimes you turn your administrative duties really into the full week and then you're falling off the schedule from being a pathologist, but I would say around 50 percent of the time.

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COFFEY, Q.C.:

Q. Was there any--and I want to ask you about, when you took over as interim clinical chief and continued on as clinical chief, was there any written stipulation as to how much--or recognition of how much of your time would be administrative, as opposed to clinical?

DR. DENIC:

A. I don't believe it was written one, but it was my understanding, talking to Dr. Williams as well and to Dr. Cook, and just to see how much time this takes, because there was discussion that I would have with Dr. Cook before I took this position.

COFFEY, Q.C.:

Q. And I take it then that in taking on the workload of a staff pathologist, the recognition would be, for the clinical chief would be that he or she would, if it was 50 percent of the time administrative, then they would do 50 percent of the regular staff person's time taking in cases, clinical cases?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

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Q. That would be the way that -
DR. DENIC:
A. That would be the way that it would try actually to accomplish. However, you see that being a clinical chief and being an administrative duties, I personally don't consider myself as administrator because administrative duties, they have the limited life and you don't want to lose your medical skills, and while this would be sometimes on the paper that I would be twice less put on the rotation through the surgical pathology service, I would go and take additional cases myself, and especially when Dynacare come into place, the cases that would be supposably sent to Dynacare, whenever I had the free time, I would go to that room and pull out the cases back from the Dynacare file and bring it to my desk.
COFFEY, Q.C.:
Q. Now Doctor, you've indicated that in April of this year, April 2008, that the title of your position changed, or the position changed?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. And it's now the -
DR. DENIC:
A. Now I'm Chief of Laboratory Medicine for Eastern Health.
COFFEY, Q.C.:
Q. Okay, so it's Chief of Laboratory Medicine as opposed to clinical chief?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. So in your capacity as Chief of Laboratory Medicine, what are your duties and how do they differ from your clinical chief's duties and the reporting structure?
DR. DENIC:
A. Reporting structure have been changed, not all the way down, but changed from the top. Reporting structure is that we still have on the top of the pyramid, if you will, the Vice-President of Medical Services and Diagnostic, which would be Dr. Howell, and then I would be under him as Chief of Laboratory Medicine for Eastern Health, and then we would have Mr. Terry Gulliver who is the regional program

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director for the Laboratory Medicine who would be accountable to me, although there is an arm that goes between him and Dr. Oscar Howell. So if there's any budgetary issues, which he still handles, or some kind of administrative issues that he can then directly report to Dr. Oscar Howell. The remaining portion of the structure hasn't been changed, yet be in a process of revisiting. We were looking in some models recently just to see how that works in other big labs and for that purpose, we took a trip to Toronto, actually Ontario in general, and visited four labs just to see how they operate and what is the way of operation.
The plan is now that we work, the words, developing the bottom part of the chart and just to see what are the responsibility of other personnel and what's going to be the interaction of other personnel, and I think yesterday, they were supposed to have a meeting because the new regional body for the quality assurance is going to be established and I was asking Ms. Lynn Wade to bring this issue up to the managers and the divisional chiefs as well and just to see what they

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think, give them time to think what would be the best way for them to work.
COFFEY, Q.C.:
Q. So as you sit here now, okay, in the administrative structure, who reports to you on the clinical side? Not the technologist's side, but the clinical side?
DR. DENIC:
A. On a clinical side, I have all divisional chiefs and -
COFFEY, Q.C.:
Q. Which would be people such as?
DR. DENIC:
A. You have people in biochemistry, like it would be Dr. Ed Randell. You have immunology, molecular genetics and cytogenetics, this is Dr. Yagang Xie. Microbiology, Dr. Jim Hutchinson. Laboratory hematology, Dr. Cindy Whitman. Cytology would be Dr. Dan Fontaine and I have two site chiefs, one out of St. Clare's and one at the General Hospital site, Lynn Morris-Larkin at the General Hospital site and Dr. Cook at St. Clare's. Also under my jurisdiction are the two pathologists at the Clarenville hospital and one pathologist

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in Carbonear.
COFFEY, Q.C.:
Q. And when did the Clarenville pathologists and the Carbonear pathologist begin to report to you?
DR. DENIC:
A. Officially?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. It would be April.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. But they knew about the changes that we are trying to implement, I believe in February of this year.
COFFEY, Q.C.:
Q. Okay, so and this has happened in this year, 2008?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Now Doctor, in relation to the idea of reporting to, at least in the sense of, you

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know, one doctor, the site chief reporting to you, Dr. Baker in Carbonear reporting to you, like that notion, in practice, what does that actually involve? What sorts of things would they deal with you on?
DR. DENIC:
A. In practice, what it mean that I see that Dr. Baker, and the same, the two pathologists at the Clarenville, while are geographically far away, they still have to become the part of the team, and becoming a part of the team is that being involved in the activities that we offer, that get involved in the quality assurances and quality controls program that we offer, and they can get support from us, as a centre.
COFFEY, Q.C.:
Q. So Doctor, and in relation to the idea of you reporting as Chief of Laboratory Services to Dr. Howell, what, in practice, does that involve? Because Dr. Howell has testified here and my understanding certainly was that he doesn't know a whole lot about laboratory medicine. He would acknowledge that himself, I mean, in the day-to-day sense, certainly not

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on the technical or clinical sense like you would. So when you're reporting to Dr. Howell in your capacity now, what, in practice, does that mean or involve? What sorts of things do you report to him? What does it mean to report to him?
DR. DENIC:
A. What it mean to report is I think of this as one of the layers that every single organization has regards to as who is on the top, because whenever we look various organizations, there's always somebody at the top and that's on the top could be CEO and as you know, that CEO is not really trained in laboratory medicine and he would be on the top, but then the surgery department also reports eventually to the CEO, and to the Board, then to the Department of Health. So I see that as a layer of responsibility that people should feel accountable to one of the persons, person or persons really, towards the service they provide. So this is again one of the layers of the quality assurance, because while Dr. Oscar Howell is not laboratory medicine trained physician, but he's still a

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physician. So he's understanding about laboratory services, he has has, through his own practice, and that's where I see the mechanism of like a second layer of somebody overseeing what's being done in the lab, as a third person.
COFFEY, Q.C.:
Q. Would--and in terms of the technical aspects of clinical laboratory medicine, I take it that you would understand that someone in the VP's position, VP Medical's position, would be relying upon the person in your position to be accurate, full, fair and frank with them about clinical medicine itself?
DR. DENIC:
A. That's correct. That has to come not only from my layer, but has to come from the technological layers, from the base of this pyramid, accountability and frankness and openness and truthfulness have to come all the way up.
COFFEY, Q.C.:
Q. Doctor, could you tell us, I won't ask about the individual structures, individual institutions, but which institutions, which

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four did you look at?
DR. DENIC:
A. We went to London, Ontario, Mount Sinai, Kingston, that's where and I did a separate tour, I was on my vacation and coming back from my vacation through Toronto I organized a meeting with UHN, which is UHN, it's University Health Network.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. Used to be Toronto General. That's one of the biggest hospitals in Toronto.
COFFEY, Q.C.:
Q. So either you, yourself went to the one institution?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. You arranged for that and you certainly, but this, the group that went from here went to three other institutions?
DR. DENIC:
A. That's right. Dr. Oscar Howell, Mr. Gulliver and myself, we went to Mount Sinai. Then Dr.

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Oscar Howell had to go to attend one of the meetings regarding the safety and the quality. And Mr. Terry Gulliver and I, we went to London and Kingston.
COFFEY, Q.C.:
Q. And do I understand you correctly then in terms of based upon your observations at those four places and otherwise that the structure and the final form it will take is still evolving? You're still giving thought to how finally you're going to structure Eastern Health?
DR. DENIC:
A. That's correct, because I think all stakeholders should be included in that and the decision should be made by all of us.
COFFEY, Q.C.:
Q. Doctor, are there any draft structures, kind of discussion documents in place or available as to kind of where we are currently or various options?
DR. DENIC:
A. Not to that extent. What we have is what I'm going to submit to the divisional chiefs and regional managers are the structures that have

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been presented to us in these four labs as a model.
COFFEY, Q.C.:
Q. Sure.
DR. DENIC:
A. But not necessarily means that they shouldn't come up with something else. As long they come up with a structure they think is going to work, I'm going to be quite satisfied.
COFFEY, Q.C.:
Q. And these visits to the four facilities in Ontario, when did they occur?
DR. DENIC:
A. In June.
COFFEY, Q.C.:
Q. Of this year?
DR. DENIC:
A. Of this year.
COFFEY, Q.C.:
Q. And so these four structures, do you actually have like flow charts or diagrams for them?
DR. DENIC:
A. I do. We received some of those at the time of the visit and some of those were mailed to us after the visit.

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COFFEY, Q.C.:
Q. and I take it then what you're saying to the Commissioner overall is is, look, I'm going to put the four, those four options out there, one or other or none of them may be adopted or some other structure or some combination of them?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. I take it it's still in that state right now?
DR. DENIC:
A. They're just the models. And we might not stop there, we might even look further up if this is not satisfactory.
COFFEY, Q.C.:
Q. Now, Doctor, I wanted to ask you about-- actually, I'll just show you a couple of things first. P-2636, please, Registrar? Doctor, this happens to be the annual review of medical staff report for yourself for 2002. And I just, at the time you were fulltime staff pathologist at St. Clare's and there were some other activities that you were involved in, some of which you've already

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outlined for the Commissioner are referred to here. And there's a reference to acting chief of the department in absence of Dr. Don Cook. So even going to, back as early as 2002?

DR. DENIC:

A. 2002, yeah.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you now about your exposure to immunohistochemistry, okay, just to--when did you first have any exposure to immunohistochemistry?

DR. DENIC:

A. During my residency training program.

COFFEY, Q.C.:

Q. Well, you've had at least two residencies, so which?

DR. DENIC:

A. I'm sorry. This one in St. John's, so from 1995.

COFFEY, Q.C.:

Q. And I take it when you were trained in Yugoslavia, because of what you were being trained in and the state of immunohistochemistry at the time in the sense of its development at the time, you were not

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involved in that?

DR. DENIC:

A. In immunohistochemistry is not, usually not a part of forensic pathology practice.

COFFEY, Q.C.:

Q. Pathology, yes. So, Doctor, then in 1995 when you started a residency here in St. John's, what happened then in terms of your exposure to IHC?

DR. DENIC:

A. The only exposure to the IHC were through the various stains that were at the time performed in the department. Those stains were utilized in a way that we are trying to determine or subclassify the tumours, so that's most what we'd been using. So the tumour had been stained, we would look and based on the staining we can say, yes, this tumour is malignant tumour of the skin, what we call malignant melanoma or this is a tumour that could be from other regions, breast, bowel.

COFFEY, Q.C.:

Q. Okay. I take it at that time, in 1995, 1996, as you went through your residency, when you first started, ER and PR, was that being done

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by immunohistochemistry here?

DR. DENIC:

A. No. It was done by the biochemical assay.

COFFEY, Q.C.:

Q. And before I go on then about it and ask you about ER/PR itself, Doctor, how much, looking back on it as a resident in the late '90s in St. John's, how much were you actually expected to know about immunohistochemistry, like the science of it?

DR. DENIC:

A. Science, very little. Very little had been even written. The textbook that I was using was the Rosai Ackerman, and that was the book that I used all through my residency. Even now I think it's a book that I like and utilizing a lot whenever -

COFFEY, Q.C.:

Q. And there's not, at the time there wasn't a whole lot in it on immunohistochemistry?

DR. DENIC:

A. Not really. The basics, they're the basics, but that would be it because it was been expectation from the residents even for the exam just to know the basics of it, but not

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really ins and out.

COFFEY, Q.C.:

Q. Doctor, as a resident, and you had been a resident when Dr. Khalifa introduced the ER/PR, IHC method here in St. John's in Newfoundland and Labrador, in fact, as a resident if someone had asked you who in this building would know about the science of this, who would you have identified, what group or what type of person would you have identified, if anyone?

DR. DENIC:

A. You mean at the time when Dr. Khalifa was -

COFFEY, Q.C.:

Q. In your residency, in your residency? If there was a problem or a question you had about immunohistochemistry at the time?

DR. DENIC:

A. I don't believe there was any particular person dedicated to this. I know that Dr. Khalifa had an interest in immunohistochemistry and eventually when the immunohistochemistry of ER/PR was put in place by Dr. Khalifa, you know, at that time it was obvious that he has an interest in that field.

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But I don't remember before that, that I could rely on anybody except for your staff as much as they can provide the information about it.

COFFEY, Q.C.:

Q. And the staff in this sense would be who?

DR. DENIC:

A. Pathologists.

COFFEY, Q.C.:

Q. Pathologists, okay, the staff pathologists.

DR. DENIC:

A. Yeah.

COFFEY, Q.C.:

Q. When Dr. Khalifa arrived and you got to know him--well, actually, he would have arrived around the time you started your residency, I understand, around that time?

DR. DENIC:

A. Yeah, that's correct.

COFFEY, Q.C.:

Q. You developed the understanding that he knew more than the average pathologist or seemed to know more than the average pathologist about immunohistochemistry?

DR. DENIC:

A. Yeah, that was my understanding, but to which

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extent, I really never challenged that.

COFFEY, Q.C.:

Q. Okay. Doctor, ER/PR and the IHC approach, we've seen--just a second now, please? Just looking, the exhibit where Dr. Khalifa's memo of February 16th, 1998, anybody know the number off the top of their head? Yes, I'm looking your way, Mr. Simmons.

MR. SIMMONS:

Q. Sorry, I'm -

COFFEY, Q.C.:

Q. I'm sorry you were going to say something else. February 16th, 1998, Dr. Khalifa's memo. I have it. Pardon me?

REGISTRAR:

Q. P-1850.

COFFEY, Q.C.:

Q. Yeah, it may very well be.

REGISTRAR:

Q. (Inaudible).

COFFEY, Q.C.:

Q. Yes, thank you very much, Registrar.

THE COMMISSIONER:

Q. The registrar comes to our rescue again.

COFFEY, Q.C.:

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Q. Oh, yes. I had all the others lined up here except that one. Doctor, just again so the Commissioner gets some sense of, we've heard from Dr. Khalifa and Dr. Cook, who was site chief at the time but also a staff pathologist at St. Clare's as to what his memory was about this. You would have been, in February of 1998, about a year away from finishing, year and a half?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Your residency. A memorandum addressed to all Newfoundland pathologists, as a resident would you have received this?

DR. DENIC:

A. No. No.

COFFEY, Q.C.:

Q. No, okay. And when was it, do you recall, the first time you saw this memo? Is it in connection with the--like, the whole -

DR. DENIC:

A. I mean, it got to be a connection from the Inquiry, really.

COFFEY, Q.C.:

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Q. It wasn't back in the '90s?

DR. DENIC:

A. No, no.

COFFEY, Q.C.:

Q. So back at that time, and this is all being introduced, actually, while you're a resident. Now, I take it as a resident you do services, you rotate so many months on this service and so many months on that service, is that the way -

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. - your residency worked? And which service would have, if it did, expose you to immunohistochemistry, ER/PR?

DR. DENIC:

A. I mean, general, general service, because the breast pathologist was considered as the general service.

COFFEY, Q.C.:

Q. Okay. And do you recall when you were doing your general service, was that the whole of your residency or just a particular part of the residency?

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DR. DENIC:
A. Particular--most of the parts you would do the general, but you would rotate it through the certain subspecialty field, like in a renal pathology, cytology, paediatric pathology, neuropathology, but the breast wasn't the part as a separate rotation.
COFFEY, Q.C.:
Q. Doctor, I appreciate this is a decade ago or more now, but do you recall what you were originally taught in your original exposure to ER/PR, IHC, as a resident what were you told?
DR. DENIC:
A. What I was told was how to report it.
COFFEY, Q.C.:
Q. And do you recall -
DR. DENIC:
A. And what to look for, and that's about it.
COFFEY, Q.C.:
Q. Do you recall who would have done that?
DR. DENIC:
A. But then you see, I wouldn't recall the name of the certain pathologist, but lot of breast tissue we seen at the Grace Hospital site because I think they had a very rich

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(phonetic) surgical menu for the breast surgery and at the St. Clare's Hospital somewhat in a General Hospital site. So you would rotate to the pathologists and whoever would be there -
COFFEY, Q.C.:
Q. On that particular day?
DR. DENIC:
A. And working with you on that particular case would tell you.
COFFEY, Q.C.:
Q. Okay. Well, we have, I can tell you, look, I--that particular day you'd show up to work, pathologist, the staff pathologist you were working with that day would say, look, I ordered and ER/PR, here are the slides. And what would you be--what would you be taught about it, I mean, how to go about it?
DR. DENIC:
A. We were told at the time you look at the staining, that has to be nuclear staining.
COFFEY, Q.C.:
Q. Nuclear.
DR. DENIC:
A. And you look at your control.

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COFFEY, Q.C.:
Q. And, Doctor, at that time, in your residency days, how many sorts of stains were involved in nuclear staining, do you recall whether there were -
DR. DENIC:
A. I think ER/PR would be the, at that time, it's difficult to go back in a time and say when did we have a B53 as a stain which is still nuclear or KI67, which is again proliferating marker would be nuclear, but I think going back at the time maybe it's safe to say just nuclear staining with, probably would be ER/PR. It would have been -
COFFEY, Q.C.:
Q. If it wasn't the first, you're saying, it was one of the first?
DR. DENIC:
A. Yeah, that's right.
COFFEY, Q.C.:
Q. Okay, if it wasn't the actual first. Okay, so you'd look for nuclear staining. And so you had to see whether there was nuclear staining and look at the controls. Which controls were they?

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DR. DENIC:
A. Definitely would be external control there. I was trying, actually, to go back in my mind to see and I know the various issues that arose from the presence of internal control and when did I know, and I'm trying to recollect would it be at a time or would it be when I started residency and that been introduced in '97 or later on. I knew about internal controls at some point and I believe that was before Dr. Ejeckam's letter. But for whatever reason we didn't rely on internal control as a secondary control, and one of the reasons was at the time that while it stained, the benign breast stain, actually, if it's absence, if it's not there, you can still report based on your external control and that normal breast tissue does go in response to the menstrual cycle so you can have a variability and, you know, if it's not stained, it not necessarily have to stain, as such. But overall even through the training, as such, we were rely mostly on external control.
COFFEY, Q.C.:
Q. And so what were you taught in the context of

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ER/PR external controls to look for in the external control?

DR. DENIC:

A. That external control stains what we are looking--that we should be looking, actually, in our test tissue. So if you have external control that the nuclei in external controls are stained on that particular tumour, because external controls are made of tumour that would well express the antigen which would be ER/PR and based on that you would make your assessment or your test tissue.

COFFEY, Q.C.:

Q. So you were taught in your residency days in St. John's that the external control you would understand to be tumour tissue? Should contain tumour tissue?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And the nuclei of the tumour cell should stain and that the control, external control would be a strong expresser, a high expresser and suggesting that a lot of nuclei should stain?

DR. DENIC:

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A. That's correct.

COFFEY, Q.C.:

Q. Should be a lot of nuclei of the external control tumour staining?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, were you taught anything about what you should, or what approach you should take if the staining of the external control tissue was not, there wasn't a lot of it, it was weak or there wasn't very much of it at all, stained weakly, as it were? Were you taught anything about that as to what you should do? And what significance at the time were you taught, if anything?

DR. DENIC:

A. I don't believe the intensity of the stain did play a role. I believe that checking the control, you have to see that there's a staining, as such. And intensity, I don't recall that intensity played a role. Obviously if the tissue come as a control and does not stain and it's completely wrinkled or washed off, you know, as a control, they were

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asked to repeat.

COFFEY, Q.C.:

Q. Redo it, yeah.

DR. DENIC:

A. But in terms of the intensity, I don't think that was the emphasis and put as a great factor.

COFFEY, Q.C.:

Q. Doctor, every time you would reach for an external control, ER and PR external control slide, put it under the microscope, what were you expecting to see?

DR. DENIC:

A. There is the staining of the tumour cells so staining in the nuclei for the ER/PR. If it's the other immonohistochemical stain, then you know that some of them have a cytoplasmic stains, some of them have membraneous stains, so.

COFFEY, Q.C.:

Q. You expected to see, I take it, a significant number of the cells, tumour cells stained, and did you expect generally to see that they be stained intensely?

DR. DENIC:

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A. But like anything else -

COFFEY, Q.C.:

Q. No, no.

DR. DENIC:

A. - you would probably like to be staining with the full intensity to, as I said, to light up as a Christmas tree, but not necessarily that you would return external control if the stains are intermediate staining, let's say, intensity, but they stain a large number of cells.

COFFEY, Q.C.:

Q. Doctor, in terms then of then the patient's ER/PR slides, what were you taught then about--that you would look for nuclear staining. And would you go beyond that, was there any calculations you had to do? I'm thinking particular percentages.

DR. DENIC:

A. You would look at the percentages, I think there were two schools at the time of thoughts and depends where you rotate. One was that you should, you definitely look at the percentages of the cells, you know.

COFFEY, Q.C.:

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Q. Okay, so both schools agreed you'd do the calculation of percentages?
DR. DENIC:
A. That's right. And you do that in your head, you know, you look at certain number of fields and then you look entire tissue and try to estimate, really, how many cells are staining, eyeball.
COFFEY, Q.C.:
Q. Sure.
DR. DENIC:
A. Eyeball.
COFFEY, Q.C.:
Q. Eyeball, yes. Ten percent, 80 percent, you know, it's kind of whatever you're seeing there kind of the rough figure. And I take you're telling me in terms of eyeballing it that you wouldn't be surprised if you looked at a particular slide and called it 80 and one of your colleagues looked at the same slide and called it 90 and another colleague called it 70, you wouldn't be surprised by that at all?
DR. DENIC:
A. No.

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COFFEY, Q.C.:
Q. Not at all. At the time would you have been surprised if you looked at the slide and called it ten and one of your colleagues called it 90?
DR. DENIC:
A. Yeah, I would be surprised.
COFFEY, Q.C.:
Q. Yeah, that's the sort of thing we're talking about here is is that--or somebody called it 100 and you called it zero, that would be -
DR. DENIC:
A. That would be very significant -
COFFEY, Q.C.:
Q. Discrepancy, yeah, significant discrepancy. So, you're taught to do the calculation, understanding that it's a rough calculation of percentages. And you said there were two schools, so could you go on and tell the Commissioner about that? Again, you're back in your residency days at this point.
DR. DENIC:
A. I mean, in residency as much my recollection goes and while I cannot talk about certain pathologists and certain institutions, but I

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believe that people would do calculation and some of them would record as positive based on a criteria that Khalifa, at that time, put in one of his memos to the pathologists, which is 30 percent. And so if they would see over 30 percent, that they would say this is positive.; if they think that this is below, ten or 20, they can put negative. While on the other side there were pathologists that were just putting percentages.
COFFEY, Q.C.:
Q. Just -
DR. DENIC:
A. Seeing positive in 20 percent of the cells for estrogen or negative or zero of progesterone or something like that, so various combinations.
COFFEY, Q.C.:
Q. Doctor, and this has to do with reporting, in terms of how it would be reported. Do you recall--there were kind of two schools or two different approaches. Did particular institutions tend to have a particular approach?
DR. DENIC:

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A. I know that the St. Clare's Mercy Hospital pathologists were reporting percentages. I can't claim for Health Sciences and the Grace Hospital. When I came on staff, I mean, when Dr. Cook approached me, they knew that they were reporting percentages, you know, so.
COFFEY, Q.C.:
Q. So you're--the Commissioner, look, there were two schools. St. Clare's fell into the percentage school?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Reporting school. And the Grace and/or the General -
DR. DENIC:
A. They could kept going either way, depends on the pathologist, really.
COFFEY, Q.C.:
Q. So not only would it vary, in those places it might vary from institution to institution, but within the pathologists within the institution?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. And again in your training days were you ever aware that it might vary from day to day or week to week even with the same pathologist?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Okay. Your experience was any particular pathologist tended to report it in the same way?
DR. DENIC:
A. That would be my understanding. I mean, that's the way that I would do it, probably.
COFFEY, Q.C.:
Q. Okay. And, Doctor, as a resident would you actually be doing any of this reporting yourself?
DR. DENIC:
A. As a resident I would be looking into the slides and tell my attending, but my attending would have reported the slides because we didn't have a privileges signing out of cases.
COFFEY, Q.C.:
Q. So, Doctor, you joined the staff of, St. Clare's staff in 1999. And I take it you

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adopted the reporting approach at St. Clare's?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Just to use percentages. Did you ever use the--would you in reporting use the words "positive" or "negative"?
DR. DENIC:
A. I used the percentages and I think all the time when they are positive, but when they are negative, I might have used zero but I would have said negative, as such, meaning zero.
COFFEY, Q.C.:
Q. Okay, so at times you might--you're saying to the Commissioner, look, if you looked through all my pathology reports, you might find instances where I wrote simply negative?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Meaning zero?
DR. DENIC:
A. Meaning zero.
COFFEY, Q.C.:
Q. Or I wrote zero and zero means zero or I wrote

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negative and zero, there could be cases where you -
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, I'm going to ask you now -
THE COMMISSIONER:
Q. Wait now, before you go to the next point.
COFFEY, Q.C.:
Q. I apologise.
THE COMMISSIONER:
Q. So between the 30 percent and the zero -
COFFEY, Q.C.:
Q. Oh, yes. Yeah, did you -
THE COMMISSIONER:
Q. How would you report that? If you had, the percentage was 15?
DR. DENIC:
A. I would say 15, I would tell 5, I would say three percent.
THE COMMISSIONER:
Q. Okay.
DR. DENIC:
A. Any positivity I would put in a percentage.
THE COMMISSIONER:

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Q. Okay.
DR. DENIC:
A. Without making any distinctions of any cutoffs.
COFFEY, Q.C.:
Q. Okay, thanks. So cutoffs, except zero, zero and everything else, zero is the cutoff?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Anything above zero -
DR. DENIC:
A. That's right, if it's one percent, I would say one percent.
COFFEY, Q.C.:
Q. And you considered that, in a technical sense, positive, from a pathologist and clinically that was the oncologists' business?
DR. DENIC:
A. That's correct, because the thinking of that time is that we shouldn't be recommending what the oncologist should do and they should implement any number that people use in their practice and treat the patient based on the number received.

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COFFEY, Q.C.:
Q. So, Doctor, did you understand then that the number, and I appreciate it was an eyeball, to use your word, an eyeball approach, that the number, though, might have some significance? Like, there was a difference between saying ten and 90?
DR. DENIC:
A. Oh, yes.
COFFEY, Q.C.:
Q. Clinically, potentially there was a difference, you would have understood that?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And do you think that generally amongst pathologists that you worked with that there was a general understanding that there is--there could be a difference between saying ten and 90? That might have some clinical -
DR. DENIC:
A. I think that would be commonsense, you know, because you report what you see and you wouldn't expect--pathologists pretty much have a good eye, you know, spending eight hours

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behind the oculars and looking for single cells. So, yes, I think that would be commonsense, but I wouldn't expect that broad range of difference.
COFFEY, Q.C.:
Q. No, no, not only to see it, but in reporting it. At least in your own practice, your own personal practice, you understood that, look, in making this eyeball judgment, it's not enough for me to say kind of zero and anything else. In your own view, as best you could humanly possible, make the best estimate you could of the percentage because it could have --what the percentage was could have an effect in the oncologist's world?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, in your own practice, and I'm going on beyond your residency days--in your residency days, but beyond that, do you ever recall getting any--being contacted by oncologists, one or more oncologist, about your reports on ER/PR and questions about them or clarifications?

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DR. DENIC:
A. Not about the clarification. The occasional call that I would have received, I think it was at the time one oncologist, in particular, who was asking for the ER/PR to be performed on the DCIS's.
COFFEY, Q.C.:
Q. On DCIS?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. And I was going to ask you about that, but other than that in terms of--here's what I'm getting at, if you use the word "negative" in a particular case, and you did occasionally over the years, you wouldn't use the zero, were you ever contacted by an oncologist to ask you, you know, does negative mean zero, or does negative mean 10 or 5 or 20?
DR. DENIC:
A. Not that I can really recall, and I would probably recall if that frequent.
COFFEY, Q.C.:
Q. If it ever happened, you're telling the Commissioner it would be very rare?

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DR. DENIC:
A. Yes, that's right.
COFFEY, Q.C.:
Q. How about your colleagues, did you ever call them talking about getting contacts or communications from oncologists looking for clarifications in terms of what was meant by negative or what was meant by positive?
DR. DENIC:
A. They probably tried to reach the particular person, I would say, but again --
COFFEY, Q.C.:
Q. I gather at St. Clare's, the people you generally practice with, they were using percentages?
DR. DENIC:
A. They were using percentages, that's right.
COFFEY, Q.C.:
Q. Did it ever come up anywhere that you know, like in tumour board rounds?
DR. DENIC:
A. I really can't recall that that was an issue.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:

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A. It could have been on individual basis that the oncologist could have called a particular person, but I can't say that I heard in a general discussion.

THE COMMISSIONER:

Q. Just because it happens to be going through my brain at this point, at the beginning of your career, did you routinely do ER/PR or was that at that stage the call of the surgeon or was it the call of the pathologist, do you remember?

COFFEY, Q.C.:

Q. Career, which --

THE COMMISSIONER:

Q. We're talking about the beginning of his career at St. Clare's.

COFFEY, Q.C.:

Q. When you first arrived here, who was doing --

DR. DENIC:

A. I believe that was a routine order because with the biochemical assay I know that the surgeons were ordering that, but when I came on staff, I believe that that became as a routine for the estrogen progesterone order.

THE COMMISSIONER:

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Q. Thank you.

COFFEY, Q.C.:

Q. Doctor, you would have then when you obtained staff privileges at St. Clare's began to order --because certainly by 1999, it was routine for pathologists doing a breast cancer case to order ER/PR?

DR. DENIC:

A. I believe so.

COFFEY, Q.C.:

Q. Certainly by then, based upon what we've seen, it was certainly the routine thing by 1999, or at least it was a--I wouldn't say it was done in every case, but it was certainly, I gather, routine, expected. Doctor, what then would happen? You know, beginning in 1999/2000, you would order ER/PR. Perhaps you could just take us--I'll ask you to back up a bit. At that time, take us through kind of from your perspective, a breast cancer case from your perspective, your involvement?

DR. DENIC:

A. Breast specimen, on your day of rotation, you would make sure that it came in to the proper container with the formalin, and then the

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breast tissue would be sliced, and --

COFFEY, Q.C.:

Q. How would you go about that at that time, was there any particular method used?

DR. DENIC:

A. We refer to that as breadloafing, you know, probably it's not the proper term, you know, but section, you know, one or two centimetres apart, but mostly you try as frequently to cut the tissue to expose to the formalin because the breast tissue is very soft and this is really--if you can relate for cutting a loaf of very fresh bread, you know, it's very difficult sometimes to be equal cuts, you know, it could be one centimetre one cut, the other one could be 1.5 centimetres, you know, but that would be the way the entire tissue is being cut and left in a fixative for 24 hours for the grossing. Then you would assess this tissue the following day, and take samples from the tissue, put it in cassettes. Those cassettes would be given to the assistant, and they would put the cassettes in a tissue processor for overnight.

COFFEY, Q.C.:

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Q. Uh-hm.

DR. DENIC:

A. And the following day, the technologist would continue with moving the tissue to the various steps from the embedding stations and to the stations of the cutting and staining, and the final product would be your H & E glass slide that would come to your desk. Then you would look at the case, make assessment of the case just to see first whether or not you have a breast cancer, or there's any other lesion. If you have the case of the breast--of the cancer, then you would pick up the block that you would think is more appropriate and send that block for immunohistochemical staining.

COFFEY, Q.C.:

Q. So what criteria would be--at that time, did you use, '99, 2000, 2001, to pick the appropriate block or most appropriate block?

DR. DENIC:

A. The most appropriate block and trying to put the region that is better differentiated to tumour. The large number of the tumour represented on the slide so that you can make an evaluation of larger portion of the tumour.

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COFFEY, Q.C.:
Q. At that time, would you be looking to have internal control tissue there when you first started?
DR. DENIC:
A. When I first started--I might not have did in every single case.
COFFEY, Q.C.:
Q. Sure.
DR. DENIC:
A. For the single reason that the part of the practice that we learn as well from the biochemical assay, you want to have as much as possible tumour.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. Because you're going to try to make that kind of assessment. The other thing is, yes, we relied a lot on external controls. We know that the external control is going to come, and sometimes it depends on the breast, you wouldn't even have the normal breast tissue around for the various reasons that by the way of sampling, which you cannot know when you

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sample the tissue whether you're going to have internal control. There's always the portion of tissue that has a fat tissue outside the tumour, and in the fat tissue, that's where your internal controls really would be your benign tissue situated, but not every breast tissue distribution of the normal tissue, it's not equally distributed around. So if you have that elderly lady, you know, so with the atrophy, you're always going to have all fat tissue around, so regardless of the sampling, but at the time when you take the sample, you cannot know that you have benign breast tissue inside. You can only assume that you might hit those ones.
COFFEY, Q.C.:
Q. Sure.
DR. DENIC:
A. But we did rely a lot, based on past experiences, that you need--as more tumour you get, and try to get the better differentiated tumour rather than the poorly differentiated portions of the tumour because within the sections you can see the various grades of the tumour. While the tumour can in one section

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be a high grade tumour that's going to be your final probably in your diagnosis, you still are looking for a better differentiated portions of the tumour that you can submit for the estrogen and progesterone receptors, and reason being that this portion could be positive.
COFFEY, Q.C.:
Q. So at least in the early days of your staff days at St. Clare's, are you telling the Commissioner that you might not have, in fact, been purposely, for example, like you might now look for internal control tissue, pay more attention to it? Back then you've indicated that perhaps that's not so, I wouldn't have.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. It may or may not have been there at the time?
DR. DENIC:
A. Yes, I think it's fair to say that.
COFFEY, Q.C.:
Q. Doctor, so you picked the most representative block, ordered the ER/PR. I take it that would be a requisition form?

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DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Filled out, and you'd circle the ER/PR?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And the next thing you'd see is what? See the slide or slides?
DR. DENIC:
A. You finish your case at that time before--because you know that this is not going to happen overnight, and usually take four, five, seven days even, to get your slides back. So I would conclude my case so that clinicians know what they're dealing with, this is carcinoma, give them all parameters they've been looking for, for the margins, you know, the margins involved, so they can act upon and schedule the patient for sooner visits rather than later, and then I would receive the slides and I would report those slides, and issue the amended addendums.
COFFEY, Q.C.:
Q. Doctor, would you ever have to reorder the

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ER/PR test to be done? You know, you get the ER/PR slides, and you were unsatisfied with the first slides, would you ever have to reorder them?

DR. DENIC:

A. Yes, I did.

COFFEY, Q.C.:

Q. And what sorts of reasons would cause that?

DR. DENIC:

A. Most of the time reordering would be that tissue is not there, the tissue has been washed off. Most of the tumour is not there because that portion is washed off and then you have the tissue broken into pieces, and there would be occasion that you would order because it's a lot of brown staining that shouldn't be there on the tissue, so background would be very hard and overwhelming actually for interpretation. So those would be less rare than the first mentioned.

COFFEY, Q.C.:

Q. Yes, washing off the slide or broken up tissue on the slide was the most common problem?

DR. DENIC:

A. Yes.

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COFFEY, Q.C.:

Q. That's a common problem.

DR. DENIC:

A. That's right, that is a common problem.

COFFEY, Q.C.:

Q. What was your understanding as to what caused that?

DR. DENIC:

A. My understanding at that time, speaking to the technologist as well that tissue boils off because one--the part of the procedure is boiling the tissue, and obviously boiling the tissue, you can expect something as such. There's a different knowledge that they acquire now --

COFFEY, Q.C.:

Q. I appreciate that.

DR. DENIC:

A. Through all of these, the fixation could be the problem, the time, but I believe that's one of the explanation that I've been given.

COFFEY, Q.C.:

Q. Just simply that there's nothing here on the slide, why not, and you would be told, well, it boiled off?

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DR. DENIC:

A. That's correct because --

COFFEY, Q.C.:

Q. What caused --

DR. DENIC:

A. If you repeat it, you got it back, so you wouldn't think that what they're saying wouldn't be the right thing.

COFFEY, Q.C.:

Q. Doctor, we've heard references--the Commissioner has heard references to tissue reprocessing at St. Clare's. The idea of reprocessing tissue, in particular, breast tissue --

DR. DENIC:

A. There's been occasion that the tissue has been reprocessed and that came into play when the technologist would try to cut the tissue.

COFFEY, Q.C.:

Q. That would be to make the slides?

DR. DENIC:

A. To make the slide because the tissue is embedded in the paraffin blocks and the next station would be cutting the tissue which there's a special cutting machine called

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microtome which cuts very fine slivers from the surface, cutting the wax and the tissue itself embedded in the wax. They will say we have a difficulty cutting this because tissue has more water inside because obviously the fixation didn't harden the tissue as much, but also means that the tissue has more water inside and probably the processing would have longer because the processing is not fixation. Processing is moving the tissue from the different grades of alcohol in order to extract the water because breast tissue is fatty tissue and fatty tissue contains water.

COFFEY, Q.C.:

Q. Doctor, so your understanding about tissue reprocessing--when you first arrived at St. Clare's as a staff person in 1999, was tissue reprocessing going on then at St. Clare's?

DR. DENIC:

A. I really can't tell you.

COFFEY, Q.C.:

Q. You can't recall, but during your time certainly at St. Clare's, 1999, 2000, 2001, you became aware that tissue reprocessing at times occurred there?

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DR. DENIC:
A. At times, you know.
COFFEY, Q.C.:
Q. And --
DR. DENIC:
A. But not as frequent.
COFFEY, Q.C.:
Q. And this is the explanation you got. What was your understanding about what the effect of reprocessing was? What was the advantage of reprocessing and were there any disadvantages?
DR. DENIC:
A. What I understood at that time, the advantage is, as I said, to make tissue easier to cut.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. So that it can give you the full surface of the tissue because if a tissue is still soft in the block, you know, when the blade goes over the surface, you know, the tissue can give so you might not necessarily going to get the full section, you can get the rim of the tumour, but not the entire tumour. So that was my understanding at the time, and again

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since the tissue reprocessing is not fixation really, it's just making the tissue harder.
COFFEY, Q.C.:
Q. So your understanding is it had no effect on fixation, the tissue reprocessing process itself would not affect fixation one way or the other?
DR. DENIC:
A. That's right, because it's already fixation been finished at that point, finished on the bench, and there's only one hour that still tissue sits in the chamber with formalin in a processor. If it's a weekend, then it's a longer time it sits in the chamber with formalin because I think it's even six hours or so, and then start moving towards other solutions.
COFFEY, Q.C.:
Q. Doctor, your understanding was that tissue reprocessing process would have no effect on - at least no negative effect on fixation of the tissue?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. Did you ever make any inquiries about whether there were any potential problems with conducting tissue reprocessing?
DR. DENIC:
A. Frankly speaking at that time, no.
COFFEY, Q.C.:
Q. Have you since?
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. And when did you do that, and whom did you ask, and what did you learn?
DR. DENIC:
A. Through all of this preparing for the inquiry and hearing about this stuff being said about the process--I know even Dr. Ejeckam in his memo did mention reprocessing can affect the tissue. I tried to search the literature myself and I couldn't find it really, to which effect the tissue can sustain being reprocessed, because again what the reprocessing is, the tissue goes into the alcohol, already gone to the formalin and to the certain point have been fixed, and now being exposed to alcohol, alcohol is a way

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that can also fix the tissue, it's a different type of fixative as such, but through my search of the literature I really couldn't find just telling this is what is happening. I did go through the manual for the technologists which Sakura published, and I think they even have their journals which is again evidence-based as such. They are recommending the way that you reprocess the tissue, but I even couldn't find there that it said don't reprocess the tissue if you want to do immunohistochemistry.
COFFEY, Q.C.:
Q. The Sakura method, does that use formalin fixative or alcohol fixative?
DR. DENIC:
A. I think Sakura is only--they reflect on the practice, not necessarily on Sakura System as such. They also reflect to the practice of tissue reprocessing, so they're giving the advice how to do it, but at the end of the day I couldn't find evidence how it can affect it. The only evidence I found in the article 2007, just a comment that was written--the article was written by Clive Taylor, Goldstine, and

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there's--a page of that article there was also discussion about it, and in that article it says that alcohol while it can be used as a fixative, the only affect that it can have could be giving a false positive result, but nothing in terms of reprocessing I could find in the literature. I'm not saying it doesn't exist --

COFFEY, Q.C.:

Q. But you, yourself --

DR. DENIC:

A. But my efforts didn't bring anything to my satisfaction.

COFFEY, Q.C.:

Q. Doctor, tissue reprocessing such as was occurring at St. Clare's when you started on staff and continued while you were on the staff there, does that continue now, is there any tissue reprocessing going on there now?

DR. DENIC:

A. There's no--processor is not any more at St. Clare's.

COFFEY, Q.C.:

Q. So when did the processor move to the General?

DR. DENIC:

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A. Moved in 2006.

COFFEY, Q.C.:

Q. 2006. So up to 2006, up to the time that the processor left St. Clare's, was tissue reprocessing from time to time going on at St. Clare's?

DR. DENIC:

A. Occasionally.

COFFEY, Q.C.:

Q. And who would know how frequent it was? Who at St. Clare's at the time would have known how frequent that was?

DR. DENIC:

A. Technologist.

COFFEY, Q.C.:

Q. And who was that between, say, for example, from 1999 through 2006, who was that?

DR. DENIC:

A. I mean, we have Mr. Ken Green and --

COFFEY, Q.C.:

Q. So Mr. Green before he went to the General?

DR. DENIC:

A. Yes, before he went to the General, he was moved at some point, and Catherine Parnell, she came from the Grace Hospital as well.

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COFFEY, Q.C.:

Q. Within that--it's a small lab, so within that --if it's going on, those people would know?

DR. DENIC:

A. It's a small group of people that's left behind really.

COFFEY, Q.C.:

Q. They'd know. Doctor, so you would get then the --we'd gotten to the point where you get the slides back, when you might or might not have to--when you might have to, the causes of asking for a repeat, ER/PR. How frequently would you have to ask for an ER/PR to be repeated? Was it a very unusual incident or not uncommon?

DR. DENIC:

A. It's difficult to extract on ones mind how frequent ER/PR because we were dealing with other immunochemistry stains and we were asking them to be repeated too.

COFFEY, Q.C.:

Q. Uh-hm.

DR. DENIC:

A. So it's difficult for me, I can say, but I would say, yes, it happened, but how

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frequently it happened --

COFFEY, Q.C.:

Q. I take it, it wasn't something you were doing every third day?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. That kind of --

DR. DENIC:

A. Actually, we haven't been ordering ER/PR every third day because that would be probably once or twice a month that I would be exposed to that.

COFFEY, Q.C.:

Q. While we're on that topic, I'll ask you that, how often would you order ER/PR tests, as a staff person? I appreciate, again because it might vary from month to month, week to week, but how many ER/PR cases would you do a year?

DR. DENIC:

A. One to two cases a month.

COFFEY, Q.C.:

Q. So somewhere between 12 and 24 roughly a year, 12 to 25 a year?

DR. DENIC:

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A. I think one of first years I probably did less because I started in half of the year. I would say that year was 12, but I think maximum that it went about 24 cases a year, so not frequently.

COFFEY, Q.C.:

Q. And, Doctor, at St. Clare's, were the cases kind of divided up equally amongst the pathologists generally?

DR. DENIC:

A. Not really. It depends what falls on your day.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. So it might be the day during rotation you don't receive any breast tissue, or it could be the day that you receive two, but --

COFFEY, Q.C.:

Q. I appreciate that. In terms of would you--at the time, would you have thought, like, if I'm doing about two a month, 24 a year, would you have expected the pathologist in the office next to you to probably be doing around the same number per year throughout the year?

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DR. DENIC:

A. That's right. I mean, every single specimen, not only breast, over the period of time they equalizes. So at the end of the year, I think, we would all be in the same ball park.

COFFEY, Q.C.:

Q. Doctor, just while we're on it, you started--you just mentioned 1999, half way through the year. You did, in fact, start on July 1, 1999? I take it that's half way through.

DR. DENIC:

A. Yes, that's right.

COFFEY, Q.C.:

Q. Doctor, did you sit or attend--sit on the Medical Advisory Committee before your clinical chief days?

DR. DENIC:

A. Before I did as the President of the Medical Staff for one year.

COFFEY, Q.C.:

Q. And do you recall when that started, which year was that?

DR. DENIC:

A. Oh, when I was President of the Medical Staff, that's 2004/2005.

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COFFEY, Q.C.:

Q. And, Registrar, if we could bring up, please, P-2447. Doctor, here there's--these are just the minutes of the MAC of September 9th, 2003, and the fourth column--I'm sorry, the third column, fourth name is yours?

DR. DENIC:

A. Yes, it is, 2003. At that time, I was Vice President of the--that's correct. I think as Vice President as well. Dr. Barry Rose, he was the President at that time.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. So that's correct, I think at some point I started attending those ones as well with him.

COFFEY, Q.C.:

Q. And, in fact, when we look, your name appears on the October 8th minutes and the December 10th minutes as well.

DR. DENIC:

A. Yes, so --

COFFEY, Q.C.:

Q. So the fall of '03?

DR. DENIC:

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A. That's correct.

COFFEY, Q.C.:

Q. In your capacity as Vice President?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Of that organization, you would have attended these.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, at the MAC meetings, do you recall whether or not at times the topic of reporting of adverse events or guidelines on disclosure of adverse events and clinical errors was discussed, and I will show you, Doctor, this is the same meeting, page three of this exhibit, paragraph nine, second bullet, guidelines on disclosure of adverse events and clinical errors, "A discussion was held at a recent clinical chief's meeting on guidelines on disclosure of adverse events and clinical errors", and it goes on to talk about that, "MAC is asked to review documents", and so on. This does appear a number of times afterward,

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references to this. I just wanted to ask you, in 2003, as a member of the MAC, were you exposed to this?

DR. DENIC:

A. If it was discussed and I was there, obviously, you know, I would have been aware of, you know, and bringing the memories back, I can't recall exactly what was discussed about it and what document produced.

COFFEY, Q.C.:

Q. Doctor, in relation to ER and PR, we've heard from Dr. Ejeckam about his experience in the fall of 2002 when he first arrived in St. John's, and he was on the General Hospital staff, and then about what happened in early 2003. Doctor, do you ever recall in 1999, 2000, 2001, 2002, into 2003, before Dr. Ejeckam's memo, do you ever recall any discussion amongst the pathologists in St. John's about ER/PR and any problems?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. In terms of, you know, there's a problem with the ER/PR slides?

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DR. DENIC:

A. No, not in any general discussions as such.

COFFEY, Q.C.:

Q. Doctor, did you ever attend routinely, for example, in 2002 or 2003, would you be routinely attending meetings of pathologists at the General Hospital, like, kind of group meetings?

DR. DENIC:

A. They had a meeting that occurred only for the General Hospital pathologists, which I wouldn't attend, but there were like program meetings in place that they were --

COFFEY, Q.C.:

Q. I'm sorry, what kind of meetings?

DR. DENIC:

A. Program meetings.

COFFEY, Q.C.:

Q. Program meetings, okay.

DR. DENIC:

A. That I would attend, the entire group of pathologists.

COFFEY, Q.C.:

Q. And these program meetings would be--all pathologists would be invited?

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DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And they would be held how often?

DR. DENIC:

A. They were supposed to be happening on a monthly basis, but I can't be certain that they happened on a monthly basis, so they could be on and off.

COFFEY, Q.C.:

Q. And they would normally be held where?

DR. DENIC:

A. At the Health Sciences.

COFFEY, Q.C.:

Q. And the purpose of those meetings was what?

DR. DENIC:

A. The purpose of this meeting is to discuss any operational issues that the program overall might have, and give any additional information that you can convey to your staff.

COFFEY, Q.C.:

Q. Doctor, do you ever recall at any of those meetings back, you know, up to at least April, 2003, any concerns being expressed about immunohistochemistry stains?

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DR. DENIC:

A. Not until Ejeckam's letter really, that I can recall.

COFFEY, Q.C.:

Q. And if we could look, please, at Exhibit P-0113. Doctor, this is--page one is Dr. Ejeckam's memo of April 4, 2003. You would have received this back in April, 2003?

DR. DENIC:

A. I would have.

COFFEY, Q.C.:

Q. You did. Doctor, this refers, of course, not only to ER/PR, but a number of antibodies, six other antibodies, and were you aware before April 4th of 2003 of these sort of problems that Dr. Ejeckam is referring to here?

DR. DENIC:

A. No, not in my practice.

COFFEY, Q.C.:

Q. And you received this, and what was your reaction to it?

DR. DENIC:

A. The first thing you relate to your own practice as such, and I couldn't talk about high molecular rate keratin which was utilized

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in prostate biopsies because St. Clare's doesn't do prostate. The other ones, the stain used in lymphomas or these are malignancy of the lymph nodes -

COFFEY, Q.C.:

Q. There are four of those?

DR. DENIC:

A. There are four of them, CD3, CD5, CD20, CD79A, and CA was the marker, epithelial marker. It's very non-specific, and then we have ER/PR, of course.

COFFEY, Q.C.:

Q. The ones that concerned you at the time?

DR. DENIC:

A. It wasn't any of the great concern because he was talking about durability, sensitivity, specificity. To me, while we probably did have some discussions at St. Clare's, unofficial discussions about it, we were taking this as pretty much he would like to not these stains -

COFFEY, Q.C.:

Q. I'm sorry -

DR. DENIC:

A. Because the stains were working--I know that

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CD3, CD5, CD79A, and, you know, I didn't have a problem. Every now and then pathologist is going to come and tell you I would like this stain to be stronger, and when we sit behind the microscope and look even today at immunohistochemical stains and you're dealing with the various tumours, sometimes expression is not there to that extent that you would probably be more confident to do. So it was taken as a quality assurance process, that he's going to try to tweak (phonetic) the stains.

COFFEY, Q.C.:

Q. Now i.e. make them stronger or more intense?

DR. DENIC:

A. More intense, more crispier, outlined exact number of the cells because some of these lymphoma markers, they stain geographical areas in the lymphoid tissue, you know. So maybe that geographical area was--in one portion was stronger, and as it goes to the periphery becomes a little bit weaker. So that's the way it's perceived.

COFFEY, Q.C.:

Q. So the four lymphoma markers, you, yourself,

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in your own practice would at times have ordered them? You were utilizing the lymphoma markers yourself?

DR. DENIC:

A. Yeah, we were utilizing that, but not just them, as you understand.

COFFEY, Q.C.:

Q. There were others, and I'll be talking to you more about that, but CEA, you utilized that in your practice?

DR. DENIC:

A. We did, but occasional.

COFFEY, Q.C.:

Q. And the ER/PR you utilized in your practice occasionally -

DR. DENIC:

A. That's right, once or twice -

COFFEY, Q.C.:

Q. Once or twice a month, probably about 20/25 times a year you would have utilized that. A statement "unreliable"--it doesn't say "just are", it says, "have remained", which suggests past tense, gone on for a period of time. "Have remained unreliable, erratic, and unhelpful for diagnostic purposes". In this

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context in terms of the other six stains, they are used for diagnostic reasons, aren't they?

DR. DENIC:

A. Be careful about diagnostic as well. We make a diagnosis on H & E.

COFFEY, Q.C.:

Q. H & E, yes.

DR. DENIC:

A. And these are pretty much the sub-classified, the lesion, you know, tumour, whether it's staining, population stain CD20 because they're used for a number of --

COFFEY, Q.C.:

Q. They're used for sub-classifications?

DR. DENIC:

A. Exactly.

COFFEY, Q.C.:

Q. But the ER and PR are not used for diagnostic or sub-classification, they're used for treatment?

DR. DENIC:

A. That's right, they're prognostic.

COFFEY, Q.C.:

Q. They're the two out of the eight?

DR. DENIC:

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A. That's correct.
COFFEY, Q.C.:
Q. Prognostic. Was there discussion, informal discussions at St. Clare's about this? This originated at the General Hospital, and this is where all these slides are being made.
DR. DENIC:
A. It might have been, but nobody was alarmed about it. I don't remember that anybody was alarmed. We knew that Dr. Ejeckam has interest in immunohistochemistry and this is a part that he took over in order to make the stains really better in every sense.
COFFEY, Q.C.:
Q. And where had you gotten the understanding that Dr. Ejeckam was assuming this role? You wouldn't have known Dr. Ejeckam before he came in 2002?
DR. DENIC:
A. No, I wouldn't, I wouldn't know. I think Dr. Cook might have told us about Dr. Ejeckam has interest and he's a point person for immunohistochemistry, just overseeing it.
COFFEY, Q.C.:
Q. And Doctor Khalifa, we understand, left St.

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John's, I believe, in 1999?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And Dr. Ejeckam arrived in the fall of 2002. In the period between 1999, Dr. Khalifa's leaving, and 2002, was there any pathologists who you would have associated particularly with immunohistochemistry?
DR. DENIC:
A. Not to this extent that you have a single personwith a interestin immunohistochemistry, but it was my understanding that during that gap when Dr. Khalifa left until Dr. Ejeckam took over, that that was the role and duties of the site chief.
COFFEY, Q.C.:
Q. At the General?
DR. DENIC:
A. At the General.
COFFEY, Q.C.:
Q. Doctor, you told the Commissioner now looking back in April of 2003, this did not alarm us, for whatever reason at Clare's, there was no

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alarm raised over this?
DR. DENIC:
A. Then.
COFFEY, Q.C.:
Q. At that time, yes.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Now, Doctor, if you were to receive--you go back to your office this afternoon or tomorrow and to receive a memo like this now, I take it utilizing this sort of language, it would raise alarms?
DR. DENIC:
A. Oh, certainly would. I mean, I would--I would --first I would probably ask for the meaning on all of this, and probably look at those slides that he referred to and just to see what he's referring to as such today.
COFFEY, Q.C.:
Q. Yeah. Why, Doctor, whomever you got the memo from--if it was, for example, Dr. Ford Elms, as the current Director of Immunohistochemistry was to write to you now and say in respect of any stains and he named

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them that they have remained unreliable, erratic, and unhelpful for diagnostic purposes, you would take it up with Dr. Elms right away, wouldn't you?
DR. DENIC:
A. I would, and we did in the past with one other stain and we stopped the stain.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. And we are not doing it until it's validated.
COFFEY, Q.C.:
Q. So was there any discussion, Doctor, at the time in 2003 that you recall about--well, what about the slides that were produced before April 4th? Was there any discussion about the slides we got back in the beginning of April, March, February, January?
DR. DENIC:
A. No, definitely not.
COFFEY, Q.C.:
Q. And, Doctor, yourself at the time, did it cross your mind to question or think about, well, what about my ER/PR slides or my CEA slides, my lymphoma slides, that I've been

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getting before we got this memo?
DR. DENIC:
A. No, Mr. Coffey, the way that it works, you received the memo, you have the pathologists behind all of this who is handling this kind of stuff, and then making decisions based on it. You rely that he's going to make any kind of judgment call at that time. You go back at a time--I mean, this memo comes to your desk, you read it, you process the information, you move on in your regular day routine because--while what we know today and we all look at this with a retrospectoscope, as the people would say, you know, maybe some other things would have been done at that time, but lot of these stains that are mentioned here, they are using them as part of the batteries of the stains, all those lymphomas. So you don't use only one, CD3 and CD5, then you use the various other methods which are more sensitive than this, like flocytometry, high molecular rate kerotin is one of these things that now becomes almost obsolete because we are using various better sensitive stains and batteries of three or four stains are replacing it. So

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I believe that at the time nobody was alarmed.
COFFEY, Q.C.:
Q. And you're telling the Commissioner at the time it didn't cross your mind--at the time in April when I got this, it didn't occur to me to think, well, I reported cases in March or February or January of 2003, ER/PR results that oncologists are relying upon?
DR. DENIC:
A. No, it didn't, because between ER and PR results, it would be hundreds of different cases as such, and you don't keep a track really on one or two cases, especially if you see them rare.
COFFEY, Q.C.:
Q. Doctor, the second page of the exhibit, which is the May 2nd, 2003 memorandum from Dr. Ejeckam, did you receive a copy of this?
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. And this is a three page memo and he speaks of having rectified the difficulties related to the immunostain of ER/PR and will resume requests, and he then provides the following

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information and wants to bring it to your attention, and there's--the Commissioner has been through this a number of times. Witnesses have taken her through it. At the time, Doctor, how did you view the purpose of this memo, what did you understand or take from it other than to tell you, look, the ER/PR is up and running again?
DR. DENIC:
A. I think it's very informative memo. He brought back to the attention to all pathologists about immunohistochemistry really in general, not only about ER/PR, and the flagging really, what are the factors that we should look into it, what are the factors that can affect immunohistochemical stains, and I think that was the purpose of this memo.
COFFEY, Q.C.:
Q. Ongoing educational --
DR. DENIC:
A. Educational, I would say.
COFFEY, Q.C.:
Q. And Doctor, was there discussion at St. Clare's, amongst pathologists there, about this, do you recall?

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DR. DENIC:
A. Not that I can recall in any formal sense.
COFFEY, Q.C.:
Q. How about in an informal sense, that you can recall?
DR. DENIC:
A. It could have been. I mean, if we received the memos and people said "did you receive Dr. Ejeckam's memo?" or something like that.
COFFEY, Q.C.:
Q. Was there--looking at it, and you've had, I take it, since 2005, looked at this at least once, and perhaps more than once since, since 2005, looking at it now more recently, is there anything that strikes you now as "look, that was the first time I learned something," particular certain things? And you can take your time and look through it. I'll get you control of the mouse, if you like. Anything in particular in the memo at the time that was new to you?
DR. DENIC:
A. He did mention the tissue reprocessing as such, again emphasizing on that again, this is the information that I couldn't substantiate

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myself. I'm not saying that it doesn't exist somewhere, probably the experts, that can shine the light to that better than I do. Optimal fixation, he was talking about 18 to 24 hours that most of the tissue actually being fixed, but some of them might have been fixed over 24 hours, although we know that even over 24 hours today, it's not a problem even if it go over 48 hours. So this is -

COFFEY, Q.C.:

Q. Checking the buffered formalin?

DR. DENIC:

A. Yes, I think that's something that I was not aware of, about the formalin. This wasn't a part of our--it was a part of our practice, because a tissue has to come into a formalin, and you know the specifics of the formalin as such, but this is something that really was technical and left for the technical people to make sure that the formalin is the formalin and whatever is in a container is the formalin.

COFFEY, Q.C.:

Q. And the idea that ER/PR false negative results increase -

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DR. DENIC:

A. Increase in core biopsies, I would say this was the new information for me, although doing ER and PR on a core biopsy was extremely rare, and but it was quite logical, when you think about it, because core biopsy doesn't represent a large portion of the tissue, and that you may go through the portion of the tissue which contains ER negative clone.

He said to check normal breast acini in a section, internal controls. This is a second level control, as he said, and that was something that I had been taught at that time. Nuclear staining in normal breast tissue is heterogeneous and varies with the menstrual cycle. So he pretty much confirmed what I knew about it, that it varies, and if it's not there, that not necessarily means that you shouldn't rely. He doesn't necessarily say do not report the case.

COFFEY, Q.C.:

Q. If for example, the -

DR. DENIC:

A. If you don't have internal controls positive.

COFFEY, Q.C.:

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Q. If there's internal control tissue, normal tissue there, and it hasn't stained, but the tumour has stained, the tumour itself has stained and the external control has stained appropriately -

DR. DENIC:

A. Then you would take that as such. But that you can see that we know that in our practice, especially in our recent practices as well, we know that it is a possibility that tumour stains and the negative control stains. We also learn through all of this that we have a certain number of cases that have a positive internal control on our slides and they still had converted from zero to Mount Sinai. So that brings the complexity of internal controls as a secondary level of controls.

COFFEY, Q.C.:

Q. Having received this memo and read paragraph three, did it change your practice in any way, your approach?

DR. DENIC:

A. I think it re-emphasized, that I become more cognitive about it, I would say yes. But again, having in mind that there are

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variations.

COFFEY, Q.C.:

Q. Sure.

DR. DENIC:

A. And in the practice of the pathologists that do one or two cases a month, I don't know how all of this would play out.

COFFEY, Q.C.:

Q. And Doctor, the information in paragraph four, in terms of most PR tumour, positive tumours, are also ER positive, ten percent of--he says at the time, ten percent of PR positive tumours are ER negative, appreciate this is being written in April of 2003. I mean, this sort of information about the relative rarity or commonness of combinations of positive/negatives?

DR. DENIC:

A. I think that's additional one, information that he re-emphasized. I seen those numbers, I seen the numbers reading through the literature about it, but just give it to the scope of the practice of the pathologist again who see one or two cases a month, ten percent of the cases, you never know when you look at

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a case, that one of the case that you see wouldn't fall in a ten percent. What we anecdotally say about immunohistochemistry and the tumours in general, they don't read the books, and they don't behave in a way that's written, but certainly it is a good information that he put there for that we should be aware of.

COFFEY, Q.C.:

Q. Did it change your practice or approach, do you recall? Because we have seen, and there are references when you look at the Mount Sinai retest results, bearing in mind the original results, that there are significant number of ER, originally ER negative PR positive tumours that became ER positive and PR positive, but arithmetically, and you were aware of this, I take it, Doctor, that arithmetically, there are more ER negative PR positive tumours than there should have been?

DR. DENIC:

A. If I can elaborate on that, Mr. Coffey? Yes, I'm aware, looking through the database that was compiled by Dr. Mullen, and actually, recently I had more time, because this summer,

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for whatever reason, the OR was--certain number OR was closed, so the service at one period of time wasn't that busy, so I went back and just look all of this, and there are a certain number of these cases that show ER negative PR positivity, and I think, through the statistics that have been done through NLCHI, I think this percentage is around eight percent.

COFFEY, Q.C.:

Q. And the Commission will be hearing more about that. But I'm -

DR. DENIC:

A. If I can just -

COFFEY, Q.C.:

Q. Sure -

DR. DENIC:

A. - finish this off for where I'm going with all of this. This is done on the population, only of the tests that had been reviewed. The statistics that's given in the literature about the percentages of PR negative--PR positive and ER negative is based on the population, an entire cohort of the patient that have been reviewed and published in the

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articles. So what does that mean? That in the let's say 2700 tests that we performed over the years, while we didn't examine all of those, because the other ones had obviously ER and PR positivity or ER at least positivity, the number that was presented falls to two percent on all population of the tests that had been done, and tells you that, in a practice of one of the pathology, because when you see the cases here and there, you might very well have a case which is--ten cases which are ER and PR positive or at least ER positive, and then it would be the case that you have ER negative PR positive. So it's not something that would have been picked up. So based on the calculation, I think even NLCHI did it in their review, this number, based on entire population of the tests which literature does it, looking entire population, is two percent.

So yes, when we look in this cohort that was taken out, I agree with you. It really sticks out. But in overall group, it blends in and falls within the level of published.

COFFEY, Q.C.:

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Q. Doctor, really what I'm getting at here is this, is that having received this memo at the time, in 2003, did it affect your approach in individual cases in terms of your--you know, when I look at a slide or slides and I'm calling it in a particular way, ER negative, PR positive, this is a one in ten according to Dr. Ejeckam's memo, this is one in ten situation, just as lobular invasives, if you call those negatives, it's a one in 20 or a one in ten, depending upon which stat you use. The point being, Doctor, is did you apply that, do you think, can you tell the Commissioner, after having received this? Did you change your approach in any manner to that, that you can recall?

DR. DENIC:

A. I mean, I would change overall practice in a way. You can still see ER/PR, ER negative and PR positive, but again, then you would again based of what he wrote as well, you would include your external controls. You would probably look your internal controls as well, and put all this in a blend now. So not just based on this statement I would change, but I

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would say I would change my practice based of consultations of what Dr. Ejeckam would have written.

COFFEY, Q.C.:

Q. Doctor, paragraph five refers to the reporting approach. I appreciate what's written here. Did this, in any way, change your reporting approach?

DR. DENIC:

A. This is something that we've been reporting and I've been reporting percentages, so I would report one percent, five, ten.

COFFEY, Q.C.:

Q. I take it the answer is no, it didn't change your approach?

DR. DENIC:

A. It didn't.

COFFEY, Q.C.:

Q. Didn't affect you, and you made a note of this, paragraph six, this higher staining intensity does not reflect better results and you referred to that earlier. Were you aware of this?

DR. DENIC:

A. Yes.

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COFFEY, Q.C.:

Q. Before the memo?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. The ER positive tumours is the way he refers to this here, there are four listed here, and Dr. Ejeckam has told us there was a fifth lobular that he should have included. Were you aware that these particular four types of tumours are generally thought to be ER positive?

DR. DENIC:

A. I was aware about the mucinous carcinomas and, if I can just touch bases on the positive tumours.

COFFEY, Q.C.:

Q. So you were aware of one? Just before you go on.

DR. DENIC:

A. Mucinous.

COFFEY, Q.C.:

Q. You were aware of, and were you aware yourself of lobular?

DR. DENIC:

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A. Lobular, and that's what I'm trying now just to let you know.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. I wasn't aware of lobular carcinomas for the reason being the Royal College of Physicians and Surgeons recommended textbook in pathology, which is Rosai Ackerman. The two editions that I know of were one when I started the residency training program, I think it was in '96 edition. There's another one in 2004. They state, based on the source the textbook is referring to, that there's no statistical difference between ductal carcinoma and lobular carcinoma expressing estrogen receptor. But also states that it's known that the mucinous carcinoma expressed more estrogen receptor and one of the carcinoma that we wouldn't expect to express estrogen receptor was the medullary carcinoma. It was really a textbook that I was utilizing a lot and it was my Bible, and when I came out from the residency program, people used to claim that I knew by heart.

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Then, the numbers of the lobular carcinoma, I seen the various numbers and the book of Dr. Tabassoli and it's breast pathology, and she's a well known pathologist. Her book states that positivity rate in lobular carcinomas ranged against--then, based on the statistics presented by the various authors, from 70 to 92. So it's a broad range as such.

I didn't know about papillary carcinomas. I knew about low grade ductal carcinoma because lower the grade, you would expect these to stain.

COFFEY, Q.C.:

Q. And the text you refer to, the second text, you would have seen that when? The second text you just referred to, the one that did refer to lobulars and the range from 70 to 92.

DR. DENIC:

A. That book is old book as well, you know, so this is the book that we had in our department. I can't tell you what edition it is, but -

COFFEY, Q.C.:

Q. That goes back to your residency days?

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DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. Okay, yes, so you would have been exposed to the idea that certainly -
DR. DENIC:
A. That it could go up to 90 percent, but it could be 70 percent. So it still give you the broad range of positivity really, because 30 percent of the cases, if you take the lower level. If you take the higher, 92, then you say almost every single case would be positive.
COFFEY, Q.C.:
Q. And Doctor, so again, in terms of this, at the time, paragraph seven, and I appreciate you already knew about mucinous, but these other three, again did this change your approach?
DR. DENIC:
A. It gave me extra knowledge, but these are the tumours that you see very rarely really. Even lobular carcinomas are rare, between one to 15 percent. It depends again of the stats published in the literature. Mucinous are rare. Ductal carcinoma low grade are not that

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rare, but some of them we call tubular, what you see on the top.
COFFEY, Q.C.:
Q. Doctor, paragraph eight, low grade, the contents of this, were you aware of this before April of 2003?
DR. DENIC:
A. I was aware of that.
COFFEY, Q.C.:
Q. You were?
DR. DENIC:
A. Yeah.
COFFEY, Q.C.:
Q. And so that wouldn't have changed your approach?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Doctor, did you ever have occasion, in your practice, to question the result, an ER/PR, what you were seeing on the slide or at least thought you were seeing on the slide and cause, for example, inquiries to be made or the test to be rerun because what you were seeing on the slide did not accord with what

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you knew about or understood about expected positivity rates, relative rarity of negative tumours? Do you ever remember the knowledge that you referred to, you either had or picked up in 2003, causing you then to actually question something?
DR. DENIC:
A. I can't be certain, you know. It's a lot of things going through our desk, and you know, I really cannot be certain. Maybe I have not. I might have in very rare instances, but most of the time I would not.
COFFEY, Q.C.:
Q. Doctor, in relation to these two memos, the April 4th and the May 2nd one, have you ever received any memo similar in tone or content to the April 4th memo, in terms of telling you "we're suspending -
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. - testing, unreliable, erratic." So you've been here in St. John's on staff almost a decade now.
DR. DENIC:

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A. That's correct.
COFFEY, Q.C.:
Q. Nine years, and this is the only time in your career that that sort of memo, that you've received one anyway like that, the April 4th one?
DR. DENIC:
A. No. I mean, not any other memos, except for these, these two.
COFFEY, Q.C.:
Q. And in terms of the, you know, in terms of the second memo, the May 2nd one, the sort of educative memo, informative memo, have you ever received one like that? And it could be in respect of any sort of--it could be prostate, it could be lung, I don't know, or any other stains. I'm just asking you.
DR. DENIC:
A. There were certain memos that Dr. Khalifa sent around, but if you will ask me what was in the memo, and I know it was educational, he was informing -
COFFEY, Q.C.:
Q. So Dr. Khalifa would, in his time, at times send around educative memos.

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DR. DENIC:
A. Would there be anybody else?
COFFEY, Q.C.:
Q. That you recall?
DR. DENIC:
A. I don't recall, Mr. Coffey.
COFFEY, Q.C.:
Q. So the point I'm making with you, Doctor, is if--I'm not suggesting that you're going to--you're telling the Commissioner that there were no others, there could have been others?
DR. DENIC:
A. There could have been others.
COFFEY, Q.C.:
Q. But it was relatively rare, this sort of educative memo?
DR. DENIC:
A. Yes, yes, I would say relatively rare.
THE COMMISSIONER:
Q. Mr. Coffey, it's well past the time to have a break.
COFFEY, Q.C.:
Q. One final question, if I could, Commissioner, on this? And in terms then of that, Doctor, I take it then that you did not--you don't

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recall any real discussion about, for example, the educative memo? It didn't occasion like discussion in any semi-formal way?
DR. DENIC:
A. This memo in particular?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. Not that I remember.
COFFEY, Q.C.:
Q. If I could just push it a little bit further, one--a little bit further, Commissioner. The final sentence -
THE COMMISSIONER:
Q. (inaudible) Mr. Coffey.
COFFEY, Q.C.:
Q. - "we are working on the remaining antibodies, and hopefully all normal immunostains will resume soon." What happened with the remaining antibodies, do you recall? Because there were six others and what do you recall about what happened with them?
DR. DENIC:
A. I don't think so that we ever received that they were back online at a time, but I can

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only assume because knowing Dr. Ejeckam that he would follow this through, and that they would have been validated.
COFFEY, Q.C.:
Q. And did you ever receive an explanation, seek one or receive one, as to what the problem had been in 2003?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Break.
THE COMMISSIONER:
Q. We'll take 15 minutes.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you. P-0113, please, again. Doctor, the third of Dr. Ejeckam memos is June 19th, 2003, addressed to Mr. Gulliver, and it's copied to a number of individuals. You're not listed amongst them. Were you aware of the existence of that June 19th memo?
DR. DENIC:
A. Of this one, at that time?

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COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Not at that time. When did you first become aware of this yourself?
DR. DENIC:
A. Became aware, I think it was May 2007 when Premier -
COFFEY, Q.C.:
Q. Referred to it in the House of Assembly?
DR. DENIC:
A. - referred to that in the House of Assembly.
COFFEY, Q.C.:
Q. So Doctor, then in terms of the, kind of the overall approach then to ER/PR, your own experience with it, you've described your training in the late 90s and your introduction, what you did as a staff person beginning in '99. You've indicated that at some point, and probably before Dr. Ejeckam's memo, by the time of Dr. Ejeckam's memo, you were aware of internal controls as a subject matter involving ER/PR. You say not so much

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the significance that you would now accord to them, but the idea of utilizing internal controls, you were aware of?

DR. DENIC:

A. That's right, not only for the ER/PR, but for the other antibodies too.

COFFEY, Q.C.:

Q. Sure, and Doctor, because some pathologists have told the Commissioner that until they got this memo, they weren't aware of it, but in your case, you were aware of internal controls as an approach?

DR. DENIC:

A. As an approach.

COFFEY, Q.C.:

Q. And then you got this memo, saw it as--or didn't view the first memo, the April 4th, one with alarm. Didn't raise any alarms. The May 2nd one, it was an educative memo.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. You've told the Commissioner that "some things were new to me. I integrated them into my approach."

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DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And then you continued to do ER/PRs?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And the next time then that ER/PR as a subject matter was brought to your attention, in terms of directly as a concern, was when?

DR. DENIC:

A. It was concern when I think that was 2005.

COFFEY, Q.C.:

Q. Okay, and when in 2005?

DR. DENIC:

A. I would say some time in the summer of 2005 that -

COFFEY, Q.C.:

Q. Okay, so this is when it was really the retesting has started or they were thinking about it?

DR. DENIC:

A. That's right, the thinking.

COFFEY, Q.C.:

Q. I'll get to that then in a bit, but so in

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between then, kind of the only time then between 1999 and summer of 2005 that ER/PR was kind of on your radar as a concern, and it wasn't a big concern at the time, was Dr. Ejeckam's memos?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And other than that, you don't recall any discussion about problems with ER/PR staining or concerns about any--here's why I'm asking about that, Doctor. I'll just ask, Exhibit P-1913? Doctor, this is minutes of the site chiefs and divisional manager, division of anatomic pathology meeting, March 31st, 2004, and you're not in attendance, okay. But you were, at the time, sort of the person who filled in for Dr. Cook on occasion at St. Clare's, okay.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. You had performed--and had been doing that for a while before this, and on page two, under new business, paragraph 4.2, there's new

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technology. "The immunoperoxidase stainer appears to be working generally well," and we understand otherwise that that would be the Ventana.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And then it says "however, there continues to be some problems with estrogen and progesterone receptors." So Doctor, I take it from what you've told the Commissioner, that as you have no conscious memory of ever having that sort of concern about there continuing to be some problems with estrogen and progesterone being brought to your attention?

DR. DENIC:

A. No. No, definitely not.

COFFEY, Q.C.:

Q. If we could, and I'll just pick another one, P-1876? And this is a bit earlier, Doctor, in your career on staff at St. Clare's, but these are minutes of a meeting of site chiefs and divisional managers, division of pathology, April 25, 2001. There are number of present. They don't include, of course, yourself at

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that time. "Business arising: quality control of immunoperoxidase staining. Generally, the immunos appear to be very good. There appears to be some problems with the estrogen and progesterone receptors. Positive controls are checked daily by a pathologist. However, these need to be documented. Dr. Parai is going to follow up on that." And they talk about the heavy utilization of immuno services. But here, Doctor, the assertion in the minutes that "there appears to be some problems with the estrogen and progesterone receptors," this was again, about two years into your staff life at St. Clare's, again, you don't recall this, it ever being brought to your attention?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Now Doctor, and that's not the only one. There are one or two others. I'm not going to take you to them, but during the time you were on staff. The Commissioner has seen references to them in the minutes of various meetings or groups. Doctor, reflecting upon

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it now, okay, would it have been helpful, do you think, if there were concerns about estrogen and progesterone receptors amongst the management, this is Doctors Cook, Parai, Haegert, Mr. Gulliver, and we looked at the exhibit we just had up there, Registrar, please, the one just before this? Oh yes, this one, Doctor, and this is '04. Again, Doctors Cook, Parai and Robb and Mr. Dyer, oh, Mr. Dyer is not present here, but Doctors Cook, Parai and Robb. Would it have been helpful, do you think, Doctor, as a staff pathologist, to have been kind of kept apprised of if there are concerns about estrogen and progesterone stains, and whatever they might be? To at least be alerted to it?

DR. DENIC:

A. Well, I cannot comment exactly. They say there's some problems about it. I can tell you what's my current practice.

COFFEY, Q.C.:

Q. No, and I -

DR. DENIC:

A. And that may answer some of the questions because -

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COFFEY, Q.C.:

Q. Okay. Well, if there were problems now, what would be your approach?

DR. DENIC:

A. That's what I'm saying. But if you have a problem, that's why the director of immunohistochemistry, he has his report to give on the joint program and the discipline meeting. So this would be the venue that all pathologists been apprised for any kind of issues that may arise, that would be the venue that pathologists would express the issue of any general concerns. So while I cannot comment on at the time, I can just tell you what's my practice now, and -

COFFEY, Q.C.:

Q. Your practice as clinical chief and now as director or chief of the lab?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Is to make sure that if there are problems with immunohistochemistry stains, brought to your attention by Dr. Elms, the director?

DR. DENIC:

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A. That's correct.

COFFEY, Q.C.:

Q. That the staff pathologists are told from time to time what's going on?

DR. DENIC:

A. That's correct. And Dr. Elms has his standing on my meetings and he give the report.

THE COMMISSIONER:

Q. Are you referring then to the regular meeting of pathologists?

DR. DENIC:

A. That's right.

THE COMMISSIONER:

Q. All right.

COFFEY, Q.C.:

Q. And this regular meeting of pathologists, had that been going on in one form or another all the way back to 1999?

DR. DENIC:

A. Yes, they were going on from the -

COFFEY, Q.C.:

Q. Over the years?

DR. DENIC:

A. Over the years, that's right.

COFFEY, Q.C.:

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Q. And there'd be meetings of the pathologists at St. Clare's and there was the larger program meeting at the General Hospital?
DR. DENIC:
A. Program meeting that been chaired by the clinical chief or discipline chief.
COFFEY, Q.C.:
Q. Doctor, and in terms of the MAC, because you, at various times, did attend the meetings?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Prior to 2005 do you ever recall anyone saying anything about ER/PR, expressing any concerns about ER/PR at an MAC meeting?
DR. DENIC:
A. Not that I can recall.
COFFEY, Q.C.:
Q. You don't. If we could look, please, at Exhibit P-2638? This is again a review of yourself for 2004, Doctor, just the third entry, acting chief of department in the absence of Dr. Cook. So it had gone back, certainly back to '02 and you were continuing in '04?

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DR. DENIC:
A. That's correct. And was -
COFFEY, Q.C.:
Q. That continued right up until the time you -
DR. DENIC:
A. That's right. Whenever he's away, he -
COFFEY, Q.C.:
Q. You took over for him, okay. Doctor, look, please, at Exhibit P-1918? Again, this is October 7, 2004, it's to all pathologists from Dr. Cook. It's involving estrogen and progesterone receptors. And it says, "I'd like to remind everyone that estrogen and progesterone receptors should be ordered automatically on all excisional biopsies." And he goes on to talk about the other types of specimens. "It has come to my attention that these receptors are not being ordered on a number of cases." Do you remember receiving this memo?
DR. DENIC:
A. I believe so.
COFFEY, Q.C.:
Q. And at the time, and I appreciate it's addressed to all pathologists, which would include yourself?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. But did you actually think it was directed at yourself, were you ordering ER/PRs before this?
DR. DENIC:
A. Yes, I was.
COFFEY, Q.C.:
Q. Okay, so if some staff were not doing it -
DR. DENIC:
A. Didn't affect my practice. It would be on occasion it had been picked up people finish the case, they report the case, give everything ready and just slip through their mind to order estrogen and progesterone receptor, you know, so the oncologist would call and ask for the results.
COFFEY, Q.C.:
Q. Doctor, again, before you became interim clinical chief, I'm going to ask you about quality assurance activities as a site--I'm sorry, as a site, as a staff pathologist at the St. Clare's site, what, if any, quality

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assurance activities were you involved in beginning in 1999 all the way up through your clinical chief days, up until you became clinical chief?
DR. DENIC:
A. Quality assurance activities, the ones that the pathologists been involved, you can divide into the continuing medical education because that's a part of the quality, as well, and the quality of practices that we had. In terms of the educational portion, pathologists were attending various meetings of their interest, conferences. We would have been subscribing the certain journal, like American Journal of Surgical Pathology, which is the most current and one of the best journals for practising pathologists, so that they could be apprised for the new coming knowledge in the field of pathology. We had various rounds where we would meet clinicians which would include tumour board rounds, lymphoma rounds, some of these rounds that you can see from my CV I chaired for awhile, clinical pathological rounds, then we had the med-path rounds, so these are all educational activities that we

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exchanged the knowledge between the clinicians. The rounds, type of quality control rounds we had the surgical rounds. Those rounds would be held once a week where the cases of interest, and not necessarily great difficulties, but those ones, too, would have been shown to the pathologists and asked for their opinion. And we found those very valuable to assure that the good quality of reports are going out, that everybody is on the same page and that we can provide the best care for the patients.

COFFEY, Q.C.:

Q. Okay. Anything else, Doctor? The idea of here is an example, okay, like, for example, have somebody randomly check a case that you had done or you check somebody else's case, like in effect an audit of some sort or another -

DR. DENIC:

A. Not at that time.

COFFEY, Q.C.:

Q. Not at that time. Doctor, do you recall whether it was ever discussed back then, the idea of, between '99, say, and before the

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summer of 2005, the idea of--did it ever come up, that you recall, of having randomized audits, not directed at any one individual, but just to assure everyone that, look, things are being done properly?

DR. DENIC:

A. I cannot recollect it. It might have been among Dr. Cook or Dr. Haegert or -

COFFEY, Q.C.:

Q. In terms--yeah, but I'm asking about in terms that you were aware of?

DR. DENIC:

A. That I am aware of -

COFFEY, Q.C.:

Q. You're not -

DR. DENIC:

A. No, that I can recall. Maybe it was mentioned. So many things been mentioned in the last ten years. But not that any great initiatives was put in it, but was it discussed, I believe it might have been, but I don't have a knowledge of it.

COFFEY, Q.C.:

Q. Doctor, we've seen a reference to an exhibit, it's September, 2004 minutes where Dr.

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Fontaine raised, at the General Hospital site, and it wouldn't--I believe you wouldn't have been in attendance, the idea of a request by Dr. Carter to have her be able to see all the ER/PR cases, the slides? She wouldn't report them, but she wanted just to see them because she's breast pathologist. Were you aware that Dr. Carter, in 2004, was interested in kind of looking at all slides, all ER/PR slides?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. It wasn't -

DR. DENIC:

A. No. That was discussed, obviously, at the General Hospital site.

COFFEY, Q.C.:

Q. And within St. Clare's itself, because she was at St. Clare's at that time.

DR. DENIC:

A. You know, but I don't recall that was discussed. Dr. Carter was there and her services were anyhow utilized by the pathologists.

COFFEY, Q.C.:

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Q. Yes.

DR. DENIC:

A. At the St. Clare's.

COFFEY, Q.C.:

Q. And it was put in the note that we've seen, in effect, not that people were consulting her so much as she just wanted to keep her skills sharp and she would want to see, just because of the sheer volume, would have liked to see more ER/PR slides?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. But that expression of interest on her part, you weren't aware of that?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. All right. Doctor, before I get right down to the ER/PR itself, beginning in 2005, I understand that you were involved in the pathology working group? Because you're certainly referred to in their minutes, and I'll just bring it up here, or have the Registrar do it, P-0922? Doctor, this is who

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attendees are, you're listed second there.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctors. Pardon me?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Yes. And this is the first meeting of the group referred to under the general introduction. And the Commissioner again has seen a number of exhibits related to this already. But I'm just going to ask you generally about your involvement, if you could describe the nature of your involvement on behalf of pathologists generally in relation to the issue of compensation, remuneration and working conditions?
DR. DENIC:
A. I took my position in December, 2004 as president of Newfoundland Association of Pathologists. I was elected by the members of the group. And one of the first initiatives that I saw in my goals is to bring up the issue of pathology and the pathologists in

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this province to the eyes of the public as well as to government. Because at that time and really over the years and still it continues as we speak, pathologists were under valued, pathologists were last on the list of any medicine type of reviews and the scopes. We were at the time minimally paid and I think at the time even worst paid across the country, if not across North America, and my goal is and it was at that time to bring this forward. So I got involved in NLMA at a time almost first thing in January. And I was asking Mr. Ritter just to organize a meeting so that I can meet the government officials and bring this forward. Because I realized that we are in the situation that we are for the several reasons, and one of them is the people don't know what we do. People see the lab as the black box that something comes down, comes back on the other end, and the people are not involved, really, that everything, machines been done and people never saw how extensive training we had, which was still five years of residency training, which is the same as the surgeons do.

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COFFEY, Q.C.:
Q. Yeah. So, Doctor, just while we're on this point, and I want to clarify this for the Commissioner, people, you used the word "people" okay, so I take it don't understand what you do or appreciate what you do and perhaps without an educational effort, they couldn't be expected to?
DR. DENIC:
A. That is correct.
COFFEY, Q.C.:
Q. You're off to yourselves. People in this context would include, I take it, the health authorities administration?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Government civil servants, bureaucrats?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Politicians?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. Members of the public at large?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Patients?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Clinicians who are not pathologists?
DR. DENIC:
A. That's correct, too.
COFFEY, Q.C.:
Q. Yeah. It also includes your fellow physicians but the ones who are not in the lab with you?
DR. DENIC:
A. Exactly.
COFFEY, Q.C.:
Q. Okay. So I just wanted to clarify that. So when you say "people" this is, you know, this is not directed at any one group, this is the world at large, in effect, from your perspective?
DR. DENIC:
A. That's correct, that's absolutely correct.
COFFEY, Q.C.:

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Q. Okay, go ahead, Doctor, I'm sorry. So you-- something had to be done?

DR. DENIC:

A. Something had to be done. So the meeting was organized by, at that time they called them Physician Service Liaison Committee. That was in March. I did prepare a presentation, and I designated the part of my presentation to Dr. Fontaine and I brought Dr. Ford Elms with me, as well as--in case any other questions and to got involved with this. And I believe at the time Dr. Elms was sitting on one of the committees for the salaried physicians to NLMA, so any kind of input that he had. So we brought this presentation forward to the government officials, and at the time that was Mr. John Abbott, Dr. Ed Hunt from the government that I remember. And there were the members, as well, from the NLMA and Dr. John Haggee and Dr. Susan King and Mr. Ritter was there. Probably was some more people there, as well. So we brought that up as a presentation, but the presentation was set up really to describe what the pathology is all about, what are we dealing with and

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what is our role and specialty in delivering the patient care and in particular the cancer patient care. We were talking about the workloads. We presented some of the numbers. And we were talking about the problems about all of these starting from the, again, people not knowing, including even under grads did not know what we do and it is difficult to attract somebody. But the argument, as well, is under grads know what the pathologists do, but they also know how much they are paid for it. They also know how much effort you have to put into it in order to get into the speciality, which is not recognized, on the top, we don't see patients and maybe that's not attractive for the physicians because, you know, if you say medicine, automatically connected to patients. But we were talking about overworked pathologists, what does that mean, what does it mean to be burned out and how that can affect the patient care when tired pathologists are reading the slides and making the diagnosis based on which the treatment depends. So -

COFFEY, Q.C.:

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Q. You made your presentation. And what was the result, initially?

DR. DENIC:

A. I think it was well taken, it was well taken. And I did have a few conversations after that with Mr. Abbott at the time and he was very receptive, I must say, for whatever we said. He didn't know what to do because when you say pathologists, people are thinking these people are autopsy only and the autopsies was less than .5 percent of our workload.

COFFEY, Q.C.:

Q. Yeah.

DR. DENIC:

A. So this is something that we almost didn't do. And -

COFFEY, Q.C.:

Q. So where did it go from there, Doctor? You got a sympathetic ear and -

DR. DENIC:

A. The government at the time decided they would like to bring this back to the physician service, or medical service committee where the various representatives including the medical directors across the region would have

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been involved in order to give their opinion. And the pathology working group was struck, as you can see on the screen.

COFFEY, Q.C.:

Q. That would be in the middle of June?

DR. DENIC:

A. That was in the middle of June.

COFFEY, Q.C.:

Q. 2005.

DR. DENIC:

A. And we produced, actually, we met twice, I believe so.

COFFEY, Q.C.:

Q. Yeah.

DR. DENIC:

A. And we produced a document.

COFFEY, Q.C.:

Q. The Commissioner has seen that document.

DR. DENIC:

A. Yes, the document that really explain everything that I said now and the seriousness of situations and -

COFFEY, Q.C.:

Q. Exhibit P-1286? That's the document that you're talking about?

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DR. DENIC:
A. That's the document.
COFFEY, Q.C.:
Q. Yes. And so, Doctor, the group kind of diligently works away, produces this document. Who did you present it to and what was the reaction?
DR. DENIC:
A. This document was presented by Dr. Williams, I think he passed back to the government officials obviously around September, as such. And there was no, actually, there was no, any kind of feedback from government based on this. Although the document itself was very strong and showed the support across the board, not only that the pathologist were involved but the medical directors, too.
COFFEY, Q.C.:
Q. Yeah. There are letters of support attached, appended to this report here.
DR. DENIC:
A. That's right, there are some letters of support that we received from the Cancer Centre signed by Dr. Laing and Dr. P.K. Ganguly.

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COFFEY, Q.C.:
Q. I take it, Doctor, that there was no immediate positive response in the sense of the concerns that were expressed there were not immediately addressed?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. If I could, please, Exhibit P-1338? Doctor, this is a letter of--it's from yourself to Mr. Ritter, Dr. Williams and Mr. Abbott, December 7th, 2005, it's called "Joint Statement, Newfoundland Association of Pathologists and Laboratory Directors, Chiefs of Pathology Departments."
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And it's from yourself in your capacity as president of the Newfoundland Association of Pathologists. You write, "Due to the current shortfall of pathologists in Newfoundland and Labrador and significant increase in workload and demand, it is our decision to restrict the daily maximum number of specimens that can be

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safely reported by each pathologist. The current workload is not sustainable. Continuing to practice under present circumstances would jeopardize patient care, pathology practice standards." And you go on to explain that you do not expect the decision will have an adverse effect on patient care, however, increased turnaround times could occur over certain specimens.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Now, Doctor, I take it then that two questions in this regard. At that point, in December of '05 it existed, I take it, a current shortfall of pathologists at that time?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And it was province wide?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Had that existed for a period of time?
DR. DENIC:

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A. That existed through all of this time.
COFFEY, Q.C.:
Q. And that's what I'm getting at. So this wasn't something that happened in November of '05, this had gone on for a period of time?
DR. DENIC:
A. That's correct, that's -
COFFEY, Q.C.:
Q. First thing, so there was a shortage of pathologists. You report, in fact, in September, in fact, refers to that, I think, and workload issues and so on.
DR. DENIC:
A. Actually, the report in March.
COFFEY, Q.C.:
Q. Yes, in the first one, but then the one we just looked at -
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. - then a couple of moments ago. So, Doctor, you're pointing out in your view, at least, the current workload is not sustainable. Doctor, what then happened? I take it you wrote this because there was no, in effect, no

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practical reaction to what you had done up to this point in time?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Your concerns were not addressed.

DR. DENIC:

A. I mean, we had to--I mean, the purpose is to tell the official how bad situation is, to tell them that without reacting on this we are jeopardizing the patient care, but we don't want to take the blame on it. We are just ringing the bells and just tell you this is definitely going to affect the patient care and while we know that we're going to give everything that this doesn't happen, that yes, we're going diminish the number of cases, but we're going to be still working with the urgent cases. So this was the whole point of this, trying to protect the, firstly, to protect the patients because minimizing your workload you dedicating your time more to the patients slides rather than to rush them through. And secondly, protecting the profession as such, again, having burned out

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pathologists. So that was the purpose of this document. What happened after that is that Dr. Don Cook, Dr. Williams and Mr. Gulliver, they start working on outsourcing the, some of the tissue out.

COFFEY, Q.C.:

Q. Um-hm.

DR. DENIC:

A. And they found the agency in Ottawa is called Gama Dynacare and they struck the deal with them. I wasn't quite certain about the other regions, what they have done, and I was told that they're going to pursue as we agreed, so obviously they did, I think I spoke to Dr. Neil at that time, that they did curb the number of specimens that the pathologists going to see over the course of a day.

COFFEY, Q.C.:

Q. Now, Doctor, what then happened? Again, you know, not necessarily in a minute-by-minute -

DR. DENIC:

A. I mean, nothing didn't happen at that time until again around May of 2006.

COFFEY, Q.C.:

Q. Exhibit P-1372, please? I said 172, 1372.

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It's a letter of May 16, 2006, Doctor. I think you'll recognize it.

DR. DENIC:

A. I do.

COFFEY, Q.C.:

Q. It's addressed to Mr. Osborne and Mr. Sullivan. And it's from yourself and Mr. Ritter. Signed it right there, last page?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Okay. So what do you recall about how it came to be that this letter was written?

DR. DENIC:

A. I think Dr. Ritter--Dr. Ritter, Mr. Ritter received a call or the information came from the government they're not going to react upon our demands unless the workloads being conducted.

COFFEY, Q.C.:

Q. A workload?

DR. DENIC:

A. For the pathologists.

COFFEY, Q.C.:

Q. So I take it -

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DR. DENIC:

A. Workload study.

COFFEY, Q.C.:

Q. And when we bring--and the Commissioner again has seen the contents of this.

DR. DENIC:

A. Okay.

COFFEY, Q.C.:

Q. Already. At least, I don't know if she's had it all read to her, but she's had portions of it read out here. It just begins, "We are writing in follow-up on our recent request that the government implement a new annual bonus commensurate with existing oncology bonus for all pathologists practising in Newfoundland and Labrador." And it goes on from there. And it does refer to the, if we look at page 3, the second--the last paragraph it begins, "We are not opposed to a workload review." So -

DR. DENIC:

A. That is correct.

COFFEY, Q.C.:

Q. Workload review had come up by this point in time. This is addressing it and saying, look,

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we will participate.
DR. DENIC:
A. That's correct. But when we started all of this in this letter tells that you have to address this issue very fast. For workload review, while we didn't oppose it, that is going to take time to develop the terms of reference to find who's going to be doing it and frankly speaking, we were thinking that's a stalling technique or tactic.
COFFEY, Q.C.:
Q. Doctor, here at page 4 of the exhibit you did note on the middle paragraph it reads, "The pathologists in Newfoundland and Labrador feel under valued, unappreciated and demoralized. The pathologists diagnose disease and work with other physicians to develop the best treatment regimes for their patients." And you go on then to conclude by, toward the end of that paragraph by saying, "The malaise among our pathologists have reached a critical point and needs to be addressed without further delay. If we are not treated with respect and fairness we are entitled to, these services will no longer be sustainable in our

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province." And you then conclude the whole of the letter by saying, "In the best interests of all concerned we respectfully ask to meet with you at your earliest convenience so this crucial matter may be addressed without further delay." I take it there was -
DR. DENIC:
A. There was a meeting.
COFFEY, Q.C.:
Q. - meeting. And what was the outcome of the meeting?
DR. DENIC:
A. The outcome of the meeting is that I think Minister Sullivan, he understood the issue and but still he wanted the workload review to be done. He was thinking that this is the only way that the government can address this issue.
COFFEY, Q.C.:
Q. And Mr. Sullivan at the time was the Minister of Finance?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. The workload review was conducted by Dr. -

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DR. DENIC:
A. Raymond Maung.
COFFEY, Q.C.:
Q. Maung. And again, the Commissioner has seen the report as an exhibit here. I take it that you and your fellow pathologists participated in that review?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. We know if you were interviewed, you cooperated in that? Dr. Maung's report was filed, I believe, in early 2007?
DR. DENIC:
A. It was filed in January, 2007.
COFFEY, Q.C.:
Q. 2007. And in summary he recommended what?
DR. DENIC:
A. In summary he recommended the extra staff. Even what we had on the books wasn't sufficient for something where tertiary care institution should go.
COFFEY, Q.C.:
Q. I was going to ask you to expand upon that. I'm sorry, would you just repeat that, Doctor?

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He recommended extra staff because?
DR. DENIC:
A. Where the tertiary care institution such as ours should go in terms of the number of staff, based on his calculation, based on a number given, not number had, was sufficient. However, in order to take on extra consultative work from the other regions of the province, because it's a tertiary care institution, we should take--and we have been doing consultative work for the rest of the province, so the pathologists would send some of these cases out to our place so that we would help them out, interpret and come to the conclusions of the diagnosis. The extra two positions that he assigned to were also to relieve some of the workload that periphery might have since we have the single practitioners and these people cannot go on a vacation. So -
COFFEY, Q.C.:
Q. Because they can't get -
DR. DENIC:
A. - people to do their job -
DR. DENIC:

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A. - they can't get a locum?
DR. DENIC:
A. That's right. So the pathology, who's going to take on that workload until they find a locum position and somebody to, replacement for that period of time they are absent. Also, the part of having more people is to get involved in more of cancer patient treatment, you know, secondary reviews of the cases, you know, that can come to the Cancer Centre, as such. So this is necessary to have a full compliment even more in order to properly function.
COFFEY, Q.C.:
Q. As a tertiary care --
DR. DENIC:
A. As a tertiary care institution.
COFFEY, Q.C.:
Q. Institution, in the context of Newfoundland?
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. So right now--I want to make sure that I understand. Your reading of Dr. Maung's report was that the number that was there

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would be sufficient for the institutions in which they worked, but not take into account the role of the institution as a tertiary care facility, is that --
DR. DENIC:
A. That's correct, that's correct, and he designated extra number of pathologists. Even for Corner Brook, there's a certain point of FTE, given even to Carbonear, and so forth. So almost every single centre was, based on his report, given additional support.
COFFEY, Q.C.:
Q. So he filed his report. Did he say anything about compensation in the report?
DR. DENIC:
A. He also said that the compensation in the report has to be addressed, that they cannot allow just keeping the level of compensation as such because they're not going to recruit anybody, and subspecializing, he also put in his report as the way that we should go, but in order to subspecialize, you have to have manpower, and how you're going to have manpower when you have a 30 percent turnover, and in a ten year period of time, 34

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physicians occupying 18 positions, so that we had--so in ten years time you had almost 80 percent of turnover. So this was--that eventually we took a term "revolving door" from Dr. Banerjee's report, "syndrome", and based on the high turnover, you cannot sustain the quality of service that we all cherish. We want subspecializers because I think that's the way to go, and to deliver the best service for the patients.
COFFEY, Q.C.:
Q. Doctor, he filed this report or made it available in January of 2007. What then happened?
DR. DENIC:
A. In 2007, nothing happened except that I started receiving again resignations.
COFFEY, Q.C.:
Q. So by this point in time--I'll be coming back to that, but you're clinical chief by this time?
DR. DENIC:
A. That's right, and in 2006, just to back up a little bit, we recruited four residents from our program, which we found a nice influx of

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fresh blood, the people that we trained, the people that we can trust, and by March of 2007, they were all gone.
COFFEY, Q.C.:
Q. So you had recruited them coming out of--finishing up LSATs?
DR. DENIC:
A. We invested in them, spend the time -
COFFEY, Q.C.:
Q. So they had been residents here?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. They were finished their residency in '06?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. I'm sorry, go ahead, and by March of '07?
DR. DENIC:
A. By March of 2007, all four were gone, and I think I even forwarded a letter to Mr. Abbott, a copy actually of the letter of one of our former residents and who was on our staff who left in December of 2006 where he expresses his opinion about the entire system. So I did

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write the letter to Mr. Abbott at the time. I might have cc'd it to some other people, and if you have the exhibit --

COFFEY, Q.C.:

Q. And, Doctor, so the point being that Dr. Maung's report came in. It was commissioned by the government, they wanted it. You participated in it?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. As a group. The report came in and there was no immediate positive response by the government to it?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. In the sense of implementing the recommendations?

DR. DENIC:

A. No. I get a telephone conversation with Mr. Abbott sometime in March, and he told me that the department is supporting it, meaning the Department of Health.

COFFEY, Q.C.:

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Q. Yes, and Mr. Abbott has been here and described for the Commissioner, in fact, that that's, in fact, how he felt and that's what he did?

DR. DENIC:

A. And I believe he was very supportive all along.

COFFEY, Q.C.:

Q. So what then happened, Doctor?

DR. DENIC:

A. Then I think--in the same period of time, I think it's March, I delivered another letter. At that time, Dr. Carter was looking for position somewhere else, I think in BC. She approached me asking to be a reference because she realized as well that she was underrated here and being a high professional as she was, so I filed another letter to Mr. Abbott.

COFFEY, Q.C.:

Q. Exhibit P-0201, please. This is March 8th, 2007, Doctor. It's certainly one of the letters, anyway.

DR. DENIC:

A. Yeah.

COFFEY, Q.C.:

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Q. Is this one of the letters you would be speaking about?

DR. DENIC:

A. I think it is another one after that. There's another one that--again this is the time that even Dr. Fontaine was supposed to leave at that time, and he was--his main interest was in cytopathology and actively involved and losing him as well would jeopardize the cervical screening program.

COFFEY, Q.C.:

Q. Exhibit P-1695, please. A letter of March 27th, 2007, addressed to Mr. Abbott from yourself, copied to Ross Wiseman, the Minister, and Dr. Howell, VP Medical.

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. And there's an enclosure letter from Dr. B. Carter and a job advertisement. I take it this is the letter to Mr. Abbott?

DR. DENIC:

A. To Mr. Abbott, that's right.

COFFEY, Q.C.:

Q. Referring to the problem you were facing with

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Dr. Carter's imminent departure?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, in relation to this, I want to ask you about something you've written here. Mr. Abbott at the time was the Deputy Minister of Health, and, in fact, you understood from your dealings with him that he was supportive of implementing at least certain aspects of Dr. Maung's report?

DR. DENIC:

A. Definitely. He was supportive along the way and all the way really. Whenever we spoke, he would say here's my favourite pathologist, now I know, and I tell the other people what you guys do. So I knew from--that he was very supportive.

COFFEY, Q.C.:

Q. Doctor, here in the second paragraph you write, "I cannot stress enough that after all the fiasco with ER and PR testing and interpretation, the loss of this pathologist will greatly jeopardize the future of breast pathology practice in our province. She is

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currently the leader of the newly formed breast subspecialty task group at Eastern Health and an invaluable resource for pathology and oncology practice in Newfoundland and Labrador", and you go on to point out, "She's an acting chair for the breast disease site group for the provincial cancer centre coordinator for educational events for NAP and Eastern Health and the director of a quality management program for pathology, and you conclude by saying, "As stated so many times before, I hope that you and Minister Wiseman bring this serious issue to all those who care for the patients of this province and bring a resolution to pathology problems immediately". So I take it you looking from Mr. Abbott and Mr. Wiseman a resolution of this?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And in the context here, you've said to them, "I can't stress enough after all the fiasco with ER and PR testing". Now I take it that that's a somewhat colourful way of referring

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to the ER/PR problem that was identified in 2005 and what happened afterwards?

DR. DENIC:

A. That's right, yes.

COFFEY, Q.C.:

Q. And in the context here, "In light of the problems with ER/PR testing and interpretation", you're saying, look, here we are, we're about to lose the only breast pathologist we have?

DR. DENIC:

A. This is correct.

COFFEY, Q.C.:

Q. And this is what she's doing for us. Doctor, what was the response to that, initial response to that March 21st letter?

DR. DENIC:

A. I think he just acknowledged --

COFFEY, Q.C.:

Q. Receipt of it.

DR. DENIC:

A. Received the letter, and I don't remember anything else happened.

COFFEY, Q.C.:

Q. I take it that you don't have any recollection

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of there being any positive in the sense of we're going to get this done next week or next month?

DR. DENIC:

A. No, it was until--it was sometime in May.

COFFEY, Q.C.:

Q. And we'll get to that in a moment, but one other thing I wanted to ask you about, Doctor, is this, do you know if this problem and a resolution of this was ever raised with the Board of Trustees of Eastern Health around this time?

DR. DENIC:

A. It might have been by Mr. Tilley.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. I remember that Dr. Howell and Mr. Tilley told me that they're going to bring this issue to the Board.

COFFEY, Q.C.:

Q. Okay, so you weren't there if it was raised?

DR. DENIC:

A. No.

COFFEY, Q.C.:

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Q. But you were advised that it was going to be brought to the board?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. With a view--you would have understood that the Board of Trustees or someone from them would try and get something done about it?

DR. DENIC:

A. That's right, you know.

COFFEY, Q.C.:

Q. So when is the next you heard about this?

DR. DENIC:

A. I heard about this on the news.

COFFEY, Q.C.:

Q. What did you hear?

DR. DENIC:

A. But that was in May. Frankly speaking, I was very disappointed that I have to find out about this, that oncology's bonus going to be given to the pathologists, it was a news cast from the House of Assembly and I believe that Lorraine Michael was -

COFFEY, Q.C.:

Q. So you heard about it because of a news cast

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involving the procedures in the House of Assembly?

DR. DENIC:

A. News cast, but I believe I was the last one to find out officially.

COFFEY, Q.C.:

Q. Doctor, while I'm on the topic, I'll ask you this. Doctor, so the oncology--payment of what's known or referred to as the oncology bonus -

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. - was indicated in May of 2007, that pathologists in this province would be receiving that?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. In terms of the matter of workload and increasing the number of positions, particularly at the tertiary care institute that Dr. Maung referred to, has any--has that been addressed at all?

DR. DENIC:

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A. No. That hasn't been addressed. I was told in some of the conversations with Dr. Cathi Bradbury, as well, let's first fill these positions and then we're going to look after at the additional ones.

COFFEY, Q.C.:

Q. Okay, fill the current ones?

DR. DENIC:

A. Yes, fill the current ones and then we're going to see what we're going to do about it, but it's not that were given upfront.

COFFEY, Q.C.:

Q. And Doctor, again, the Commissioner has heard some evidence concerning announcements of improved compensation since May of 2007, since that announcement about the oncology bonus, improved compensation for pathologists in Newfoundland and Labrador. What can you tell us about your knowledge about that?

DR. DENIC:

A. This new compensation, as you refer to, again that came into the light during the tremendous strain that pathology was still under and in light of new resignations. Dr. Carter, again, submitted her resignation and this time was

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quite firm resignation and without any possibility of retraction.

COFFEY, Q.C.:

Q. In fact, she has since gone.

DR. DENIC:

A. And since then she's gone, and she's gone since June. That obviously provoked a lot of media attention because of the ER/PR and I think even I had an interview at that time. Then there was another impending resignation from Dr. Fontaine that he was my divisional chief of cytopathology and in my agreement with him, I gave him a full responsibility and a full-time job down there in cytopathology so that he can dedicate his knowledge and efforts in cervical screening and cytology at all. He was very actively involved in provincial cervical screening program. So losing two people of this calibre, I think it was very tough for me, because I found myself responsible for delivering the service without people.

COFFEY, Q.C.:

Q. Without the bodies to do it.

DR. DENIC:

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A. And I think that's where the media attention came into play.

COFFEY, Q.C.:

Q. So Doctor, and again, there has been reference to, the Commissioner has heard evidence, in a general way, about what happened in terms of the announcement of the enhanced compensation for pathologists. Was this something, Doctor, I mean, were you asked for your input into that or was this something you were just told, finally, "look, this is what we're going to do, we, the government, are going to do."

DR. DENIC:

A. We had input in that. I started, again, interaction with government officials, especially the Minister Wiseman, and I met him in a few occasions as well, that we discussed various issues. On one occasion that we met, we discussed the issue of Dr. Carter leaving, and what we are going to do about it. On one occasion, we discussed the issue how we immediately going to resolve this issue, and there was a third instance as well that I met with Minister Wiseman as well, discussing on all of this, asking for resolution. NLMA was

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also involved.

And the way I saw that this had been resolved is to compare our self with Ontario, because all the losses were to Ontario, most of them, and some of them to Alberta. So we were not competing any more with PEI, New Brunswick and everything else. And the only resolution that I thought at that time, to compare our package with the package with Ontario, which was already well written and implemented as such. Even then, before all of this is done, when we were losing our pathologists, they would be making over $100,000 more, at least, to Ontario.

So being foreign medical grads, which most of the pathology residents are, including myself, having no ties to Newfoundland, obviously staying here for weather and the whales and the puffins wouldn't be so much attraction, so they would be leaving the province, because there are no ties. There's nothing to keep them, and we were all starting our second life at a later age. So in order to provide the basic necessities for the families as well. When I started, I was

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already 40. When I started back in Yugoslavia, I was 23. It's quite a huge difference. So these people would leave.

COFFEY, Q.C.:

Q. So you were telling Mr. Wiseman and his officials, "look, if we're going to get these people to stay," or at least perhaps convince them to stay, "you have to match Ontario, Alberta, those sorts of numbers"?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. And packages, and I take it then that what then happened finally?

DR. DENIC:

A. Finally, we were delivered--we submitted our requests. Among the requests were that Ontario package should be implemented. There was also included a request for the CME activities. Before, we had a one-week of CME activities guaranteed with $2,000 given for us for the CME activities, which are quite insufficient.

COFFEY, Q.C.:

Q. That had been long--that had been all the time

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you'd been on staff?

DR. DENIC:

A. That had been all the time. So we were asking for two weeks and a $5,000 increase. But we were also asking for additional money to be given to the clinical chief for the various educational activities that I can organize in the department and the other clinical chiefs actually in the other regions. We were also asking for additional package equal to 18 months of fellowship training for the pathologists because we have even now new residents that are willing to go and do fellowship trainings of six months to a year.

COFFEY, Q.C.:

Q. That's after their basic residency?

DR. DENIC:

A. After residency, because a fellowship training, you want to go on fellowship training in the subspecialty of the breast, then you go somewhere else. If you want to go in prostate biopsies, you go somewhere else, or genitourinary subspecialty training. That we can utilize that budget, that we can send them away and bring them back, and they should

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be obliged to give at least two or three years of return of service.

COFFEY, Q.C.:

Q. So that's what you're looking for?

DR. DENIC:

A. That's what we were looking for, and eventually, we received the package in the mail, really, that did reflect some of this stuff. So we were given the remuneration level as of Ontario. We were given CME activity for two weeks and $5,000 which was a part--all of this is a part of that package, the money figure that you've seen. We were given $21,000 for educational activities, only it was given to Eastern Health. It wasn't given for any other regions, which I already utilized a portion of it bringing one of the expert for the workshop in June. Dr. Srigley was just talking about prostate biopsies. We were not given any additional money for the fellowship trainings, because we were talking to the government, we need to subspecialize. We need to have the people. We're going to send them away, they come back and bring it, and build the group around these people. You

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don't necessarily have to send everybody out. So this hasn't been done yet. So this package was delivered individually.

COFFEY, Q.C.:

Q. To each pathologist?

DR. DENIC:

A. To each pathologist, and -

COFFEY, Q.C.:

Q. When was that, Doctor?

DR. DENIC:

A. I believe that's May sometime.

COFFEY, Q.C.:

Q. Of 2008?

DR. DENIC:

A. Yes, of 2008.

COFFEY, Q.C.:

Q. Doctor, again, your sense of the effect on morale of that package has been what?

DR. DENIC:

A. It was well taken. You can say about it, everybody was pleased from the staff, but it was like a peers victory, as you know what I refer. We won, but in all these years, we were beaten down to the ground. At the end, when you receive it, you know, yes, you

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appreciate receiving it, and we are thankful for that, no doubt about that. But it just, you know, take time to build up all of this back to the normal.

COFFEY, Q.C.:

Q. Doctor, if we could then--I'm going to take the Doctor up on where they are right now with that, just after lunch, Commissioner, if I could?

THE COMMISSIONER:

Q. All right then, we'll meet again at 2:15.

COFFEY, Q.C.:

Q. Thank you, Commissioner.

(LUNCH BREAK)

THE COMMISSIONER:

Q. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Dr. Denic, just before we broke for lunch, you were telling the Commissioner about the developments in relation to compensation for pathologists.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And I take it then that each of the

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pathologists received this offer and you've described, you know, your understanding of their--certainly your own, and the reactions overall to it. What has the--what's the current situation, in terms of, from your perspective, in terms of recruitment, the effect, if any, it has had yet, at least up to date on recruitment and you anticipate it might have? Because I take it, as the chief, you are responsible for recruitment?

DR. DENIC:

A. That's correct. All application would come, or to Dr. John Guy, who is the medical director or would come to me, but we would exchange all applications and move the process forward. So with the recruitment and retentions since this occurred, that we were given a better package, we substantially increased the number of applicants applying for these positions, and I think that the current status of those that applied, I would say in the range of over 20 at this point of time.

COFFEY, Q.C.:

Q. For how many positions right now?

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DR. DENIC:

A. As of September, I'm going to be five positions short for the adult pathology service.

COFFEY, Q.C.:

Q. For the what?

DR. DENIC:

A. Adult pathology service.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. Because why it is to the adult pathology service, which always been and has been actually short, and then we have one neuropathology and one pediatric pathologist, which is a part of the Child and Women's Health Program. So five positions short out of 17, and unfortunately, I received another resignation of one of our newcomers. As you remember, there were two pathologists that were coming as of summer of this year. One of them did a fellowship in molecular markers in UK, and another pathologist, she came from the States and she had a fellowship in hematopathology. So this pathologist is

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leaving as end of November, the reason being family reasons in particular, and nothing else. She has a family in Montreal and while she was applying here, she applied in Montreal and so she first received the job application for Newfoundland, but since the family is still in Montreal, she is going back for family reasons, up to Montreal, so just as part of explanation. Somebody may ask why she is leaving so soon.

COFFEY, Q.C.:

Q. That's for personal reasons.

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. And Doctor, in terms of you say you are now five short?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And the person that's relocating to Montreal would be the sixth?

DR. DENIC:

A. As of November.

COFFEY, Q.C.:

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Q. As of November, and you have currently approximately 20 applicants?

DR. DENIC:

A. 20 what?

COFFEY, Q.C.:

Q. 20 applicants.

DR. DENIC:

A. Oh yes, I have 20 applicants, that's correct.

COFFEY, Q.C.:

Q. Doctor, can you tell us, please -

THE COMMISSIONER:

Q. Excuse me, Dr. Denic, this morning when you were talking, I believe, about the report of Dr. Maung -

DR. DENIC:

A. That's correct.

THE COMMISSIONER:

Q. - you were talking about the number of positions and his recommendation that there certain be an augmentation in the number of positions because of the fact that you were working in a tertiary care institution.

DR. DENIC:

A. That's correct.

THE COMMISSIONER:

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Q. So when you talk about the 17, that is not including the two extra?

DR. DENIC:

A. That is correct, because these two positions have never been given officially to us.

THE COMMISSIONER:

Q. Okay.

DR. DENIC:

A. We were told let's first fill up all the positions, then we're going to talk about it.

COFFEY, Q.C.:

Q. And the 17 are at St. Clare's, the Grace -

DR. DENIC:

A. No Grace.

COFFEY, Q.C.:

Q. St. Clare's, the General, Carbonear and Clarenville?

DR. DENIC:

A. No, I'm just talking about St. John's.

COFFEY, Q.C.:

Q. Oh, St. John's, so -

DR. DENIC:

A. Because Carbonear and Clarenville, they have their positions filled. They have two positions assigned to Clarenville, and they

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have two pathologists, and one position for Carbonear and they have one. This is just for the St. John's.

COFFEY, Q.C.:

Q. So 17 currently, the approved positions in St. John's, there are 17, and in Eastern Health, there are 20, which is the other--total, 17 plus -

DR. DENIC:

A. When Department of Health counts and when we count the pathology service, we count also the neuropathologist and pediatric pathologist as well.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. But they don't provide adult pathology service, which is most vulnerable. While they're still vulnerable because they are just single practitioners as such, you know, so overall it would be 21 positions for Eastern Health, but 17 adult serving pathologists for the adult pathology for St. John's, plus neuropathologist, plus pediatric pathologist for St. John's, plus two for Clarenville, plus

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one for Carbonear.
COFFEY, Q.C.:
Q. 17, 19.
DR. DENIC:
A. It's 21.
COFFEY, Q.C.:
Q. 21, actually, I believe that's 22.
THE COMMISSIONER:
Q. 22?
DR. DENIC:
A. Oh, there are 22.
COFFEY, Q.C.:
Q. 22, okay, so it's 17 plus the two -
DR. DENIC:
A. 17 plus two, 19 -
COFFEY, Q.C.:
Q. Plus two.
DR. DENIC:
A. That's right. That's correct.
COFFEY, Q.C.:
Q. Okay. Doctor, can you tell us please then, in relation to breast pathology, so you've told us already Dr. Carter has left, and I take it she was the only breast pathologist here for-- while she was here, she was the only one?

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DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. In the sense of breast pathologists, in the sense of, you know, was fellowship trained in that regard. What's the situation in relation to that now?
DR. DENIC:
A. As of July of this year, our former resident, Dr. Nick Makretsov, he finished his fellowship in molecular biology of the breast working on the biological markers, which include ER/PR and HER2/neu of the breast, in United Kingdom, Cambridge, where he spent a full year. He has a great interest in the breast pathology. He is a Royal College of Physicians and Surgeons of Canada certified, but he is also certified by the European Board of Pathology, and he got certified while he was there during fellowship training. The part of his training in here, while he was a resident, although he was a fully trained pathologist in his own country and came as such, he received some of the training from Dr. Beverley Carter as a part of newly established concordment (phonetic) of

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the rotation through the breast pathology, and he also received additional training through the workshop before he came here in breast pathology in London, UK. His track record in regards to breast research and interest is very long and of high quality. He spent even some times in BC Cancer Centre working with some of the people who are well known in breast pathology and immunohistochemistry, such as Dr. Gilks, Blake Gilks. So he has a relationship with the BC Cancer Centre. So putting all of this in perspective, I think I have a good person to work with and the person who can provide the quality of service.
COFFEY, Q.C.:
Q. Is he in St. John's right now?
DR. DENIC:
A. He is in St. John's and he's currently practising.
COFFEY, Q.C.:
Q. And where is he located?
DR. DENIC:
A. He's located at St. Clare's Mercy Hospital.
COFFEY, Q.C.:
Q. Doctor, in relation to then breast pathology

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service, what are your plans right now, in relation to that?
DR. DENIC:
A. Let me just back up where we were when Dr. Carter left. Obviously there was a gap in the service, and at that time, I was looking to out source certain number of breast tissue to Sunnybrook Hospital. Not all breast tissue, but the tissue that could give a problems to the general pathologists, such as needle localization biopsies and needle core biopsies of the breast. So we were working on creation of the contract with Sunnybrook, but in all of this period of time, we never managed actually to complete it because it was going between the lawyers, hospital lawyer, Sunnybrook lawyers and actually, that came to effect when Dr. Makretsov started to work. But after that, we didn't need it.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. During that gap, I was reporting myself all the needle localization biopsies and core biopsies of the breast. We were sending still

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ER/PR because I stopped ER/PR in May, 23rd, I think of May, that was my memo that came out telling that we are stopping testing in house because we didn't have a breast team any more. So from then, all ER/PR continued to go to Mount Sinai. So the breast service, in terms of diagnostic, its character, I agreed with Dr. Nick Makretsov's suggestion that he takes on all cases of the breast, which he currently is doing.

COFFEY, Q.C.:

Q. So all cases means right from the diagnostic that it is breast cancer?

DR. DENIC:

A. Breast cancer. Not necessarily have to be breast cancers, you know, any lumpectomies, needle localizations, any mastectomies that have been done, needle core biopsies. So every specimen that has the word breast in it, really, he's going to be looking into it.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. To ensure the quality of the services as such, all of these cases in review on our quality

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assurance rounds the following week. So he brings them all and we review them. Also, every now and then, he brings the cases to me and consult me, and still if he have some problems, we are sending these cases out for external review and diagnosis.

COFFEY, Q.C.:

Q. So I take it that you, at least for the foreseeable future, intend to utilize him as the source around which to structure the breast pathology service?

DR. DENIC:

A. A core.

COFFEY, Q.C.:

Q. Core group.

DR. DENIC:

A. That is correct, and I think it's a good core. The plan is I'm waiting for Dr. Cook to come back from his leave and that's going to be in the middle of September, although he's going to be on ease back for a period of time, and he's going to join the group, and in terms of reporting, when he's ready, we're going to-- I'm planning to restart ER and PR and reporting is going to be done by two people by

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consensus and Dr. Ford Elms is also going to join them as director of immunohistochemistry, so that he can monitor the quality and reproducibility of the results. So that's the plan.

COFFEY, Q.C.:

Q. So that ER/PR, ER and PR testing, testing in the sense of the slides that will be interpreted has not been performed in St. John's since May of 2008?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And when do you anticipate that it will actually start again, like in the sense that they will prepare slides here locally in St. John's, or intended to be actually used and read by pathologists?

DR. DENIC:

A. As I said, I'm just waiting for Dr. Cook to come back and which is the middle of September, to give him some time to get back into a program, and so we can say some time in October.

COFFEY, Q.C.:

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Q. And Dr. Elms has been--has testified here, and he has told the Commissioner that he referred to the fact that they discontinued ER/PR in '08 temporarily and he said, well, even in restarting it, that it would have to be -

DR. DENIC:

A. He has to validate the test.

COFFEY, Q.C.:

Q. - revalidate it, that was it, yes, revalidate it again. So again, that will take -

DR. DENIC:

A. A week.

COFFEY, Q.C.:

Q. - a week, certain amount of time, so and I take it that that won't be done until there's an actual date when you anticipate that Dr. Medved (sic), I'm sorry his name is?

DR. DENIC:

A. Makretsov.

COFFEY, Q.C.:

Q. Makretsov, I apologize, Dr. Makretsov and Dr. Cook are both in the building working?

DR. DENIC:

A. That's right, and we're going to make--any decision of such nature is going to be made

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together, and when Dr. Cook comes back, Dr. Elms is any how still at St. Clare's Hospital, I'll be applying to move him out to Health Sciences, but this is--that discussion is going to occur and we're going to start from there.

COFFEY, Q.C.:

Q. Doctor, and I will come back and revisit some of that toward the end of your testimony. Doctor, I'd like to return now to the spring and summer of 2005. I asked you about when you'd first heard about this, kind of what has turned out to be ER/PR problem, I'll describe it generally that way, in you think the summer of 2005.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, I'm just going to ask you then, what did you--what's your recollection of who you first heard about this from, what you heard and then what you knew as time went on? So who'd you first hear -

DR. DENIC:

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A. I heard this from Dr. Don Cook. And this was more like hallway talk, really. Because Dr. Cook and I, we practice at the same department, although our offices are little bit remote, there's a group of offices separated from mine, actually, I'm a little bit more separated from the others, but basically within 20 metres. So this was a hallway talk that he told me there is a case that the results changed, actually using the words converted from estrogen negative to positive and that he had been informed by oncologist that it happened and that the oncologist actually consulted somebody in the States, some of the oncologist in regards to that patient, trying to help out the patient and that they were told that this was a lobular carcinoma so it should have been positive. So that's as far as it went at that time.

COFFEY, Q.C.:

Q. In terms of what you were told?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

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Q. So he told you about what turns out would be Peggy Deane's case, presumably?

DR. DENIC:

A. Correct. I didn't know Peggy Deane at the time and I didn't know her relation, be the husband--I didn't even know of her husband.

COFFEY, Q.C.:

Q. So he just, Dr. Cook was just telling you about her case, as it turns out?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Would have been Ms. Deane's case. And at the time the explanation was that, well, it was a lobular cancer and should have been positive or would be expected to be positive and that had resulted in the retest?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Did Dr. Cook tell you at that time what he proposed to do, if anything?

DR. DENIC:

A. I don't know that he told me at that time. But, you know, again, it would be probably

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uninformative formalization that they're going to retest some of the additional cases just to see the scope of the problem.

COFFEY, Q.C.:

Q. Doctor, had you before Dr. Cook mentioned this to you, you know, and I gather he used the word "conversion" at least you've indicated that's the word he used, going from ER negative, it converted to ER positive?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. He used the word "conversion". In the entire time you'd been in St. John's before that, had anyone ever told you about an ER negative converting to positive that you're -

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. And I ask that because there has been evidence that the Commissioner has seen in some pathology reports back, in particular, 2003, that for whatever reason they were retested and it went from, certainly from what has been described as clinically negative to

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clinically positive and--the ER status. And I gather if that did happen, you certainly weren't aware of it?

DR. DENIC:

A. I wasn't aware.

COFFEY, Q.C.:

Q. Made aware of it. Had you ever, up to that point Dr. Cook spoke to you about this conversion, had you ever heard of ER cases, not only in St. John's, but anywhere, converting? Were you aware of--were you familiar with the concept of ERs on retesting converting?

DR. DENIC:

A. I would say no.

COFFEY, Q.C.:

Q. Okay. And I take it then that you, at that time you wouldn't have been familiar with Dr. Rhodes' papers in the UK in 2001, 2002, that time period? You'd know what I'm talking about now?

DR. DENIC:

A. I know what you're talking about. I mean, that was paper that would be probably more of interest to the people who just do breast and

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-

COFFEY, Q.C.:

Q. Yes, I appreciate that.

DR. DENIC:

A. - directly specialized service, you know, but not necessarily that I would dig through that literature at that time.

COFFEY, Q.C.:

Q. So at the time, because in those papers they do talk about what they had found in their studies, in their surveys and they talk about conversions, I believe, or words to that effect. So the idea of conversions, ER converting was not something that before Dr. Cook spoke to you about really was something you were familiar with in this context of ER?

DR. DENIC:

A. What I know now and the literature obviously it was written before and been a global problem.

COFFEY, Q.C.:

Q. But at the time you weren't aware of that?

DR. DENIC:

A. No.

COFFEY, Q.C.:

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Q. Okay. Doctor, at the time Dr. Cook spoke to you and after the conversation ended, you understood or had the understanding that if there was a problem, whose responsibility was it to address it or to investigate it? And I appreciate Ms. Deane's case was not yours, I appreciate that. But you understood, Dr. Cook tells you about this and kind of walk--you both go your separate ways. You understood he was--if anybody was going to do anything about it, look further into it -

DR. DENIC:

A. You mean at that time or -

COFFEY, Q.C.:

Q. At that time, at that time or in the day or two or three afterward when you started to talk about retesting, who was responsible for dealing with this, from your perspective?

DR. DENIC:

A. But even today I would be responsible to start dealing with it.

COFFEY, Q.C.:

Q. Okay. So it would be the clinical chief, he in his capacity as clinical chief?

DR. DENIC:

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A. Clinical chief, that's right.

COFFEY, Q.C.:

Q. What then did you next hear about this?

DR. DENIC:

A. Not much happened, actually, because I went back with the impression that this could be isolated case.

COFFEY, Q.C.:

Q. Um-hm.

DR. DENIC:

A. And you go back to your daily routine and you deal with this regular surgical workload.

COFFEY, Q.C.:

Q. And when did you next then hear about ER/PR?

DR. DENIC:

A. I think was sometimes through the media or could have been even again that maybe from Dr. Cook before the media that they retested the additional number of patients.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. And they found additional numbers of patients that converted.

COFFEY, Q.C.:

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Q. And did he tell you, do you recall was he telling you this kind of as hallway chat or -
DR. DENIC:
A. It's a hallway chat, it's nothing more than a hallway chat.
COFFEY, Q.C.:
Q. Not like he sat down the group of you and -
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. - told you formally?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. What then happened in terms of just again, looking back on it from your perspective?
DR. DENIC:
A. I think the next development, if I can recall, was that it was the memo issued by Dr. Cook stating that we're going to stop testing ER/PR.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. And -

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COFFEY, Q.C.:
Q. Go ahead, Doctor.
DR. DENIC:
A. That ER/PR is going to be sent away for retesting.
COFFEY, Q.C.:
Q. Now, the Commissioner has heard evidence that certainly that Dr. Cook was engaged in a number of activities around that time and in fact, as well, that Dr. Carter was certainly in June and July of 2005. Were you aware of-- that Dr. Carter had been asked to--or had suggested that she undertake a review, a large-scale review in July of 2005 and had been told by Dr. Cook to go ahead and do it, were you aware of that?
DR. DENIC:
A. I mean, I knew that it happened, but I don't want to mislead you at that period of time.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. I cannot be certain. I might, I might not have had that kind of knowledge, because I know subsequently I had that knowledge that

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Dr. Carter was to review all the--I knew that she was involved in all of this, but to which extent, I wasn't completely certain.
COFFEY, Q.C.:
Q. Okay. And, Doctor, if I could, if we could bring up Exhibit P-1994, please? Doctor, this is a document, the Commissioner has seen this before, it relates to a meeting of pathologists that was held August 5th, 2005, a list of pathologists who attended there. You're recognize certainly the names. And I gather that with the exception of Dr. Cook the other pathologists would be General Hospital pathologists, am I--Fontaine -
DR. DENIC:
A. Dr. Naghibi is here.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. Bibi Naghibi, she was a St. Clare's -
COFFEY, Q.C.:
Q. St. Clare's, so at least one from St. Clare's. Dr. Barron.
DR. DENIC:
A. Barron is from Health Sciences, she's a

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neuropathologist.
COFFEY, Q.C.:
Q. So you'll see over here it's a meeting of pathologists?
DR. DENIC:
A. Okay.
COFFEY, Q.C.:
Q. There's been evidence that there was a meeting of pathologists and there was discussion at the time about concerns expressed about the current problem, including some of our suggestions about how to approach this. They talk about an ongoing study and ensuring no bias is introduced into it. Assume that the pathologist reported the original test correctly. "Persons conducting the study do not need to know which pathologist signed the report originally." I'm skipping over some of it. "Anything else is an audit of the individual pathologists and if that is the aim, that is not the proper procedure for an audit. This is not the proper procedure for an audit of a pathologist's performance." And it goes on to refer to some generalized statements, critical statements that suggests

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pathologists were, or at least some were hearing. Now, were you aware, first of all, that such a meeting had occurred?

DR. DENIC:

A. I wasn't even present for -

COFFEY, Q.C.:

Q. No, you weren't present, but were you aware that it occurred?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Now this is August 5th, 2005 and that memo suspending, advising pathologists suspending is being--testing is being suspended is August 8th, 2005. So what I wanted to ask you about is at the end of July and early August, 2005, this seems to suggest that certainly a number of pathologists were fairly aware of the fact that there was an ongoing study, they were viewing it as a potential audit, expressing concerns about, talking about what would be negative statements or certainly negative statements that were being overheard about pathologists' work. Were you aware of that in the summer of, like in late July, early

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August, 2005?

DR. DENIC:

A. I mean, I'm trying to remember why I wasn't at that meeting, really, because--and that's something that's difficult to go back. I take usually my vacations in the end of July and August, so I could have been on vacation.

COFFEY, Q.C.:

Q. Yeah. But not only so much the meeting as the subject matter, what they're talking about, were you informed -

DR. DENIC:

A. Eventually did, eventually. I mean, this is something that conveyed all of a--even up to these dates, you know, about pathologists being concerned about how many cases they've been involved, what are the consequences of all of this. I mean, it wouldn't surprise me, it's only the context of all of these documents. But I haven't seen this document and I wasn't on this meeting.

COFFEY, Q.C.:

Q. Sure. But then as the summer of 2005 went on, is it your recollection that it began to become more and more a topic of conversation

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amongst pathologists?

DR. DENIC:

A. I remember that because, as I said, concerns mostly.

COFFEY, Q.C.:

Q. Yes. With that in mind were the staff pathologists, and I'll call you that because you were one of them at the time, were you being kept apprised of what was going on? And aside from a hallway chat now, I'm talking about as a group were you being apprised or being kept informed?

DR. DENIC:

A. I'm trying to remember did it come up on any of the meetings, really, that we had, and I cannot recall such thing.

COFFEY, Q.C.:

Q. Ever coming up?

DR. DENIC:

A. I won't say it never happened, but I cannot recall. I don't know are there any minutes of the meetings at that time. But I don't believe that officially we were apprised until a certain time.

COFFEY, Q.C.:

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Q. And this is what I'm really getting at, Doctor, is this, is that as a staff pathologist at the time and looking back on it, your fellow staff pathologists which you observed at the time, was the lack of information disconcerting?

DR. DENIC:

A. I mean -

COFFEY, Q.C.:

Q. I'm not asking you to be critical of Dr. Cook -

DR. DENIC:

A. - in general -

COFFEY, Q.C.:

Q. - I'm just asking you -

DR. DENIC:

A. In general the lack of information, obviously not only the pathologists, I think in the general world where we live the lack of information could have a negative effect. In regards to this, obviously eventually we find out that they are doing testing, they're going to be sending out, more than a concern. And I wasn't quite sure did Dr. Cook had all the informations about it, did he know the full

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scope of it. And like the scope that eventually is going to get to light when the results comes and just to see how many patients affected and then pathologists probably would try to find out what are their cases and how many cases they were affected. But I wouldn't go to any--there's a lot of unknown at that point, I would say.

COFFEY, Q.C.:

Q. I take it that you weren't being, you, and I mean you as a staff pathologist, were not being told that, in any kind of official or semi-official way that we don't know what the problem is and this is what we're doing to try and find out?

DR. DENIC:

A. I don't think so they knew at the time what the problem was.

COFFEY, Q.C.:

Q. No, no, I appreciate. But you weren't even being told, I take it, at the time, that they didn't know? They weren't telling that they didn't know, or were they? I'm trying to get some sense for the Commissioner -

DR. DENIC:

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A. And I understand your line of questioning, but just trying to put myself back and just to say if they didn't know what went wrong, I don't know--he might have expressed that, as well, he didn't know what went wrong and I wouldn't be surprised that Dr. Cook wouldn't say that, because he didn't know what went wrong.

COFFEY, Q.C.:

Q. Doctor, you refereed to certainly receiving a memo, would be August, it's an August 8th memo telling yourself and other pathologists about the suspension of testing?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And plan to retest--in future tests elsewhere?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. In Mount Sinai. And to retest?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Did you make any inquiries, having received that memo did you make any inquiries further

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about what's going on?

DR. DENIC:

A. Probably I didn't because that was left to Dr. Cook to deal with this issue. They are addressing the issue. They are working on it. They are stopping testing for the ER/PR. But in the life of a busy pathologist going on, I mean, I'm still dealing with hundreds of completely different cases that had to be processed and reports got out in record time.

COFFEY, Q.C.:

Q. P-0076, please? Doctor, this is a memo of July--it's dated July 28th, 2005 to all pathologists, and, in fact, pathology residents from Dr. Cook and Carter. It's "Re Optimal Assessment Reporting of Hormone Receptor Status in Infiltrating Carcinoma." And you'll see it goes on for nine statements. There are spaces for signatures by Doctors Cook and Carter. We have not seen, we have been provided with any signed copy of it. Do you know if you ever received this at the time? I'll let you read down through.

DR. DENIC:

A. It looks familiar, I believe I did.

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COFFEY, Q.C.:

Q. Okay, so "When ordering and reporting ER/PR status in infiltrating carcinoma of the breast" and it list about how you should go about it. Do you think you saw that at the time?

DR. DENIC:

A. I beg your pardon, can you repeat the question?

COFFEY, Q.C.:

Q. I'm sorry. Do you think you saw this at the time?

DR. DENIC:

A. Yes, I think so.

COFFEY, Q.C.:

Q. Okay. And, Doctor, so it's within just over a week after this that the testing stopped in St. John's, or at least you were formally advised?

DR. DENIC:

A. Um-hm.

COFFEY, Q.C.:

Q. It was stopping in St. John's. Having received this at that point in time from Dr. Cook and Carter, did you have any thoughts

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about what they were finding in this review? Because you understood by this point in time, by the end of July you would have understood that there's a big investigation going on into ER and PR, and now you're getting a memo dealing with ordering and reporting ER status. And this is a how-to list. So did you have any thoughts at the time as to what, if anything, they were finding in their review?

DR. DENIC:

A. No, I would say no.

COFFEY, Q.C.:

Q. Okay. We've heard, Doctor, that there were external reviews conducted, reviewers were brought in, and I'll ask you about those in a moment. But after the suspension of testing, and you were advised of that in early August, and the retesting effort, what do next remember happening in terms of what you knew next?

DR. DENIC:

A. I think that was October, probably, that the story broke in the newspaper.

COFFEY, Q.C.:

Q. Okay. And that's -

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DR. DENIC:

A. Looking back.

COFFEY, Q.C.:

Q. - from looking back on it, that's the next thing really that you recall?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. This being brought to your attention?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, Dr. Banerjee was here in September of 2005, as was Trish Wegrynowski. Did you know that they were coming to St. John's?

DR. DENIC:

A. I believe we were told that they are coming or Dr. Cook said, but I never met them.

COFFEY, Q.C.:

Q. Doctor, they were here, they were debriefed, exit interviews were conducted and then the reports were filed in October and then November of 2005. Were you told anything about what they found?

DR. DENIC:

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A. I think Dr. Cook at one point in one of program meetings, he read Dr. Banerjee's report.

COFFEY, Q.C.:

Q. He read the report--all the report, or at least a portion of it?

DR. DENIC:

A. I can't tell, but I know that he read the report. It could be the entire report.

COFFEY, Q.C.:

Q. Do you recall when that was?

DR. DENIC:

A. I can't exactly. It could have been December or -

COFFEY, Q.C.:

Q. Of 2005?

DR. DENIC:

A. Of 2005.

COFFEY, Q.C.:

Q. And did he show the report to anybody at that meeting? I take it, it was at a meeting.

DR. DENIC:

A. He was reading from report.

COFFEY, Q.C.:

Q. Yes, I'm sorry.

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DR. DENIC:

A. But he didn't hand around the report.

COFFEY, Q.C.:

Q. Did anyone ask him in your presence for a copy of the report?

DR. DENIC:

A. No, I think he told us right from the get go that reports protected peer review documents, and that he's going to read it to us.

COFFEY, Q.C.:

Q. Okay. He could read it to you, but couldn't give you a copy, and hope that no one had a recording device, I take it. That's what happened--okay, you're describing what happened.

DR. DENIC:

A. (Inaudible) but that happened during my tenure, I know.

COFFEY, Q.C.:

Q. And, Doctor, how about Trish Wergynowski's report?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. Doctor, up to the point where Dr. Cook

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was reading some or all of Dr. Banerjee's initial report to you, and you think it was probably December of 2005, up to that point had Dr. Cook, Carter, or anyone else told you what Dr. Cook and Carter themselves had observed in their review in the summer of 2005?

DR. DENIC:

A. I can't say then, but I know eventually I heard about it, so would it be that period of time, as I said, it's difficult with somebody who has current knowledge about entire situation to go back and say did I know. I think I would mislead you if I said yes or no.

COFFEY, Q.C.:

Q. Perhaps I'll put it--come at this way. Doctor Cook has testified, as has Dr. Carter here, that in their review in the summer of 2005, they noticed that there were problems with internal controls, either they weren't in the tissue or they were there and weren't stained, there were fixation problems with the slides they were looking at --

DR. DENIC:

A. That's correct.

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COFFEY, Q.C.:

Q. Were reviewing. You--if we could bring up, please, Exhibit P-0046. Doctor, this is the cover letter, October 17th, 2005, but this is the--page two. That's the report dated the same day, cover sheet, and, Doctor, at page three of the exhibit, review of cases, he said, "I reviewed a number of cases from the retrospective testing, sat with Dr. Donald Cook. All the cases that had converted from negative to positive by switching platforms had one or more of the following characteristics; one, poor fixation; two, negative internal controls, normal ductal epithelium when present was completely negative; three, absent internal controls, (no normal ductal epithelium present to evaluate). It is apparent that too much reliance is being placed on external positive controls with no attention paid to internal controls". Doctor, that suggests to me that--well, it says outright that every conversion that he saw involved one or more of the following, right, and there's three of them, three different factors there. You'll recall I've told you

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that Dr. Cook and Carter have told the Commissioner that in the summer of 2005, they realized, and looking at the mass of slides they did, there were fixation problems and problems with internal controls. When Dr. Cook read Dr. Banerjee's report out to you and referred to these three things, was that news to you at the time, was that the first time you heard that? You're sitting there and listening to this for the first time. Was that really news to you at the time or did you already know this because of something that you learned from Dr. Cook or Dr. Carter?

DR. DENIC:

A. That's why I'm saying, Mr. Coffey, it's a difficult to know--he read this, so that's knowledge that I definitely received at that time, and as much you can assimilate the knowledge that somebody is reading you the text rather than to have--to look into the text and to analyze yourself. So that makes a big difference in terms of any kind of recollection, but as I said, he could have said to me or anybody else that some of the problems could be the fixation, internal

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controls, and I know definitely that over all this period of time he said that so many times. So whether this was done before he read the report or not --

COFFEY, Q.C.:

Q. Or afterwards.

DR. DENIC:

A. I cannot be absolutely certain.

COFFEY, Q.C.:

Q. Doctor, where were you when the report was read to you? Where was that done, at St. Clare's?

DR. DENIC:

A. That was at a meeting--we usually had a meeting at the Health Science Centre.

COFFEY, Q.C.:

Q. Oh, this was this kind of monthly program meeting?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Okay, so it was --

DR. DENIC:

A. With a group of people.

COFFEY, Q.C.:

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Q. A group. And at the time, did you have any understanding about why it was being read to you at that point?
DR. DENIC:
A. It would have been logical if had the reviewers coming, you want to share what they found.
COFFEY, Q.C.:
Q. Right. Doctor, while I have P-0046 up on the screen here, on page four of the exhibit there's a paragraph entitled--section entitled "Conclusions about the reasons for tests failure", and he says that in his view the DAKO System, to paraphrase it, is not faulty, the Ventana System is not too sensitive, in general, there's nothing inherently a problem in either of those pieces of machinery. "Is there a problem with tissue fixation", and he says in his view there is. Inadequate or no attention being paid to the status of internal controls by pathologists and inappropriate choice of blocks because they don't contain normal tissue, and then he says, better education is required for all the people involved; technologists, pathologist, and

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clinicians, and about the pitfalls of IHC, the importance of quality control and interpretation of IHC results. Doctor, what effect did being told this have on you at the time? I want you to kind of--your own personal reaction of being told, okay, this fellow Banerjee is a pathologist, he's come in here and looked at this, and this is what he has observed.
DR. DENIC:
A. The observation was two-fold. One, yes, I'm surprised with all of this. The other thing is that there was some statement made that cannot be really substantiated, just looking at the slide that tissue taken are thick, that tissue taken for the slides are thick. This is a statement that Dr. Banerjee wouldn't have knowledge how thick was the tissue in the cassette and in the block.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. So if you can go further up -
COFFEY, Q.C.:
Q. Further up.

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DR. DENIC:
A. If you can move it--there's a few --
COFFEY, Q.C.:
Q. This is paragraph three, and there appears to be inadequate attention paid by the pathologists to the thickness of tissue slices.
DR. DENIC:
A. We can analyze one by one if you want with me.
COFFEY, Q.C.:
Q. Sure. What I'm getting at is this, and I appreciate that, and I'll come back to that overall --
DR. DENIC:
A. Okay.
COFFEY, Q.C.:
Q. But what I'm asking--because at the time, as you just told the Commissioner, look, this is just being read to me and --
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. It's difficult to keep track of --
DR. DENIC:
A. That's right.

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DR. DENIC:
A. Something that's read and process it. The Commissioner has some experience listening to people, and process things, but generally most of us when they're read to us, without being able to read it--when something is read and not being able to read it and think about it, it's difficult to follow.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And keep track of it all. So at the time your overall reaction was what?
DR. DENIC:
A. I mean, we were surprised that this kind of comments were made and what they found as direct cause of it, yes. I mean, just a general sense of being caught off guard, you know, that this is what they found, and in this particular statements, directly a lot of things goes on the backs of the pathologists.
COFFEY, Q.C.:
Q. Yes. Now, of course too, you were not given access to Ms. Wegrynowski's comments in her report, which the Commissioner has certainly

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seen the report. You would have seen the report since?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. And you would agree that certainly most of her comments are directed at the technologist end of things?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. That would be a fair comment.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. So here, Doctor, in paragraph--what's numbered number 7 here, I want to ask you about this, about the pitfalls of IHC, the importance of quality control and interpretation of IHC results. He's suggesting better education required for technologists, pathologists, and clinicians about the pitfalls of IHC, the importance of quality control, and the interpretation of IHC results. I want to ask you this. Up to the point that this was read

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to you, at that point, December of '05, how attuned were you, how alert were you to the idea that there are pitfalls with IHC, and quality control is very important with IHC because of the nature of the test, and the interpretation of IHC, in particular in relation to ER/PR requires particular attention to internal controls? How aware of IHC as a problematic subject--if not done very carefully and properly, how aware were you of that before this, or was IHC just another test that, you know, stain as ordered?

DR. DENIC:

A. At the beginning, and as such, it was considered as another test. Most of the pathologists, I believe, in talking to--while I know through Dr. Ejeckam's letter and later on when I saw what he wrote to Mr. Gulliver, as such, he said this is not another test, but the way that that immunohistochemistry was presented to the pathology at that time in training, and based on the literature, and again I can go back to the same surgical pathology book recognized by the Royal College of Physicians and Surgeons as a textbook,

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Rosai Ackerman, you have there the basics of immunohistochemistry. In the basics of immunohistochemistry, there's a few lines about false negatives. I think it's a small paragraph about it.

COFFEY, Q.C.:

Q. Uh-hm.

DR. DENIC:

A. I think part of--ten sentences, just a part of one column, and there's another part about false positives, which at the time for the immunohistochemistry at all, not about ER/PR, I'm just talking in general, they think that false positives are the bigger problem.

COFFEY, Q.C.:

Q. In immunohistochemistry?

DR. DENIC:

A. In immunohistochemistry as such, that overall any stains--they don't talk about ER/PR, and that--so that the pitfalls were addressed just in general of immunohistochemistry as such, so nothing to any greater extent. As I said, even for the exam, we just had to know the basic principles; antigen antibodies attachment, secondary antibodies, and with the

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chromogen, then how to get the stains, and just very basic about pitfalls, false positive, negatives, and as I said, it was more written about positive, but there is a sentence there that states pathologists shouldn't rely on immunohistochemistry if you have your tumour which is negative, you should go after what you see on your H & E slides. So there was limitation in immunohistochemistry as such, and I think that --

COFFEY, Q.C.:

Q. This is immunohistochemistry at large?

DR. DENIC:

A. But we are talking what the pathologists were trained about immunohistochemistry as such, and this is as much that we were trained, we had to know this is not done on a wet bench, you know, just that you have somebody showing you, oh, this went wrong on this case, this was a false negative, this was a false positive, because of this kind of stuff.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

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A. So it was very basic training that we knew of, and for the long time we would think it is a technical procedure that observed and done by the technologist. You receive your slides and you report what you see on the slide.

COFFEY, Q.C.:

Q. Doctor --

THE COMMISSIONER:

Q. Before you leave this, Mr. Coffey, on the subject of--let's go back to this, yes, better education, paragraph seven here, "Required for technologists, pathologists, and clinicians about the pitfalls of ICH". Who's responsibility is it to identify for a clinician a pitfall or pitfalls of IHC?

DR. DENIC:

A. That has to be done mutually, but should address the issue of--like, we have the issue of cutoffs, that we can say, okay, we recognize the cutoff is one percent in our lab, and that's why we think this should be done. This is one of the--so the oncologists probably would know where the lab stands from that perspective. Maybe--I would say maybe we can--as a pathologist, we can say none of the

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tests has to be taken at face value because every single test has build up false positive and negative in its procedure, so it has to be taken in a clinical context and probably queried, but the oncologists and clinicians, they would know for the most of the time that no tests ever done in medicine is 100 percent sensitive, 100 percent specific. So it goes both ways. I would say it goes both ways in terms of education and--it could have played a role, but they had a role to educate themselves as well.

THE COMMISSIONER:

Q. Well, it just seems to me that, just as an observation from somebody completely outside of your profession, at least from the material that's been coming in here, that the lines of communication are not optimal, shall we say. A number of people say things like, well, so and so would know that, and the other one says I wouldn't know that. It just seems that on both ends of the spectrum you are assuming that the other person to whom you are sending information knows the limitations of the information and knows the content of the

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information. Your point about cutoffs is a good one because a number of the test results would say positive or negative, and just that, no percentages. Now if you send a percentage, and I see those pathologists who have come here and said it is my practice to give a percentage, and I understand that in that case you are being clear to the clinician who is receiving the information that this is your opinion as to what the percentage is, and it's then for the clinician taking that percentage to decide how to put that in the mix and what treatments to offer in the case of ER done for the purpose of treatment to a patient, but if what's being sent is a straight positive or negative, particularly in the years 2001, 2002, then the opportunity for confusion is there, and it would seem from the material that we received, there was confusion in respect of some of the persons involved. So I, frankly, am somewhat concerned about the communication between the pathologist and the clinician, and are there gaps--is it just that in medicine everybody assumes that everybody else knows the purpose of the test that you're

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giving and the limitations of the test so that when you send it off outside of your lab, then there will be no doubt from the person who is receiving your information as to what you are saying, or is there a role here anywhere for people to start talking to each other about exactly what that means?

DR. DENIC:

A. I agree with you. I mean, the communication could have been the problem, although I believe that Dr. Khalifa, I think, carried through this 30 percent cutoff value based on the literature. It was literature and evidence-based that he delivered to the oncologists as well. So that not completely-- in terms of some stuff, like, it says pitfall of immunohistochemistry, I don't expect that the oncologists should know about--should know about fixation, that's not the scope of their --I shouldn't expect the oncologist know about internal control. They could know through their general knowledge, but to ask me and call me, Nash, did you look at internal control, I--that would be the same as I would call Dr. Laing and say --

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THE COMMISSIONER:
Q. But do you really think that that's what's being referred to by Dr. Banerjee here? He's not really talking about your telling them about internal controls.
DR. DENIC:
A. No, no, but the pitfalls in immunohistochemistry have broad area, and as you said, with the communication in terms of cutoff, you know, probably could have been better communicated and pathologist should have been first on the same page.
THE COMMISSIONER:
Q. Uh-hm.
DR. DENIC:
A. And I think we were not on the same page, and obviously through high turnover of the pathologists and oncologists, nobody--we didn't have a chance to be on the same page at some point.
THE COMMISSIONER:
Q. Are there better methods of communication in your view now than there were in 2001, 2003, etc?
DR. DENIC:

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A. Yes, definitely there are better, and as I said, we are now meeting over the breast disease site group, not only pathologists, but oncologists, surgeons, geneticists, and everybody involved in patient care of the breast patients, and we discuss the various stuff, we are developing policies and procedures and guidelines of the treatment. We are all involved, so this was one of the initiatives that maybe--the issues in the future of similar natures can be addressed.
THE COMMISSIONER:
Q. Uh-hm, and for example, if there is within your world, and obviously in the world of a pathologist, you would be expected to know, I presume, the limitation on the use of a particular test. Would it be--I'm thinking particularly of when the switch occurred and you went from the bio assay method, which as I understand it, somebody sent numbers to somebody and they kind of took those numbers and they were the gospel.
DR. DENIC:
A. That's right.
THE COMMISSIONER:

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Q. And then all of a sudden, you went to IHC, and the same kind of mentality about the results got in the mix, and maybe that shouldn't have been the mentality, and I'm wondering is the problem that groups are not talking to each other, is it that clinicians should be educated better in terms of what a pathologist does and what use you can make of particular tests, or is it something else? Just sort of help me with the lines of division here and who talks to whom to make sure that there is no confusion when somebody is trying to make a decision about the treatment of a patient?
DR. DENIC:
A. I mean, the lines of communications, I believe, they were there, maybe not to the strength as we have it today.
THE COMMISSIONER:
Q. Uh-hm.
DR. DENIC:
A. But never been broken--we were always communicating our results and available to the clinicians, not only oncologists, to everybody. So the line of communications were there. We're realizing through all of this

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there was obviously a link here and there missing in the lines of communications, but in the lab we performed so many tests, I think, 11 million tests are coming out--lab general, blood work, and everything else that have been done, and if new test is present in the lab or we are changing certain values of reporting, we send that information to the clinicians. Most of the tests that--you think that the clinicians when they receive the results, they have to process themselves, they have--everything has to be put in a clinical content. That's why some of these patients with even low ER were treated because they put the various parameters in the content, and they prove that through their practice. So to answer on your question is I agree with you that obviously we have to work on strengthening--I'm not say that there's never been a communication, and I would disagree with that, but obviously when something goes wrong, then you go back and you try to find the weak points, and that's where we are now.
THE COMMISSIONER:
Q. And you think that the breast site group is

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the answer to communications in respect of at least this issue?

DR. DENIC:

A. I think it's one--one of very good answers, and again I said interaction between these two groups is very tight, and I think that we have the vehicle to address any future issues.

THE COMMISSIONER:

Q. Okay. Sorry, Mr. Coffey, I interrupted.

COFFEY, Q.C.:

Q. And in a wider vein in that regard, I take it, the breast site group--and I take it the plan is certainly to have other disease site groups as well as time and resources permit?

DR. DENIC:

A. As times goes on.

COFFEY, Q.C.:

Q. And resources permit. Doctor, one thing in terms of education, I'll ask you about education--you would now be, I take it, in charge of education for technologists?

DR. DENIC:

A. Ultimately.

COFFEY, Q.C.:

Q. Ultimately, yes.

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DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. So who, in practice, is in charge of it?

DR. DENIC:

A. It's going to be Mr. Gulliver, and the managers, and also there's going to be a great influence of the new Regional Quality Management Manager, Ms. Lynn Wade.

COFFEY, Q.C.:

Q. Okay, we'll come to that then, and in terms of pathologists, I take it that--you've indicated that it's going to be limited, at least breast pathology is anticipated in the future to be limited to a small group within Eastern Health?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And I take it that either to get made a member of that group, you would be expected to know something about breast pathology more than the average pathologist?

DR. DENIC:

A. That's correct.

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COFFEY, Q.C.:

Q. Doctor, in terms of residents, I want to ask you about this, because you kind of summarized to--the Commissioner was asking you about, and not so much even as breast pathology as IHC and wider scope, this wider scope, what's the situation right now in the residency training program for pathologists in terms of their education about IHC?

DR. DENIC:

A. Nothing official yet.

COFFEY, Q.C.:

Q. So if I could then, it hasn't changed from the day that you were a resident, in the sense of officially it hasn't changed?

DR. DENIC:

A. In the sense of official.

COFFEY, Q.C.:

Q. I apologize, go ahead.

DR. DENIC:

A. Because again through all of this, what we are going through, every single pathologist is aware of all of this what we were talking about, about possible factors influencing and affecting IHC testing. So again when you work

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with residents and looking into the IHC stains, you're going through all of this with them, and recently we started initiative and it's going to be very soon, that the residents spend couple of weeks rotating through the immunohistochemistry.

COFFEY, Q.C.:

Q. So the actual business end of creating the slides and at least why slides are being created?

DR. DENIC:

A. Just to see in's and out's of immunohistochemistry and go from one station to another and review the slides and--various slides and go through the validation of the process, optimization of the process. So that's going to be Dr. Elms' job, and the residency training program directors, (unintelligible) job.

COFFEY, Q.C.:

Q. Doctor, you've indicated that at the meeting where you were first read this report by Dr. Cook, I take it there wasn't at least immediately in the room at the time much reaction from the pathologists?

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DR. DENIC:
A. Not really. I mean, he said this is it, what he wrote, but nobody have seen the document or dwell on the document.
COFFEY, Q.C.:
Q. Was it discussed afterward by yourself with others?
DR. DENIC:
A. I don't recall it being discussed to any degree.
COFFEY, Q.C.:
Q. Bring up Exhibit P-0025, please, page 10, please. Doctor, you have--before I get into this because this takes you into your time as clinical chief, the beginning of it, you told the Commissioner that after being told the testing was being suspended in St. John's in the summer, your next real memory of this is breaking in the news in October?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, had you been aware that there had been a discussion within Eastern Health about whether or not patients should be told or not

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about the fact that they were being retested? Had you been aware --
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. You weren't aware of that?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. We understand based upon some exhibits we've seen that the first of Dr. Mullins retest results came back, arrived in St. John's probably in the evening of September 26, 2005. Dr. Cook had them in the morning, September 27th, and then--there were quite a number of them that day and a couple of days after that. AS the fall of 2005 then went on, were you told anything about what the results were?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. In terms of the conversions, how many there were?
DR. DENIC:
A. No.

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COFFEY, Q.C.:
Q. Nothing at all. I take it then that if you weren't told--you work in the same office complex that Dr. Cook did and Dr. Carter did, certainly Dr. Cook did, that you had no reason to believe anyone else was told either, pathologists?
DR. DENIC:
A. I don't know if they were told, but I was not told.
COFFEY, Q.C.:
Q. It wasn't the topic of conversation?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Was it a topic of conversation amongst pathologists wondering about, well, what are the results?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. People were wondering. Do you know if Dr. Cook was asked, you know, "Don, are you going to tell us what the results were"?
DR. DENIC:

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A. He might have been asked as well, and I remember one point of conversation, but again it's difficult to put a timeline of this one, that he might have said that large number of pathologists or almost everybody, that kind of word, is involved.
COFFEY, Q.C.:
Q. Is involved, and you would have taken the word "involved" to mean have had one or more conversions?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. In terms of their own caseload?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. The point being, I take it, that you understood from his remark at the time that, look, this involves really almost all of us?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. Doctor, looking at this, this is February 23rd, Exhibit P-0025, February 23rd,

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2006, a report to the Board of Trustees, MAC, and there's a note that Dr. Cook here has submitted his resignation as clinical chief, they thank him for his work, and then Dr. Williams advised that Dr. Nash Denic has agreed to serve as interim clinical chief for a six month period. So you had signed on to that role at least by February 23rd. How is it that you came to be interim clinical chief?

DR. DENIC:

A. Dr. Cook approached me and he told me that his term is coming to the end, he is looking for somebody to replace him, and I told him to let me think about it. I have a young family, you know, that's a lot to be dedicated to, it is very hard work that the clinical chiefs are put in, especially seeing him in that period of time when he took himself of the service just to deal with this matter. So I told him to go and ask the other pathologists as well and to see if anybody else would take on this position. So eventually he came back to me and, obviously, this wasn't a desirable position as such, and his term was coming to the end, and I think he was also exhausted as

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well after all of this, and I decided to step in and take on the position.

COFFEY, Q.C.:

Q. Doctor, you had not been, based upon what you've told us up to this point, involved in ER/PR matter except to the extent that you've already told us about? I mean, that's--is there anything else we haven't covered?

DR. DENIC:

A. That is basically it.

COFFEY, Q.C.:

Q. Is there anything else you can think of that we haven't covered?

DR. DENIC:

A. Not really.

COFFEY, Q.C.:

Q. Okay. So you're going to become clinical chief. Did you discuss with Dr. Cook where they were with it at the time? I mean, you're taking over his role and he has been in charge of the overall--I shouldn't say "in charge", I protract that. He had been significantly involved in the response to it. So did you get briefed on it?

DR. DENIC:

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A. To a certain extent. I knew that tumour panel was established, that he was working through the tumour panel, and he was--he even asked me and brought me to the tumour panel just to basically see how it works, rather than (unintelligible) wall because Dr. Cook, I, and Dr. Williams, we had understanding that Dr. Cook started all of this. While he's not the clinical chief any more, he should continue in completing this task because for me going through his notebooks, spreadsheets, it could be very difficult and wouldn't be beneficial to anybody. So I did go to the tumour board to see what they were doing and how they were panelling the patients, and I went a few times, and not to any greater extent, nobody at that time processed any data. We were working as hard as possible, usually evenings after the regular work job that they had, just to put all the patients through in order to present them with the results or their attending physicians so these patients could be treated.

COFFEY, Q.C.:

Q. The tumour panel --

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DR. DENIC:

A. Tumour panel.

COFFEY, Q.C.:

Q. They're doing their work as best they can at the time.

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. And your understanding was a quickly as they could?

DR. DENIC:

A. As quickly as they could, and as I said, they were meeting late at night.

COFFEY, Q.C.:

Q. So in terms of handling from the pathologist end, kind of the representative of the pathologists and the group that's handling this within Eastern Health, Dr. Cook is going to remain as that?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. That's bearing in mind that you're going to be the clinical chief, though?

DR. DENIC:

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A. That's right, and Dr. Carter was there too.
COFFEY, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. Sorry, I just want to make sure I understand.
COFFEY, Q.C.:
Q. Sure.
THE COMMISSIONER:
Q. Dr. Cook was to carry on effectively dealing with the issue as a whole or -
DR. DENIC:
A. The group that he had started.
THE COMMISSIONER:
Q. Or related to the tumour panel?
DR. DENIC:
A. No, the whole group, because that we are eventually coming to the panel and again he had to -
THE COMMISSIONER:
Q. All right. So while you were becoming clinical chief the issue of ER/PR was going to remain with Dr. Cook?
DR. DENIC:
A. Pretty much.

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THE COMMISSIONER:
Q. Yeah, okay. Mr. Coffey, wherever you can find a spot, we'll take the afternoon break.
COFFEY, Q.C.:
Q. Yes. What, if any documents, were you shown at the time or given at the time relating to the ER/PR issue? Were you given at that point Dr. Banerjee's report back, the October 7th report and Ms. Wegrynowski's report in November or, in fact, a status, like, based upon something you could read, a status account -
DR. DENIC:
A. Sometime in March, I believe, could be the April, March or April I received a spreadsheet from -
COFFEY, Q.C.:
Q. Okay, so -
DR. DENIC:
A. - Mr. Gulliver, but not their documents.
COFFEY, Q.C.:
Q. Not the original reports?
DR. DENIC:
A. No.
COFFEY, Q.C.:

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Q. So you got a spreadsheet, and we'll come to that. And in terms of where they were with-- and there are certain memos that the Commissioner has seen, kind of internal memos about, you know, we've got so many back, 800 and some odd have been tested, we have so many back, we've informed, panelled so many and so on and so forth, those sorts of documents at that time?
DR. DENIC:
A. Not really because for me those document wouldn't mean much just coming into the middle of it if not at the end of it.
COFFEY, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. All right, we'll take the afternoon break.
(RECESS)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey?
COFFEY, Q.C.:
Q. Thank you, Commissioner. Exhibit P-1749? Doctor, I'll be taking you to this in a moment, but this, I take it, it's dated March 6th, 2006. And you would have just started

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this, I know you were interim clinical chief, but I'll be calling you clinical chief in that context here. And that's why at this point in time you would be copies or you would be sent, you would be one of those sent the e-mail because it would somewhat relate to your duties?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. Doctor, you've told the Commissioner that from your perspective, up to this point, up to that point in time you would report, as a pathologist, a percentage of ER and PR, whatever you saw?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Made your own eyeball and you called it the way you saw it?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And the oncologist, you felt, would, of the number you gave them, make what they felt

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appropriate?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, and you would have understood, I take it, that there might be clinical ramifications in you making a correct call between calling something 20 and calling something 80? You understood, look, you know, I got to be at least fairly careful about this in the sense of if it's closer to 20, call it 20 rather than call it 80 if, in fact, it was 80?
DR. DENIC:
A. We are pathologists, we always trying to be objective, so whatever we see, we report.
COFFEY, Q.C.:
Q. Would you have understood there might be clinical ramifications between, for a particular patient, between an ER of 20 and an ER of 80 at times, depending upon the context that there might be? Did you know that there might be, at that time? You're just getting yourself involved in this now as clinical chief, did you appreciate that?
DR. DENIC:

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A. You mean now from the point of 2006?
COFFEY, Q.C.:
Q. Yes, in '06, when you're getting yourself involved in this in the sense of you're being asked to and -
DR. DENIC:
A. We knew that, and I, as well, that clinical consideration for the positivity rate is above ten percent of -
COFFEY, Q.C.:
Q. Cutoff, so -
DR. DENIC:
A. Cutoff. But I wouldn't completely use cutoff. If you say cutoff, the people just say this is ten and this is not. Because at the time I believe it was well known that there was a group of low expressers, as well, and it's recognized it was a working meeting in Switzerland, I believe, so--and where subclassification of the positives came into the place, so you have the ones which are zero, which are negative, then you have a low expresser, from one to ten, and everybody else well expresser from ten. So -
COFFEY, Q.C.:

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Q. But even the fact there might be, say, 15 to 95, a 15 and a 95 wouldn't necessarily be treated the same by an oncologist, you would have understood that for some patients it would matter whether it was 95 or 15? Would you have understood that?
DR. DENIC:
A. But that wouldn't be my call -
COFFEY, Q.C.:
Q. No, I appreciate it's not your call.
DR. DENIC:
A. - (inaudible) would be that it's positive. I wouldn't go into the treatment because the treatment wasn't something from the very beginning, obviously from St. Clare's Hospital that why we were reporting, so we report whatever it is, what we see on the slide and if it's 15, so be it.
COFFEY, Q.C.:
Q. Oh, yes.
DR. DENIC:
A. So oncologists have to take that as 15.
COFFEY, Q.C.:
Q. But did you understand that there might be, whatever the clinical ramifications might be,

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that there might be clinical ramifications, depending upon whether the call was 15 or 95, did you understand that at that time, when you first got involved in this? Did you appreciate that? I appreciate if you're calling it, seeing it as 15, you'd call it 15, if you saw it as 95, you'd call it as 95. But did you, at that time were you aware that there might be for the particular patient?
DR. DENIC:
A. I mean, it could be any ramification for the patient who is positive and still is not going to receive the therapy. I mean, I knew about those kind of instances. But any great ramification unless--I really don't know what are you heading at because -
COFFEY, Q.C.:
Q. It will become apparent in a moment. So at the time you called it like it was, as you saw it, and that really then it was in the oncologists' world whatever they were to make of it?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:

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Q. Their approach?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Okay. Now, Doctor, in relation to this, as you said, in fact, you just told me now that cutoff, it's in the documents a number of places, you're a bit uncomfortable with the word itself, as a pathologist?
DR. DENIC:
A. You know, just because somebody is ten, I would say don't--just because number ten and cutoff is there so you just say, oh, you're not going to receive the therapy or something like that. That's why I don't like the word "cutoff".
COFFEY, Q.C.:
Q. Doctor, were you aware of what the criteria were that had been used to determine who was going to be retested?
DR. DENIC:
A. The criteria, it was my understanding that criteria was to use until 2000 the patients that were tested until the end of 2000, 30 percent and less and from 2001 to 2005, ten

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percent and less.
COFFEY, Q.C.:
Q. And when did you become aware of that?
DR. DENIC:
A. I mean, I had that knowledge through the tumour board, which was in February. I could have known that before or Dr. Cook might have briefed me about it and what was the cutoff, but I wasn't a part of the group that made any kind of decision.
COFFEY, Q.C.:
Q. Doctor, when you began to actually act as clinical chief in March, 2003 and then continued on, and we'll see your name then throughout certain documents, did you ever have occasion to question or to have any doubts about or concerns about the way that the 30 and ten had been utilized as cutoffs, and they were used as cutoffs in those periods of time in choosing the patients to be retested?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Have you up until now, up until today as we

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sit here, as you sit here now, have you had any--do you have any concerns about it now? And here's where I'm going with it, Doctor, is this, is that we've heard evidence that certainly in 2001 some oncologists here in St. John's were still using 30 as kind of the rule of thumb determination of whether somebody was positive or not. And if, for example, in 2001 someone was called a 20, say one of your patients you said was 20 percent and you reported it that way, that patient might have been, may very well have been treated by an oncologist as if the patient was negative but the patient wouldn't have been retested and whether the 20 is accurate or not, the patient has not been retested but was treated as, clinically as negative. So what I've just referred to now, are you aware of that possible scenario?
DR. DENIC:
A. I am.
COFFEY, Q.C.:
Q. Okay. When did you first become aware of that?
DR. DENIC:

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A. I came aware of that approach and the concerns recently, it was this year. I would say sometime April, May.
COFFEY, Q.C.:
Q. And what, if anything, was thought about it, was it discussed, if so, by whom, and what was done about it?
DR. DENIC:
A. It was discussed at one of the meetings, I think involved various individuals from Ms. Pilgrim, Heather Predham, Dr. Laing, myself, Terry Gulliver, could have been Oscar Howell, so I think it was even Mr. Barrett, who is the epidemiologist, as well, that we discussed that.
COFFEY, Q.C.:
Q. And were any decisions made about it?
DR. DENIC:
A. I am not aware that any firm decision was made at the time, but it was, it was brought at the time to my attention that Dr. Laing also consulted one of the oncologists should we look into this group and I think the advice from that oncologist, I think, Maureen Trudeau, was that it would be worthwhile to

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look into this group and she was advised to go through the database. And I think the first thing is that we don't have a database that covers such a thing. Then we did discuss how, if we can go around this and that we can probably involve the various individuals from NLCHI, Mr. Wayne Miller, Terry Gulliver, as well, people going through the charts, which would be an extremely strenuous job which was to try through the charts to identify these patients. But I don't think so that any firm decision was made ever since that I know of on this group and whether this was moved forward or not.

COFFEY, Q.C.:

Q. So at that point, I take it, the focus was on considering possibly identifying all patients during whatever a particular period of time who fell between ten and thirty?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. Okay. Now, Doctor, in a similar vein, okay, I take it that you are certainly now aware of, generally, certainly, of the retest results in

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the sense of there were a number of, certainly, I won't say many, but certainly a number of people who went from zero to 40, 50, 70, 80 ER?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Went from very, zero or very low ER to a relatively high ER based upon Mount Sinai's results?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, for example, for a patient in 2002, 2001 or 2002 patient who tested at 20, okay, I take it that even leaving aside whether or not the oncologist treated the person as positive or negative, leaving that aside for the moment, based upon 30, is it entirely possible that if that patient's block was retested now, that they might go from 20 to 80 or 20 to 90, if other blocks went from zero to 80, is it entirely possible that it would go from 20 to 80?

DR. DENIC:

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A. This is medicine, nothing is impossible. We've seen those examples of such. But if you ask me for opinion what I would do, I mean, if the patient is in a 20 and she was falling into the group of positive patients, I would say that patients should be offered Tamoxifen since we even know that everybody above one percent should be offered Tamoxifen if they are a candidate, of course, for the therapy.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. But just in terms of the--some kind of caution that I would put through all of this is the science has changed. You remember the days of the x-ray without CTs? We never CTed every single patient that we x-rayed the year before the lesions couldn't be identified and the MRI when it came, you know, we were treating at a time when the diagnosis was made. And we've seen even through the Mount Sinai's retesting on their own blocks, when they retested, they got different results.

COFFEY, Q.C.:

Q. Yes.

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DR. DENIC:

A. So is that possible? Yes. So I would say that if the patient falls in the group at that time of positive and if it's a candidate, should have been treated, should have been offered a therapy if the patient was a candidate for it.

COFFEY, Q.C.:

Q. Doctor, we have also heard about--so before I leave that. So I take it in respect of that aspect of the matter the idea that here in St. John's between '97 and 2005, the slides processed here tended, at times, to be low or under report ER, and you're aware of that?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. The overall result. The fact that that was so in under reporting ER, then for the years 2002, 2001, 2002, 2003 that if the current results you were aware of hold true on the others, the positives?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

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Q. The positives, as a group, would probably, on retest, be higher, wouldn't it?
DR. DENIC:
A. Some of them they could, some of them they wouldn't change at all.
COFFEY, Q.C.:
Q. And how much higher and for which patients, you wouldn't know until you did it?
DR. DENIC:
A. That's correct. I mean, we retested some of the positive patients recently, not much difference that we found in these patients. They were positive, they stayed positive. Some of them were almost neck to neck with our results that we reported, some of them have a small variation. So -
COFFEY, Q.C.:
Q. Were there any with a large variation, do you know?
DR. DENIC:
A. Depends what you define as a large variation.
COFFEY, Q.C.:
Q. I know, I know.
DR. DENIC:
A. The way I'm -

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COFFEY, Q.C.:
Q. Go up by 50 or 60 -
DR. DENIC:
A. - looking, Mr. Coffey, is is there any significance for these patients in terms of the positivity rate, as such. As I state before, if we look at Mount Sinai's results, we look results on the two blocks done in Mount Sinai they reported zero on the block and I look at some of those cases, internal control, positive staining, they reported zero, then if there was a second block sent, report is 50. So while we, both of us, you and me, want the patient to receive the best therapy as such. The answer which I don't know how far we should go.
COFFEY, Q.C.:
Q. Okay. And, Doctor, in, again, similar aspect--well, similar, another aspect of the matter but relating to the whole idea of who got tested, who got retested, is it your understanding that in St. John's, anyway, for the St. John's hospitals, that the only patients that were retested were those who had been--had primary breast tissue, tumour

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tissue, primary breast tumour tissue, they were the only ones that were retested for ER/PR and outside St. John's, for example, some ER/PRs that were non-primaries were retested. Are you aware of that?
DR. DENIC:
A. Might have been that they'd been picked up during the search. And I'm only aware of probably one case or -
COFFEY, Q.C.:
Q. Okay. I'll come at it this way, then. In St. John's it's your understanding that the only people retested were primary breast?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Are you aware of what happened outside in the other health authorities in terms of which ER/PRs they had retested?
DR. DENIC:
A. No, but I assume that they should send -
COFFEY, Q.C.:
Q. Only primary breast?
DR. DENIC:
A. Primary breast. I think based on the memo

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that I seen from Dr. Cook or something like that, they should send out -
COFFEY, Q.C.:
Q. Doctor, in relation then to non-primary breast, okay, when you got involved as the clinical chief at the point you got involved, you understood that it was primary breast tumours that were being retested?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Did you understand, were you given to understand the rationale as to why the other ER/PR tissue samples were not being retested, the non-primary breast tissue?
DR. DENIC:
A. You mean metastatic tissue in the lymph nodes, for example?
COFFEY, Q.C.:
Q. Yes. Or whatever. By the other ER/PR, and there were a number of other ER/PR tests ordered, why they were not retested?
DR. DENIC:
A. Why they are not retested, you want to test the primary lesion, I mean, that's the bottom

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line, if it's present and you want to test it. So I think that's the right way to do, test the primary lesions. What can happen if you test metastatic lesion, that the estrogen expression in the metastatic lesion could be different than the primary.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. So therefore, and the reasons are well described in the literature, that the metastatic tumour is negative, the primary is positive and other way around but in a lesser degree. So, of course, you would go after the primary source, which would be the primary breast cancer rather than to go to the metastasis. In case that for whatever reason you don't have slides, blocks for the primary, then you would opt to do metastasis and just to see what you're going to get.

COFFEY, Q.C.:

Q. Doctor, are you aware of whether any consideration was given at least by Eastern Health to retesting ER/PR--I'm sorry, retesting tumour tissue for ER/PR that was not

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primary breast?

DR. DENIC:

A. I only know of one case.

COFFEY, Q.C.:

Q. Okay. So I take it then no consideration is being given to -

DR. DENIC:

A. Not to my knowledge, just for the reason I stated.

COFFEY, Q.C.:

Q. Is there a possibility that if such retests were to occur and there were changed results, conversions, is there a possibility that any one, any one patient might be assisted by that?

DR. DENIC:

A. Could you repeat that?

COFFEY, Q.C.:

Q. If all of those that have not been retested, all the non -

DR. DENIC:

A. Which one?

COFFEY, Q.C.:

Q. All the non-primary breasts.

DR. DENIC:

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A. Oh, non-primary breast.

COFFEY, Q.C.:

Q. In other words, all the ER/PRs, all the other ER/PRs, okay, there are a whole bunch of blocks sitting over there in the General Hospital and probably at St. Clare's that are ER/PR tests were done, they have not been retested because they're not primary breast tissue tumours, right?

DR. DENIC:

A. (Inaudible).

COFFEY, Q.C.:

Q. If they were to be retested, the negatives, for example, I'll use negatives here now, and they were to convert, some of them, one or more of them were to convert, is there a possibility that the clinical care of a patient could be affected by the result, by the changed result?

DR. DENIC:

A. But depends on the primary tumour. Now, if the patient had the primary tumour tested, if that's the case, primary tumour and she has metastasis tested, we usually don't test metastasis unless, as I said, for the reason

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that there's no primary tumour. So you would treat the patient based on that expression.

COFFEY, Q.C.:

Q. Example, primary is negative, retested negative, but there is a possibility that the metastasis is positive, isn't there?

DR. DENIC:

A. That's correct, it is, it is a possibility because rare occasions that can happen.

COFFEY, Q.C.:

Q. If that, the block representing the metastasis was to be retested and it was now found to be positive.

DR. DENIC:

A. Okay.

COFFEY, Q.C.:

Q. Because it hasn't been retested as of yet, could that affect the patient's care? Is it your understanding that it might?

DR. DENIC:

A. It can. However, that has to be a part of the clinical guidelines, you know, how they treat the patient. Because I don't think it is our practice, and I don't think so--probably Dr. Laing can reflect to that, when do you retest

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secondary tumours like a metastasis. So I-- that's not part of my forte, really. And I know that in most institutions that's not the practice. If you do research and just to look how many of these patients convert into the metastasis, I would say yes. And sometimes you do, I remember sometimes you do, but this is not that I am comfortable with talking about a treatment.

COFFEY, Q.C.:

Q. Doctor, do you ever order ER/PR testing for non-breast cases? Is ER/PR used in any sorts of pathology reviews or tests or analysis other than breast?

DR. DENIC:

A. Oh, yes.

COFFEY, Q.C.:

Q. It is. None of them have been retested, I take it, certainly not at Eastern Health?

DR. DENIC:

A. There's no need for those ones.

COFFEY, Q.C.:

Q. Okay. That's what I was going to ask you about. Okay. If--I take it in those cases ER/PR is reported in the same way, it's

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reported as a percentage?

DR. DENIC:

A. No. It wouldn't be percentage -

COFFEY, Q.C.:

Q. It's not -

DR. DENIC:

A. - it's positive, negative.

COFFEY, Q.C.:

Q. Oh, positive, negative, okay. So zero or something, okay?

DR. DENIC:

A. No, no, not even percentage. It would be word positive or negative.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. For metastasis of unknown origin. Okay, I understand where you're getting now, because if we kept an metastatic tumour which is a secondary tumour, would we order estrogen and progesterone receptor on some of those? Yes, the answer is yes. We would have ordered then. Today we would say that this is not-- this is over utilization of the stuff, and I can explain why.

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COFFEY, Q.C.:

Q. Okay. Well, what--so the ER and PR, in your experience in St. John's as a pathologist here, is is that you would circle the ER/PR part of the requisition form?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. For non-breast cases?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And they might be utilized in any one of a number of particular circumstances, and you could kind of list them off for the Commissioner?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. Give her some examples.

DR. DENIC:

A. I'll give you, Commissioner the example. The patient have a history of the breast cancer, for example, and that cancer has been removed ten years, 20 years ago. Now the patient is

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presented to the physician, they do CT or MRI and they find a lesion in the lung. So two things goes through your mind, is this is a tumour that's coming back from 20 years ago that she had the breast cancer or this is the primary lung tumour, which wouldn't be unusual. So you are trying to figure that out. What we used to do is, okay, she had a breast cancer. We ordered the batteries of the stains and there's batteries of immunohistochemical stains who are trying to subclassify, broad subclassification and tell you, like--you probably heard the various stains and the name, like cytokeratin 7, cytokeratin 20. These are the basic stains. Cytokeratin 7 would stain the breast, but would also stain the tissue coming from the gastrointestinal tract, like liver bioducts or pancreas, because you don't know where the tumour is coming from. Cytokeratin 20, if it's positive, it's usually positive in bowel. So this patient, which wouldn't be unusual, if cytokeratin 20 is positive and cytokeratin 7 is negative, tell that lesion most likely can come from the bowel. So you narrow down

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clinician and say, she has that lesion, you know, but cytokeratin 7 is negative, but cytokeratin 20 is positive, that rules in bowel, but rules out breast.

So if somebody has breast cancer, as such, most common would be to think that this is coming from the breast, if you don't know anything about this patient. So you still would be ordering cytokeratin 7. I would order the cytokeratin 20 to rule out the other possibility, which is bowel cancer, which is very common in Newfoundland, but I would order S100, which is still positive in the breast. I would order gross cystic disease fluid protein, which is another immunostain which is positive in the breast, and I could have ordered ER and PR.

So when I receive the batteries of the stains and I go through all of this and I said, okay, cytokeratin 20 negative, move the bowel cancer away. So cytokeratin 7 positive, that means still breast, could be lung primary, could be pancreas or other biliary tract cancers. So it did narrow down, but not completely. Then I said, okay, what about

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S100? S100 is positive, it's not specific, is positive in some tumours of the--malignant tumours of the skin, for example, like melanomas, but it's also positive in the breast. So now I have cytokeratin 7 positive. I have S100 positive. So I am closer to think that this lesion is the breast lesion. And third stain that I'm ordering is gross cystic disease fluid protein. It's large number of breast, they express this antigen or gross cystic disease. So if you find this, now I have three of them telling me that this is breast.

And on top of this, if I order PR, ER/PR, that could be negative because people are negative with ER/PR of course. Still doesn't rule it out, breast, because I have the three of them telling me it's breast. But if it's positive, I nailed it down that this is--so I have four or five stains utilizing to pinpoint the lesion, because it's a different treatment of metastatic than a primary lesion of the lung, for example.

So ER/PR in that context would be just adjunct to batteries of the stains trying to

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determine where the lesion is coming from, but furthermore, why I said these days are over-utilization of the stains, and we even send a memo around and "don't use ER/PR because we are wasting the stains for that reason," but the single reason that ER/PR negative stain doesn't rule out breast. So if you have the lesion on the skin and could be still metastatic lesion from the breast, it could be negative. So you didn't rule it out, breast, because ER/PR can be positive in lung cancers and the cancer come from the genitourinary tract like endometrium, you know, so you didn't go anything with ER/PR. So in that context, you don't retest those patients, because this is not done for the prognostic purposes. That's what the pathologist uses, utilizing the stain trying to narrow down where the tumour is coming from.

COFFEY, Q.C.:

Q. So Doctor, for the prognostic purposes, ER/PR is used for primary breast and metastatic breast cancer, that's two instances?

DR. DENIC:

A. That's correct.

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COFFEY, Q.C.:

Q. Prognostically. Are they the only -

DR. DENIC:

A. Metastatic breast cancer.

COFFEY, Q.C.:

Q. Yes. Are they the only two prognostic situations in which ER/PR is ordered? Is there any other? I'm not suggesting there is.

DR. DENIC:

A. Not that I know of.

COFFEY, Q.C.:

Q. Okay. In terms then, Doctor, of ER/PR's utilization otherwise, for all other purposes, okay, the results are either accurate or they're not. If they're false negatives, if the results that have been done between 1997-2005, in all those other situations were false negatives, if there were any false negatives there, could there have been an effect on how the tumour was classified and how it was dealt with?

DR. DENIC:

A. I would say absolutely not, because this is not a way that we subclassify the metastatic tumour.

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COFFEY, Q.C.:
Q. Okay, so I ask you then, Doctor, then why was anyone bothering to do it at all?
DR. DENIC:
A. Why was anybody doing it all?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. Mr. Coffey, that's why I said today we think that's over utilization of the stains and as such, why we should be using those ones because I use myself too at certain point. Again, as I say, you're working--you're trying to narrow down the stuff. If it's positive, it's great. But not alone positive, not the stand-alone positive. It's not utilized in any kind of treatment. It was utilized -
COFFEY, Q.C.:
Q. No, I'm not asking about treatment now.
DR. DENIC:
A. No, but what I'm saying, it's not--it was just utilized as a panel of the stains to narrow down where the tumour is coming from.
THE COMMISSIONER:
Q. Sorry, did I understand you to say that if

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such a case came through your lab today, you would not order an ER/PR test?
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. Okay, and what's more, there is a directive in effect to that effect? Seemed to be saying that that was communicated to everybody else as well?
DR. DENIC:
A. Yeah, that's right. That's right, I think we communicated, so even to outside the hospitals as well and just said "don't order it" because it doesn't have any value because positive or negative doesn't mean it's breast, because there is other tissue express estrogen and progesterone, as I said, even the lung tumours can have estrogen and progesterone receptor positive.
COFFEY, Q.C.:
Q. In terms of gynecological concern, cancers, concerns?
DR. DENIC:
A. No.
COFFEY, Q.C.:

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Q. No, ER/PR is not used there?
DR. DENIC:
A. No, definitely not. Definitely not.
COFFEY, Q.C.:
Q. And so for, in the context then of breast cancer, whether primary or metastatic, you understand that all the primaries, at least the ones you are aware of exist, and classified as negative, based upon the criteria that was used back in 2005, have been retested?
DR. DENIC:
A. That was my understanding. I know one case, the lymph node was tested.
COFFEY, Q.C.:
Q. And for metastatic breast cancer, suspected metastatic breast cancer, generally in St. John's, they were not retested? ER/PRs were not retested for them?
DR. DENIC:
A. No, unless inadvertently something fell into it.
COFFEY, Q.C.:
Q. You've indicated that for the ones in the second category there that there could be

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situations where it could have, for individual patients, treatment ramifications if the original report was a false negative and hasn't been retested for metastatic breast cancer?
DR. DENIC:
A. For metastatic in the lymph node.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. May have, but I--that depends on the case. I mean, and this is not that I'm comfortable talking about. The oncologist should address that.
COFFEY, Q.C.:
Q. And for all other ER/PR tests, for the reasons you've explained, you cannot think of any reason why a false negative ER result would be of any concern at all clinically?
DR. DENIC:
A. That's--I mean, I can guarantee that it's not a concern because it's never utilized as a single test.
COFFEY, Q.C.:
Q. No, see, Doctor, see, this is what I'm--you

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say single test, all right. Then we can get into discussions about well, was it ever utilized as a part of two tests or is one of three or one of four or one of five, and arguably, I suppose, if it's one of five, it has less significance than if it has one of two. So what I'm asking you is--I'm not just talking about the four panel or the five panel. I'm asking you, period, okay -

DR. DENIC:

A. And the answer is no.

COFFEY, Q.C.:

Q. No, okay. So no matter whether it's used -

DR. DENIC:

A. The answer is no, even if it's two panel.

COFFEY, Q.C.:

Q. Okay. Okay, now, we're looking at 1749 and in terms of that, just trying to get some sense for the Commissioner of kind of what, at the time, when you first got involved your understanding was overall. Ms. Wegrynowski is, this indicates, it's an e-mail from Denise Dunne, March 6th, 2006 to a number of individuals, including yourself. "Further to my e-mail below, with respect to Trish

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Wegrynowski, I wonder if you would follow up with her directly. She would like to have some information to update her on our progress prior to her arrival. I advised her that we have a spreadsheet of issues that we're working on in an updated format. Terry, once you talk to her, that may be sufficient to help her prepare for her visit."

Doctor, did you deal with Ms. Wegrynowski when she came to St. John's in the spring of '06?

DR. DENIC:

A. I met her and being a part of the team that conducted the exit interview.

COFFEY, Q.C.:

Q. And what do you recall about the exit interview?

DR. DENIC:

A. I think that interview was held at Mr. Gulliver's office. So Mr. Gulliver was there, Mr. Dyer, Dr. Fontaine, myself and Dr. Cook. She started with she was pleased in a way that technologists received the training, that there is support of management towards moving towards the quality in immunohistochemistry

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lab.

COFFEY, Q.C.:

Q. I'm sorry, what was that?

DR. DENIC:

A. That she was pleased that there is the support given by the management -

COFFEY, Q.C.:

Q. Management, okay.

DR. DENIC:

A. - towards moving to the quality in the immunohistochemistry lab. She also said that she wasn't sure that all SOPs were written. I think the fridges were not in place at the time. I'm not certain about thermometers in the fridges. So she had some concern. It was a positive and negative vibes that I got from her on that exit interview.

COFFEY, Q.C.:

Q. Doctor, at that time, I'm going to suggest to you that, in fact--I'm going to ask you, how many SOPs had been written?

DR. DENIC:

A. I don't know at that time because I just took my position and I wasn't checking on that.

COFFEY, Q.C.:

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Q. Did you make any inquiries?

DR. DENIC:

A. I don't remember I made at the time any inquiries.

COFFEY, Q.C.:

Q. When you did make--well, when did you make inquiries about that?

DR. DENIC:

A. Later on, I think in May. We had a meeting with Dr. Williams where we were discussing about the action items with Dr. Elms and Dr. Makarla, because at that time Dr. Fontaine was out of the picture. He resigned from that duty.

COFFEY, Q.C.:

Q. And I take it this was a meeting because this is a meeting to deal with the immunohistochemistry issue overall?

DR. DENIC:

A. I think the action plan to be made how to deal with the recommendations.

COFFEY, Q.C.:

Q. Okay, and that's when SOPs were certainly, I take it, came up at that meeting?

DR. DENIC:

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A. That's right.
COFFEY, Q.C.:
Q. And what did you learn then about the status of the SOPs?
DR. DENIC:
A. I don't think that they were written, and if anything was written about it.
COFFEY, Q.C.:
Q. Now Doctor, in relation to that, if we could, if we could look, please, at Exhibit P-1751? Doctor, this is an e-mail from yourself, March 24th 2006, to Denise Dunne re: IHC quality review. You write "Hi, Dr. Williams. Can you give her our spreadsheets so she will know in advance what has been accomplished?" Signed Nash. And because Dr. Williams, on the 24th, earlier that day had written to you saying "Nash, Terry, Barry, do we have anything to send to Trish? Thanks, Bob." And she had, herself, we look down through the page here, she had sent an e-mail on March 23rd to Dr. Williams saying "if there are any protocols or paperwork that you would like me to review prior to my arrival, they can be faxed to" her number, and so she was looking for any

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protocols or paperwork St. John's would like her to review. Bob Williams was asking yourself and Mr. Gulliver and Mr. Dyer whether you have anything to give her and you were telling Ms. Dunne to give her the spreadsheet.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. So certainly, there were no protocols to give her at that point. Otherwise, presumably you would have told her to?
DR. DENIC:
A. I think the spreadsheet, this was all happening before I even came into the picture. There were some of the items that were ticked had been done, so while obviously there was no paperwork to present, there were some of the items that were addressed at that time, so that's why I was saying at least submit what had been dealt with.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-0277? This is a spreadsheet recommendations, immunohistochemistry service, spreadsheet, Dr. D. Banerjee, Trish

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Wegrynowski, updated April 25/06, compiled December 16th '05, you see in the top right-hand corner there. And that's been updated on April 25th. Doctor, look down through this, it's--on the second page of the exhibit, there are 30 recommendations, and while we're on the topic, Doctor, I'm going to go on to the next page of the exhibit, which is the document entitled the same thing, except it's updated June 30th '06 and we go to page three and then page four of this exhibit. The number of recommendations has grown from April 25th, 2006 from 30 to 52 on June 30th '06. So Doctor, I guess, there's 22 more recommendations.
Doctor, when you took over and then met with Ms. Wegrynowski on her exit interview, what understanding did you have going into this, as to where the lab was with her recommendations from the fall?
DR. DENIC:
A. That's correct, I mean, it was to find out where the lab was.
COFFEY, Q.C.:
Q. Okay, so by the end of April, you still,

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yourself, had not had the opportunity to become apprised of where they are with all this?
DR. DENIC:
A. No, I think you have to understand, it's very early in my position and cannot expect this kind of past to be accomplished even in a month, if month.
COFFEY, Q.C.:
Q. Doctor, your impression, based upon the exit interview of Ms. Wegrynowski was that she had some positive things to say and some -
DR. DENIC:
A. Less positive.
COFFEY, Q.C.:
Q. - less positive, negative or helpful criticism?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, going out of that exit interview and coming away from it, from your perspective, whose responsibility was it or what responsibility did you have to implement or get involved in implementing that?

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DR. DENIC:
A. I had a responsibility, it is a mutual responsibilities really. Mr. Dyer and Mr. Gulliver were supposed to deal with the technical stuff, which is quite understandable, and I was supposed to address the issues of subspecialization and a few things more. While you can see in the spreadsheet, which I never objected, it says that "Dr. Denic, do evaluation of appropriate use of negative controls," which really wasn't -
COFFEY, Q.C.:
Q. Okay, you're looking at page five?
DR. DENIC:
A. Page five, and sausage block, which really it's more technical stuff, but I never objected, as I said, I'm going to just assign this to Dr. Elms and Dr. Makarla at that time. So you can see that these are the technical stuff that I was charged. I think Mr. Gulliver put my name on it, probably in a good faith that probably I'm going to be pushing this to Dr. Elms and Dr. Makarla, and so, but the main item that I had to deal with is to

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subspecialize obviously people, because vast majority of these recommendations are technical.
COFFEY, Q.C.:
Q. Doctor, what was your understanding as to what it was Ms. Wegrynowski was supposed to review in the spring of 2006?
DR. DENIC:
A. She was supposedto review immunohistochemistry lab, pathology lab as such related to the immunohistochemistry, but she also, along that course, she did made some recommendations too to the other parts of the lab and going to the Meditech, which wasn't really the part of immunohistochemistry. In one way, of course, you log and everything immunohistochemistry, but I think she made the suggestion of standardizing of reporting diagnosis versus interpretation which is really nothing relatedto immunohistochemistry.
COFFEY, Q.C.:
Q. So that was from your understanding of what her role was. Did you ask her to come or was that Dr. Williams that asked?

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DR. DENIC:
A. I think that was plan all along, you know, that pay us a first visit and then come back and just see what has been corrected, what's been done.
COFFEY, Q.C.:
Q. Doctor, we understand that Dr. Banerjee was here as well in the spring of 2006.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Were you involved in that?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. And what do you recall about that?
DR. DENIC:
A. I got in touch actually, I knew about previous arrangement that he was supposed to come, and I e-mailed Dr. Banerjee asking him when is he coming and just talking that I'm going to be at his hand if he needs any kind of help, picking him up at the airport, that sort of thing, and when he came as well, we just led him to the lab. We spent some time behind the

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microscope and there was an exit interview as well with Dr. Banerjee.
COFFEY, Q.C.:
Q. And what do you recall--you attended the exit interview?
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. And what do you recall about that?
DR. DENIC:
A. I think there are notes as well, my notes as well on this one. I don't know that you have them or not, but overall impression was that we are doing good, that we should work again over the subspecialty. The stains are good. He thinks that we are ready to reopen for the retesting. He also stated that we should continue doing UK NEQAS proficiency testing. We were talking about cutting the workload for people who are dealing with immunohistochemistry, such as Dr. Ford Elms. We touched bases on our remuneration issue for the two directors, and I think we touched bases on fixation as well, to standardize this across the province or something on those

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lines.
COFFEY, Q.C.:
Q. Did you have any understanding about why Dr. Banerjee thought that would be advisable?
DR. DENIC:
A. The idea to standardize fixation would be since we are central lab and we are receiving the tissue from the peripheral labs.
COFFEY, Q.C.:
Q. For all IHC, in fact.
DR. DENIC:
A. For all IHC, that we should have the same processes in place, such as fixation, which he found in one of his recommendations as a culprit for--possible culprit for the failure of the test, and I think that was the reason.
COFFEY, Q.C.:
Q. So in terms of implementing then, Dr. Banerjee's recommendations, who was responsible for that?
DR. DENIC:
A. It would be myself.
COFFEY, Q.C.:
Q. In particular, addressing the issue of fixation, standardized fixation protocol or

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approach, you understood that that would be your responsibility?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-2639? And Doctor, in the meantime, as it were, in your first month as clinical chief, this is an e-mail from yourself on March 27th, 2006 to--well, that's probably all the pathologists in St. John's at the time?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Subject is ER/PR and HER2/neu reports, and to be fair, it's to pathologists, for example, outside St. John's as well. I notice Maurice Dalton's name is there. It says "please be advised that due to some problems arising from inaccurate transcription or interpretation of the reports for ER/PR and HER2/neu received from Mount Sinai Hospital from Toronto, the Cancer Clinic is requesting the original report from Mount Sinai Hospital be sent along with your pathology reports. Also, please

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find enclosed a template for reporting of the ER/PR and HER2/neu. Sincerely, Nash Denic."
And you have attached there a Word document.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Which, I take it, is the template. So Doctor, why the template for reporting of ER/PR and HER2/neu at that point in time?
DR. DENIC:
A. I wasn't quite certain about what did they have at the periphery and how they would log their cases in. This was just for information to be used.
COFFEY, Q.C.:
Q. And it was a suggestion, I take it?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. And what had happened to cause you to have to send out the e-mail about sending in the actual original report from Mount Sinai Hospital along with the pathology report? I take it there had been a couple of cases at least where there were transcription errors?

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DR. DENIC:
A. That's correct. Not that I would have known that. I received a call from Dr. Joy McCarthy and she told me that they noticed there had been a couple of cases, a few, that they picked up transcription errors, and if I can address this with the pathologists across the province. Not only in the role as the clinical chief, but I signed it also as the president of NAP, you know, because I acted as the president of NAP as well.
COFFEY, Q.C.:
Q. So Doctor, were there any other problems subsequently that you were aware of anyway, were brought to your attention about kind of the transcription error relating to the ER/PR ?
DR. DENIC:
A. No, nobody brought to me from the Cancer Centre.
COFFEY, Q.C.:
Q. Okay. Exhibit P-2068? Doctor, this is entitled Discipline of Laboratory Medicine, Minutes of meeting, March 28th, 2006. Would this be a program meeting?

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DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. That's what you refer to as a program meeting?
DR. DENIC:
A. That's right. They changed its name.
COFFEY, Q.C.:
Q. Yes, but so where we see Discipline of Laboratory Medicine, minutes of meeting -
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. - in fact -
DR. DENIC:
A. These are now joint program and discipline meetings.
COFFEY, Q.C.:
Q. And here, you called it to order. I take it you were chairing it because you were clinical chief?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And then there's, under new business, quality assurance, you thank Dr. Cook for his work,

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and then "implementation of the new quality assurance program was discussed at length. Dr. Beverley Carter will act as manager of the new quality management program for the pathology department. There will be a technical member and a clerical member of the team. Dr. Carter will act independently and answer to quality management team. This is supported by Dr. Williams, VP Medical. Dr. Morris-Larkin expressed concern about being audited." I take it Dr. Larkin worked at the General Hospital?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. The next page, the minutes go on, "Dr. Denic stated that random slides would be audited." So I take it you were responding here to Dr. Larkin's expression of concern?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. "Dr. Carter says that the random cases will be picked by the technologist who is working with the quality management program. Dr. Morris-

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Larkin expressed the feeling that one pathologist should not do all of the auditing. Dr. Denic also stated there would be policies put in place regarding the auditing. Dr. Cook stated there was no QA committee before November of 2004. Dr. Matheson said he felt it was not a good policy to have the QA committee report to anybody but the clinical chief, who would then report to Eastern Health." And you inform the group that "Eastern Health will have regional managers for QA who will be involved with our managers. Dr. Morris-Larkin offered to help with the QA. Dr. Matheson wanted to know how the appointment of a new university chair for the discipline would affect QA. Dr. Denic informed Dr. Matheson the new chair would be part of the team" and you are quoted as, or noted as having said "it is very important the QA committee needs to be put in place as soon as possible." Now Doctor, was this your initiative?
DR. DENIC:
A. Of the quality management program?
COFFEY, Q.C.:

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Q. Yes.
DR. DENIC:
A. A part of it.
COFFEY, Q.C.:
Q. For the pathology department?
DR. DENIC:
A. Part of it. I'll tell that how you happened actually. In March of 2006, Dr. Beverley Carter, she approached me and she said "I think we should establish like a quality management program. I think it's good for the department" and I said "Bev, that's a great idea. Let's put something on a paper and try to create almost like a position paper towards creation of the quality management program," and I said "I love the idea. I'll carry that to Dr. Williams, because we're going to need obviously some resources in order to get that up and running." And that's how it started. I look what she wrote, submitted to Dr. Williams in one of the meetings. He welcomed that initiative very much, eventually gave us some support to move this off the ground, and that was the beginning of the quality management program. That's why it was from

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March of 2006.
COFFEY, Q.C.:
Q. So Doctor, just so we're clear, this quality management team was internal to the pathology department?
DR. DENIC:
A. It's part of the pathology department.
COFFEY, Q.C.:
Q. Part of it, and internal to it?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Now the quality assurance program, which is the way it's described, just reading what's there, where is--this here, where--this quality assurance program, how, if at all, did that relate to the quality management program for the pathology department or is it the same thing?
DR. DENIC:
A. It's the same thing, you know, just--quality assurance is really a part of the quality management, you know. Quality control or quality assurance, quality management is overseeing the entire system. So, I mean,

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it's just a wording.
COFFEY, Q.C.:
Q. Okay, and here on page two, Doctor, Dr. Cook is noted as having said, "There was no QA committee before November, 2004", and we've seen materials relating to--in fact, that there was one set up then. I take it that you were implementing one--as you were implementing one in March of 2006, had the QA committee that dated back to November, 2004, for pathology, had that been inactive?
DR. DENIC:
A. That was inactive.
COFFEY, Q.C.:
Q. Inactive. So when had it gone inactive, how long had it been inactive?
DR. DENIC:
A. I wasn't a part of that committee, so it was a short-lived committee.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. So I--I don't believe it lasted more than a year or maybe even less. I'm not quite certain about it.

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COFFEY, Q.C.:
Q. And taking over then as clinical chief, and being approached in the way you were, this was an issue you were going to push?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Doctor, there's a reference to the shortage of staff pathologists and potential for recruiting them, and--which you told the Commissioner about earlier in terms of recruiting some of the residents, about them joining after graduation in June is referred to there, and then, though, there's a reference at the bottom of the page, you encouraged the idea of pathologists subspecializing?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And the next page, "Dr. Matheson expressed that option that subspecializing is not always good. If a person subspecializing leaves, the department could have a fair amount of trouble", and you felt that this problem could

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be solved by overlapping subspecialties studied, okay, that was your response.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. How then has that evolved since, and I appreciate there had been shortages of staff?
DR. DENIC:
A. It did evolve, of course, and we were going through the certain hurdles, and, obviously, even now you realize one of the comments that's made by the professor of the pathology at that time, he was still retired, but coming at a meeting, and neuropathologist, Dr. Matheson, the man with the great experience. Being in a high turnover like we had is--sustaining subspecialties, today you have two people reporting certain tissue, and suddenly overnight, they disappear. That's what happened with the breast group. We started with four, and then one by one they left. One of them left because the pathologist found no interest in breast pathology per se. The second pathologist went to BC and currently practising in BC. Who left behind was Dr.

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Cook and Dr. Beverley Carter, and at the end of the day I came back to ground zero in May. Nobody left from them, and all of these people were reporting just breast cases. So you're almost cutting the arms from the rest of the people, just giving a certain tissue type to the certain group of people that not necessarily going to be there in a year time, and then you go back to your own staff and say, okay, guys, now you're going to take it back and now you're going to be reporting the breast tissue, and they obviously going to tell you, no, and because--not going to tell you no because they don't want to do it, because it's not safe any more. Because if you're not reporting certain stuff, then you're losing the grip on a certain tumour and tissue type and reporting, and using that eye that otherwise you would have for that tissue. So that's what it's all about. So since then, I sent another memo explaining the value of the subspecialty training, and subspecialty reporting to the pathologists, and after that I also asked pathologists to send me a list of their interests, tumour site interests, so

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that I can probably break them down into certain groups, and that's what happened. But only few groups been lifted off the ground really, which is the first breast group, and they had the first official meeting in November of 2006, defining their terms of reference and the way of the practice. The second group that was--that's practising as such is the prostate group, the group for the prostate. They are reporting on needle core biopsies of prostate. Then we have the liver group in the meantime, although now this group is cut in half because Dr. Beverley Carter was part of the group. So now I have pretty much Dr. Lynn Morris-Larkin as a group of one, and we have a lymphoma group which is active, which is a group that looks into the malignancies of--not only malignancy, but there's benign diseases as well of the lymph nodes. While we don't still have what we call ENT group for the ear, nose and throat subspecialty, it's pretty much specialized service at St. Clare's Hospital. It's only a few of us are doing ENT service. Lung group, we are still at St. Clare's, specialize at St.

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Clare's, and I have a great interest and they are using me as internal consultant for the lung. So we are moving along, and I think we addressed most vulnerable issues in pathology.

COFFEY, Q.C.:

Q. So, Doctor, is any of this written down anywhere in terms of like a schematic chart or, you know, in terms of --

DR. DENIC:

A. I think you must hear of the breast group --

COFFEY, Q.C.:

Q. Yes, the breast group, yes.

DR. DENIC:

A. And--oh, schematic chart for how we divide the interest.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. I think I submitted to my lawyers and that you can get. It was like a spreadsheet.

COFFEY, Q.C.:

Q. What I'm getting at, Doctor, is this --

DR. DENIC:

A. Is a spreadsheet.

COFFEY, Q.C.:

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Q. It has been organized to the extent that it has been reduced to writing? From your perspective, as the Chief of Laboratory Service, from your perspective in approaching this, you've actually written all this down?

DR. DENIC:

A. That's right, a spreadsheet that tells you which people belongs in it. In the meantime, obviously, it hasn't been updated because we have so many people leaving now, but that spreadsheet is available and I was thinking would have been a part of the exhibits.

COFFEY, Q.C.:

Q. Yes, and --

COMMISSIONER:

Q. Mr. Coffey, it's nearing the end of the day.

COFFEY, Q.C.:

Q. Thank you. Just before finishing up, Commissioner, if we could look at this page here, page three, "The pathology assistants", you're noted as having said some people were interviewed for the pathology assistants?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

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Q. And one with experience is starting on Monday. So this--at this point in time, March of 2006, is the beginning of pathology assistants in St. John's?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And four are going to be trained. Perhaps then what I'll do is when we come back tomorrow, I'll take up with you where you are with the pathology assistants.

DR. DENIC:

A. Okay.

THE COMMISSIONER:

Q. Okay, we'll meet at 9:30 in the morning.

COFFEY, Q.C.:

Q. Thank you, Commissioner.

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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 11th day of September, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 11th day of September, A.D., 2008

Judy Moss

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