

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

LIST OF EXHIBITS

- Exhibits entered and marked P-2635 through to P-2704 . . . Pg. 5

- Exhibits entered and marked P-2706 through to P-2728 . . . Pg. 5

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DR. NEBOJSA (NASH) DENIC (SWORN)
Examination by Bernard Coffey, Q.C. Pgs. 4 - 308

Certificate

- 1 THE COMMISSIONER:
- 2 Q. Mr. Coffey.
- 3 COFFEY, Q.C.:
- 4 Q. Commissioner, the next witness is Dr. Denic.
- 5 DR. NEBOJSA (NASH) DENIC, SWORN, EXAMINATION BY BERNARD
- 6 COFFEY, Q.C.
- 7 REGISTRAR:
- 8 Q. Would you please state and spell your complete
- 9 name for the Commission?
- 10 DR. DENIC:
- 11 A. It's Nebojsa Denic, N-E-B-O-J-S-A, Denic, D-E-
- 12 N-I-C.
- 13 REGISTRAR:
- 14 Q. Thank you.
- 15 COFFEY, Q.C.:
- 16 Q. And Doctor, while we're on your name, I take
- 17 it the first name that people know you by is
- 18 Nash?
- 19 DR. DENIC:
- 20 A. That's correct.
- 21 COFFEY, Q.C.:
- 22 Q. Okay, because we've seen references to it at
- 23 times, N-A-S-H is the ways it's spelt?
- 24 DR. DENIC:
- 25 A. That's correct.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. Doctor, before I get into my questioning, I'd</p> <p>3 ask the Commissioner, please, Commissioner,</p> <p>4 there are exhibits, new exhibits, please.</p> <p>5 Exhibits P-2635 through 2704 inclusive and P-</p> <p>6 2706 through P-2728 inclusive. In other</p> <p>7 words, all the way from 2635 through 2728,</p> <p>8 with the exception of 2705.</p> <p>9 THE COMMISSIONER:</p> <p>10 Q. Entered.</p> <p>11 EXHIBITS ENTERED AND MARKED P-2635 THROUGH 2704</p> <p>12 EXHIBITS ENTERED AND MARKED P-2706 THROUGH 2728</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Registrar, would you open, please, Exhibit P-</p> <p>15 2635? And Doctor, there on the screen in</p> <p>16 front of you is a curriculum vitae for</p> <p>17 yourself? That's yours?</p> <p>18 DR. DENIC:</p> <p>19 A. That's correct.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And it's relatively current?</p> <p>22 DR. DENIC:</p> <p>23 A. Relatively current.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. You provided it relatively recently to the</p>	<p>1 A. That's correct. I finished a year of military</p> <p>2 service. It was mandatory at that time,</p> <p>3 serving as a physician, in 1984, and in</p> <p>4 December of 1984, I started my residency</p> <p>5 training program in forensic medicine at the</p> <p>6 Institute of Forensic Medicine in Belgrade</p> <p>7 University of Belgrade. In 1985, I completed</p> <p>8 the Master of Science in Neurobiology at the</p> <p>9 University of Belgrade, and in 1988, I</p> <p>10 finished with my residency training program in</p> <p>11 forensic medicine, which is three and a half</p> <p>12 years, and been certified at further</p> <p>13 examination. So I'm a certified forensic</p> <p>14 pathology with interest in forensic medicine</p> <p>15 too. In 1991, I completed a PhD defending a</p> <p>16 thesis in the field of forensic medicine. I</p> <p>17 did some additional training in Baltimore in</p> <p>18 forensic medicine as a sabbatical.</p> <p>19 I came to Canada in 1992 at the</p> <p>20 invitation by the Hospital for Sick Children</p> <p>21 in the Chief Coroner office, to do research</p> <p>22 and consulting in pediatric forensic pathology</p> <p>23 unit, where I stayed for three years.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. That would be in Toronto?</p>
<p>Page 6</p> <p>1 Commission. Doctor, I'm going to ask you,</p> <p>2 please, to tell the Commissioner about your</p> <p>3 educational and professional background, just-</p> <p>4 -you can use this, if you need it, but</p> <p>5 otherwise, you can just simply go ahead and</p> <p>6 tell us.</p> <p>7 DR. DENIC:</p> <p>8 A. Okay, I can just use -</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Sure, you can if you wish.</p> <p>11 DR. DENIC:</p> <p>12 A. - for reminder.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Sure.</p> <p>15 DR. DENIC:</p> <p>16 A. Commissioner, I graduated in Medical School of</p> <p>17 Belgrade, Belgrade University, or Belgrade,</p> <p>18 former Yugoslavia, current Serbia, in 1982.</p> <p>19 After that, I completed the rotation, medical</p> <p>20 internship and passed a state exam and</p> <p>21 therefore been fully licensed to practice</p> <p>22 medicine in former Yugoslavia.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And that would be in 1983, Doctor?</p> <p>25 DR. DENIC:</p>	<p>Page 8</p> <p>1 DR. DENIC:</p> <p>2 A. In Toronto.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Okay.</p> <p>5 DR. DENIC:</p> <p>6 A. And after that, I had been offered the</p> <p>7 residency training program in anatomical</p> <p>8 pathology at the Memorial University here in</p> <p>9 St. John's, which I started it in 1995 and I</p> <p>10 completed the four years of residency training</p> <p>11 program in 1999 and I completed the exam in</p> <p>12 the first attempt and got certified by the</p> <p>13 Royal College of Physicians and Surgeons and</p> <p>14 became the fellow of Royal College of</p> <p>15 Physicians and Surgeons of Canada.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And that was in 1999, Doctor?</p> <p>18 DR. DENIC:</p> <p>19 A. That's correct.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And you're certified in anatomical pathology?</p> <p>22 DR. DENIC:</p> <p>23 A. That's correct.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Okay.</p>

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1 DR. DENIC:
 2 A. I passed the various exams in order for
 3 licensing and my full license was issued by
 4 the College of Physicians and Surgeons of
 5 Newfoundland and Labrador, at the time it was
 6 Medical Board, and my license is in good
 7 standing.
 8 In some of my work experiences, while
 9 practising in the former Yugoslavia, I was
 10 practising at the Institute of Forensic
 11 Medicine as assistant professor in forensic
 12 medicine and actually ending my career down
 13 there as associate professor of forensic
 14 medicine, teaching at the three faculties and
 15 in two republics at that time. Today it would
 16 be two states.
 17 After the completion of the residency
 18 training here in Newfoundland, I was offered
 19 position with the Health Care Corporation, at
 20 that time, and that my job at the St. Clare's
 21 Mercy Hospital where I'm still practising as a
 22 staff pathologist. My career actually,
 23 evolved actually just in terms of the
 24 administrative functions that I hold and I've
 25 been serving as a treasurer, vice-president

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1 and the president for the medical staff. I
 2 was also president of Newfoundland and
 3 Labrador Association of the Pathologists from
 4 2004 to 2007.
 5 I was offered the position of interim
 6 clinical chief in 2006, which was March 2006,
 7 and I hold that position until May of 2007,
 8 when this position was turned into the
 9 permanent position as clinical chief of the
 10 anatomical pathology program and laboratory
 11 medicine program. In April of this year, this
 12 position was officially changed to the
 13 position of the Chief of Laboratory Medicine
 14 for Eastern Health, and this is the position
 15 that I currently hold.
 16 COFFEY, Q.C.:
 17 Q. And Doctor, some aspects of your training,
 18 I'll be asking you about, but while we're on
 19 the topic of administrative positions, okay,
 20 Doctor, while you were at St. Clare's, and I
 21 take it you began as a staff person at St.
 22 Clare's in 1999?
 23 DR. DENIC:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. At that time, the site chief, there was a site
 2 chief and that would have been Dr. Cook?
 3 DR. DENIC:
 4 A. That's correct.
 5 COFFEY, Q.C.:
 6 Q. And at various points afterward, Dr. Cook was
 7 not only site chief, but he was also interim
 8 clinical chief while Dr. Haegert was away on
 9 sabbatical, and then in a period after Dr.
 10 Haegert came back, Dr. Cook became clinical
 11 chief?
 12 DR. DENIC:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. In fact, you took over from Dr. Cook in 2006?
 16 DR. DENIC:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. While Dr. Cook was site chief at St. Clare's
 20 and you were there as a staff person, did you
 21 hold any position? Were you assistant site
 22 chief or substitute site chief in any way?
 23 DR. DENIC:
 24 A. Yes, in a certain period of time, I think that
 25 would be a period maybe 2004, 2005, whenever

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1 Dr. Cook would take a vacation or he would be
 2 away on a conference, he would ask me, you
 3 know, just to take on these duties and deal
 4 with the issues that may arise during his
 5 absence.
 6 COFFEY, Q.C.:
 7 Q. And we'll see some reference to that in a
 8 couple of the exhibits, and in terms of those
 9 particular times that you had to substitute
 10 for--fill in for Dr. Cook in that capacity, I
 11 take it they were relatively short periods of
 12 time?
 13 DR. DENIC:
 14 A. That's correct.
 15 COFFEY, Q.C.:
 16 Q. Couple of days or a couple of weeks?
 17 DR. DENIC:
 18 A. Couple of days and even a couple of weeks.
 19 COFFEY, Q.C.:
 20 Q. Yes, but that would be about it. Doctor,
 21 other than that, I take it the site chief
 22 duties were left to Dr. Cook?
 23 DR. DENIC:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. Doctor, could you tell us, please, in relation
 2 to your duties, I just want to clarify this,
 3 even as of today, I take it Dr. Cook is still
 4 the site chief?
 5 DR. DENIC:
 6 A. Yes, he is.
 7 COFFEY, Q.C.:
 8 Q. He's remained site chief throughout the whole
 9 period of time you've been at St. Clare's?
 10 DR. DENIC:
 11 A. That's correct.
 12 COFFEY, Q.C.:
 13 Q. And Doctor, as interim clinical chief and then
 14 initially as clinical chief?
 15 DR. DENIC:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. Could you tell the Commissioner, please, what
 19 your duties were?
 20 DR. DENIC:
 21 A. The duties of the clinical chiefs are defined
 22 by bylaw, and the duties are that the clinical
 23 chief, along with the program director,
 24 they're responsible for the operation and the
 25 quality of the lab. That's a general

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1 statement and that we were accountable to
 2 vice-president of Medical Services. As a part
 3 of other duties is that clinical chief has to
 4 be the member of the medical staff that has to
 5 attend the meetings of the clinical chiefs and
 6 MACs and get involved in planning of the
 7 laboratory medicine operations, along with the
 8 program director.
 9 Also, the duties are that clinical chief
 10 is involved in recruitment and retention and
 11 some of these duties has to be liaised with
 12 our discipline chair, since a certain number
 13 of our members are the faculty members and
 14 that falls under the jurisdiction of the
 15 discipline chair. The other duties is that
 16 clinical chief has to liaise with other
 17 departments and the clinical chiefs and look
 18 into the needs of those departments that work
 19 the service that we provide. Some roles of
 20 the clinical chief are also defining the
 21 budget, but that budget should be defined by
 22 original, at that time, just program director
 23 and the vice-president, that's all.
 24 We have to promote research in our
 25 institution and liaise again in that regards

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1 with the discipline chair. We have to support
 2 educational activities, educational activities
 3 from the undergrads, post grads and anybody
 4 rotating through the program.
 5 So these are the broad-based duties.
 6 COFFEY, Q.C.:
 7 Q. Okay, Doctor, and that was while you were
 8 clinical chief, either interim or had the
 9 title of clinical chief?
 10 DR. DENIC:
 11 A. That's correct.
 12 COFFEY, Q.C.:
 13 Q. Doctor, approximately how much of your time
 14 would be devoted to clinical chief's duties,
 15 as opposed to a staff pathologist's duties?
 16 DR. DENIC:
 17 A. That would change, you know, but understanding
 18 was around 50 percent of the time would be
 19 taken by the clinical chief's duties, but that
 20 really fluctuates and it's difficult to define
 21 and sometimes you turn your administrative
 22 duties really into the full week and then
 23 you're falling off the schedule from being a
 24 pathologist, but I would say around 50 percent
 25 of the time.

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1 COFFEY, Q.C.:
 2 Q. Was there any--and I want to ask you about,
 3 when you took over as interim clinical chief
 4 and continued on as clinical chief, was there
 5 any written stipulation as to how much--or
 6 recognition of how much of your time would be
 7 administrative, as opposed to clinical?
 8 DR. DENIC:
 9 A. I don't believe it was written one, but it was
 10 my understanding, talking to Dr. Williams as
 11 well and to Dr. Cook, and just to see how much
 12 time this takes, because there was discussion
 13 that I would have with Dr. Cook before I took
 14 this position.
 15 COFFEY, Q.C.:
 16 Q. And I take it then that in taking on the
 17 workload of a staff pathologist, the
 18 recognition would be, for the clinical chief
 19 would be that he or she would, if it was 50
 20 percent of the time administrative, then they
 21 would do 50 percent of the regular staff
 22 person's time taking in cases, clinical cases?
 23 DR. DENIC:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. That would be the way that -
 2 DR. DENIC:
 3 A. That would be the way that it would try
 4 actually to accomplish. However, you see that
 5 being a clinical chief and being an
 6 administrative duties, I personally don't
 7 consider myself as administrator because
 8 administrative duties, they have the limited
 9 life and you don't want to lose your medical
 10 skills, and while this would be sometimes on
 11 the paper that I would be twice less put on
 12 the rotation through the surgical pathology
 13 service, I would go and take additional cases
 14 myself, and especially when Dynacare come into
 15 place, the cases that would be supposedly sent
 16 to Dynacare, whenever I had the free time, I
 17 would go to that room and pull out the cases
 18 back from the Dynacare file and bring it to my
 19 desk.
 20 COFFEY, Q.C.:
 21 Q. Now Doctor, you've indicated that in April of
 22 this year, April 2008, that the title of your
 23 position changed, or the position changed?
 24 DR. DENIC:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. And it's now the -
 3 DR. DENIC:
 4 A. Now I'm Chief of Laboratory Medicine for
 5 Eastern Health.
 6 COFFEY, Q.C.:
 7 Q. Okay, so it's Chief of Laboratory Medicine as
 8 opposed to clinical chief?
 9 DR. DENIC:
 10 A. That's correct.
 11 COFFEY, Q.C.:
 12 Q. So in your capacity as Chief of Laboratory
 13 Medicine, what are your duties and how do they
 14 differ from your clinical chief's duties and
 15 the reporting structure?
 16 DR. DENIC:
 17 A. Reporting structure have been changed, not all
 18 the way down, but changed from the top.
 19 Reporting structure is that we still have on
 20 the top of the pyramid, if you will, the Vice-
 21 President of Medical Services and Diagnostic,
 22 which would be Dr. Howell, and then I would be
 23 under him as Chief of Laboratory Medicine for
 24 Eastern Health, and then we would have Mr.
 25 Terry Gulliver who is the regional program

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

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1 think, give them time to think what would be
 2 the best way for them to work.
 3 COFFEY, Q.C.:
 4 Q. So as you sit here now, okay, in the
 5 administrative structure, who reports to you
 6 on the clinical side? Not the technologist's
 7 side, but the clinical side?
 8 DR. DENIC:
 9 A. On a clinical side, I have all divisional
 10 chiefs and -
 11 COFFEY, Q.C.:
 12 Q. Which would be people such as?
 13 DR. DENIC:
 14 A. You have people in biochemistry, like it would
 15 be Dr. Ed Randell. You have immunology,
 16 molecular genetics and cytogenetics, this is
 17 Dr. Yagang Xie. Microbiology, Dr. Jim
 18 Hutchinson. Laboratory hematology, Dr. Cindy
 19 Whitman. Cytology would be Dr. Dan Fontaine
 20 and I have two site chiefs, one out of St.
 21 Clare's and one at the General Hospital site,
 22 Lynn Morris-Larkin at the General Hospital
 23 site and Dr. Cook at St. Clare's. Also under
 24 my jurisdiction are the two pathologists at
 25 the Clarendville hospital and one pathologist

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1 in Carbonear.
 2 COFFEY, Q.C.:
 3 Q. And when did the Clarenville pathologists and
 4 the Carbonear pathologist begin to report to
 5 you?
 6 DR. DENIC:
 7 A. Officially?
 8 COFFEY, Q.C.:
 9 Q. Yes.
 10 DR. DENIC:
 11 A. It would be April.
 12 COFFEY, Q.C.:
 13 Q. Okay.
 14 DR. DENIC:
 15 A. But they knew about the changes that we are
 16 trying to implement, I believe in February of
 17 this year.
 18 COFFEY, Q.C.:
 19 Q. Okay, so and this has happened in this year,
 20 2008?
 21 DR. DENIC:
 22 A. That's correct.
 23 COFFEY, Q.C.:
 24 Q. Now Doctor, in relation to the idea of
 25 reporting to, at least in the sense of, you

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

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

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

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<p>1 four did you look at?</p> <p>2 DR. DENIC:</p> <p>3 A. We went to London, Ontario, Mount Sinai,</p> <p>4 Kingston, that's where and I did a separate</p> <p>5 tour, I was on my vacation and coming back</p> <p>6 from my vacation through Toronto I organized a</p> <p>7 meeting with UHN, which is UHN, it's</p> <p>8 University Health Network.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Okay.</p> <p>11 DR. DENIC:</p> <p>12 A. Used to be Toronto General. That's one of the</p> <p>13 biggest hospitals in Toronto.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. So either you, yourself went to the one</p> <p>16 institution?</p> <p>17 DR. DENIC:</p> <p>18 A. That's correct.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. You arranged for that and you certainly, but</p> <p>21 this, the group that went from here went to</p> <p>22 three other institutions?</p> <p>23 DR. DENIC:</p> <p>24 A. That's right. Dr. Oscar Howell, Mr. Gulliver</p> <p>25 and myself, we went to Mount Sinai. Then Dr.</p>	<p>1 been presented to us in these four labs as a</p> <p>2 model.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Sure.</p> <p>5 DR. DENIC:</p> <p>6 A. But not necessarily means that they shouldn't</p> <p>7 come up with something else. As long they</p> <p>8 come up with a structure they think is going</p> <p>9 to work, I'm going to be quite satisfied.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. And these visits to the four facilities in</p> <p>12 Ontario, when did they occur?</p> <p>13 DR. DENIC:</p> <p>14 A. In June.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Of this year?</p> <p>17 DR. DENIC:</p> <p>18 A. Of this year.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And so these four structures, do you actually</p> <p>21 have like flow charts or diagrams for them?</p> <p>22 DR. DENIC:</p> <p>23 A. I do. We received some of those at the time</p> <p>24 of the visit and some of those were mailed to</p> <p>25 us after the visit.</p>
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<p>1 Oscar Howell had to go to attend one of the</p> <p>2 meetings regarding the safety and the quality.</p> <p>3 And Mr. Terry Gulliver and I, we went to</p> <p>4 London and Kingston.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. And do I understand you correctly then in</p> <p>7 terms of based upon your observations at those</p> <p>8 four places and otherwise that the structure</p> <p>9 and the final form it will take is still</p> <p>10 evolving? You're still giving thought to how</p> <p>11 finally you're going to structure Eastern</p> <p>12 Health?</p> <p>13 DR. DENIC:</p> <p>14 A. That's correct, because I think all</p> <p>15 stakeholders should be included in that and</p> <p>16 the decision should be made by all of us.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Doctor, are there any draft structures, kind</p> <p>19 of discussion documents in place or available</p> <p>20 as to kind of where we are currently or</p> <p>21 various options?</p> <p>22 DR. DENIC:</p> <p>23 A. Not to that extent. What we have is what I'm</p> <p>24 going to submit to the divisional chiefs and</p> <p>25 regional managers are the structures that have</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. and I take it then what you're saying to the</p> <p>3 Commissioner overall is is, look, I'm going to</p> <p>4 put the four, those four options out there,</p> <p>5 one or other or none of them may be adopted or</p> <p>6 some other structure or some combination of</p> <p>7 them?</p> <p>8 DR. DENIC:</p> <p>9 A. That's correct.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. I take it it's still in that state right now?</p> <p>12 DR. DENIC:</p> <p>13 A. They're just the models. And we might not</p> <p>14 stop there, we might even look further up if</p> <p>15 this is not satisfactory.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Now, Doctor, I wanted to ask you about--</p> <p>18 actually, I'll just show you a couple of</p> <p>19 things first. P-2636, please, Registrar?</p> <p>20 Doctor, this happens to be the annual review</p> <p>21 of medical staff report for yourself for 2002.</p> <p>22 And I just, at the time you were fulltime</p> <p>23 staff pathologist at St. Clare's and there</p> <p>24 were some other activities that you were</p> <p>25 involved in, some of which you've already</p>

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<p>1 outlined for the Commissioner are referred to</p> <p>2 here. And there's a reference to acting chief</p> <p>3 of the department in absence of Dr. Don Cook.</p> <p>4 So even going to, back as early as 2002?</p> <p>5 DR. DENIC:</p> <p>6 A. 2002, yeah.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Doctor, I'm going to ask you now about your</p> <p>9 exposure to immunohistochemistry, okay, just</p> <p>10 to--when did you first have any exposure to</p> <p>11 immunohistochemistry?</p> <p>12 DR. DENIC:</p> <p>13 A. During my residency training program.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Well, you've had at least two residencies, so</p> <p>16 which?</p> <p>17 DR. DENIC:</p> <p>18 A. I'm sorry. This one in St. John's, so from</p> <p>19 1995.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And I take it when you were trained in</p> <p>22 Yugoslavia, because of what you were being</p> <p>23 trained in and the state of</p> <p>24 immunohistochemistry at the time in the sense</p> <p>25 of its development at the time, you were not</p>	<p>1 by immunohistochemistry here?</p> <p>2 DR. DENIC:</p> <p>3 A. No. It was done by the biochemical assay.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And before I go on then about it and ask you</p> <p>6 about ER/PR itself, Doctor, how much, looking</p> <p>7 back on it as a resident in the late '90s in</p> <p>8 St. John's, how much were you actually</p> <p>9 expected to know about immunohistochemistry,</p> <p>10 like the science of it?</p> <p>11 DR. DENIC:</p> <p>12 A. Science, very little. Very little had been</p> <p>13 even written. The textbook that I was using</p> <p>14 was the Rosai Ackerman, and that was the book</p> <p>15 that I used all through my residency. Even</p> <p>16 now I think it's a book that I like and</p> <p>17 utilizing a lot whenever -</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And there's not, at the time there wasn't a</p> <p>20 whole lot in it on immunohistochemistry?</p> <p>21 DR. DENIC:</p> <p>22 A. Not really. The basics, they're the basics,</p> <p>23 but that would be it because it was been</p> <p>24 expectation from the residents even for the</p> <p>25 exam just to know the basics of it, but not</p>
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<p>1 involved in that?</p> <p>2 DR. DENIC:</p> <p>3 A. In immunohistochemistry is not, usually not a</p> <p>4 part of forensic pathology practice.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Pathology, yes. So, Doctor, then in 1995 when</p> <p>7 you started a residency here in St. John's,</p> <p>8 what happened then in terms of your exposure</p> <p>9 to IHC?</p> <p>10 DR. DENIC:</p> <p>11 A. The only exposure to the IHC were through the</p> <p>12 various stains that were at the time performed</p> <p>13 in the department. Those stains were utilized</p> <p>14 in a way that we are trying to determine or</p> <p>15 subclassify the tumours, so that's most what</p> <p>16 we'd been using. So the tumour had been</p> <p>17 stained, we would look and based on the</p> <p>18 staining we can say, yes, this tumour is</p> <p>19 malignant tumour of the skin, what we call</p> <p>20 malignant melanoma or this is a tumour that</p> <p>21 could be from other regions, breast, bowel.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Okay. I take it at that time, in 1995, 1996,</p> <p>24 as you went through your residency, when you</p> <p>25 first started, ER and PR, was that being done</p>	<p>1 really ins and out.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Doctor, as a resident, and you had been a</p> <p>4 resident when Dr. Khalifa introduced the</p> <p>5 ER/PR, IHC method here in St. John's in</p> <p>6 Newfoundland and Labrador, in fact, as a</p> <p>7 resident if someone had asked you who in this</p> <p>8 building would know about the science of this,</p> <p>9 who would you have identified, what group or</p> <p>10 what type of person would you have identified,</p> <p>11 if anyone?</p> <p>12 DR. DENIC:</p> <p>13 A. You mean at the time when Dr. Khalifa was -</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. In your residency, in your residency? If</p> <p>16 there was a problem or a question you had</p> <p>17 about immunohistochemistry at the time?</p> <p>18 DR. DENIC:</p> <p>19 A. I don't believe there was any particular</p> <p>20 person dedicated to this. I know that Dr.</p> <p>21 Khalifa had an interest in</p> <p>22 immunohistochemistry and eventually when the</p> <p>23 immunohistochemistry of ER/PR was put in place</p> <p>24 by Dr. Khalifa, you know, at that time it was</p> <p>25 obvious that he has an interest in that field.</p>

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<p>1 But I don't remember before that, that I could 2 rely on anybody except for your staff as much 3 as they can provide the information about it. 4 COFFEY, Q.C.: 5 Q. And the staff in this sense would be who? 6 DR. DENIC: 7 A. Pathologists. 8 COFFEY, Q.C.: 9 Q. Pathologists, okay, the staff pathologists. 10 DR. DENIC: 11 A. Yeah. 12 COFFEY, Q.C.: 13 Q. When Dr. Khalifa arrived and you got to know 14 him--well, actually, he would have arrived 15 around the time you started your residency, I 16 understand, around that time? 17 DR. DENIC: 18 A. Yeah, that's correct. 19 COFFEY, Q.C.: 20 Q. You developed the understanding that he knew 21 more than the average pathologist or seemed to 22 know more than the average pathologist about 23 immunohistochemistry? 24 DR. DENIC: 25 A. Yeah, that was my understanding, but to which</p>	<p>1 Q. Oh, yes. I had all the others lined up here 2 except that one. Doctor, just again so the 3 Commissioner gets some sense of, we've heard 4 from Dr. Khalifa and Dr. Cook, who was site 5 chief at the time but also a staff pathologist 6 at St. Clare's as to what his memory was about 7 this. You would have been, in February of 8 1998, about a year away from finishing, year 9 and a half? 10 DR. DENIC: 11 A. That's correct. 12 COFFEY, Q.C.: 13 Q. Your residency. A memorandum addressed to all 14 Newfoundland pathologists, as a resident would 15 you have received this? 16 DR. DENIC: 17 A. No. No. 18 COFFEY, Q.C.: 19 Q. No, okay. And when was it, do you recall, the 20 first time you saw this memo? Is it in 21 connection with the--like, the whole - 22 DR. DENIC: 23 A. I mean, it got to be a connection from the 24 Inquiry, really. 25 COFFEY, Q.C.:</p>
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<p>1 extent, I really never challenged that. 2 COFFEY, Q.C.: 3 Q. Okay. Doctor, ER/PR and the IHC approach, 4 we've seen--just a second now, please? Just 5 looking, the exhibit where Dr. Khalifa's memo 6 of February 16th, 1998, anybody know the 7 number off the top of their head? Yes, I'm 8 looking your way, Mr. Simmons. 9 MR. SIMMONS: 10 Q. Sorry, I'm - 11 COFFEY, Q.C.: 12 Q. I'm sorry you were going to say something 13 else. February 16th, 1998, Dr. Khalifa's 14 memo. I have it. Pardon me? 15 REGISTRAR: 16 Q. P-1850. 17 COFFEY, Q.C.: 18 Q. Yeah, it may very well be. 19 REGISTRAR: 20 Q. (Inaudible). 21 COFFEY, Q.C.: 22 Q. Yes, thank you very much, Registrar. 23 THE COMMISSIONER: 24 Q. The registrar comes to our rescue again. 25 COFFEY, Q.C.:</p>	<p>1 Q. It wasn't back in the '90s? 2 DR. DENIC: 3 A. No, no. 4 COFFEY, Q.C.: 5 Q. So back at that time, and this is all being 6 introduced, actually, while you're a resident. 7 Now, I take it as a resident you do services, 8 you rotate so many months on this service and 9 so many months on that service, is that the 10 way - 11 DR. DENIC: 12 A. That's correct. 13 COFFEY, Q.C.: 14 Q. - your residency worked? And which service 15 would have, if it did, expose you to 16 immunohistochemistry, ER/PR? 17 DR. DENIC: 18 A. I mean, general, general service, because the 19 breast pathologist was considered as the 20 general service. 21 COFFEY, Q.C.: 22 Q. Okay. And do you recall when you were doing 23 your general service, was that the whole of 24 your residency or just a particular part of 25 the residency?</p>

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<p>1 DR. DENIC:</p> <p>2 A. Particular--most of the parts you would do the</p> <p>3 general, but you would rotate it through the</p> <p>4 certain subspecialty field, like in a renal</p> <p>5 pathology, cytology, paediatric pathology,</p> <p>6 neuropathology, but the breast wasn't the part</p> <p>7 as a separate rotation.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Doctor, I appreciate this is a decade ago or</p> <p>10 more now, but do you recall what you were</p> <p>11 originally taught in your original exposure to</p> <p>12 ER/PR, IHC, as a resident what were you told?</p> <p>13 DR. DENIC:</p> <p>14 A. What I was told was how to report it.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And do you recall -</p> <p>17 DR. DENIC:</p> <p>18 A. And what to look for, and that's about it.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Do you recall who would have done that?</p> <p>21 DR. DENIC:</p> <p>22 A. But then you see, I wouldn't recall the name</p> <p>23 of the certain pathologist, but lot of breast</p> <p>24 tissue we seen at the Grace Hospital site</p> <p>25 because I think they had a very rich</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. And, Doctor, at that time, in your residency</p> <p>3 days, how many sorts of stains were involved</p> <p>4 in nuclear staining, do you recall whether</p> <p>5 there were -</p> <p>6 DR. DENIC:</p> <p>7 A. I think ER/PR would be the, at that time, it's</p> <p>8 difficult to go back in a time and say when</p> <p>9 did we have a B53 as a stain which is still</p> <p>10 nuclear or KI67, which is again proliferating</p> <p>11 marker would be nuclear, but I think going</p> <p>12 back at the time maybe it's safe to say just</p> <p>13 nuclear staining with, probably would be</p> <p>14 ER/PR. It would have been -</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. If it wasn't the first, you're saying, it was</p> <p>17 one of the first?</p> <p>18 DR. DENIC:</p> <p>19 A. Yeah, that's right.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Okay, if it wasn't the actual first. Okay, so</p> <p>22 you'd look for nuclear staining. And so you</p> <p>23 had to see whether there was nuclear staining</p> <p>24 and look at the controls. Which controls were</p> <p>25 they?</p>
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<p>1 (phonetic) surgical menu for the breast</p> <p>2 surgery and at the St. Clare's Hospital</p> <p>3 somewhat in a General Hospital site. So you</p> <p>4 would rotate to the pathologists and whoever</p> <p>5 would be there -</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. On that particular day?</p> <p>8 DR. DENIC:</p> <p>9 A. And working with you on that particular case</p> <p>10 would tell you.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Okay. Well, we have, I can tell you, look, I-</p> <p>13 -that particular day you'd show up to work,</p> <p>14 pathologist, the staff pathologist you were</p> <p>15 working with that day would say, look, I</p> <p>16 ordered and ER/PR, here are the slides. And</p> <p>17 what would you be--what would you be taught</p> <p>18 about it, I mean, how to go about it?</p> <p>19 DR. DENIC:</p> <p>20 A. We were told at the time you look at the</p> <p>21 staining, that has to be nuclear staining.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Nuclear.</p> <p>24 DR. DENIC:</p> <p>25 A. And you look at your control.</p>	<p>1 DR. DENIC:</p> <p>2 A. Definitely would be external control there. I</p> <p>3 was trying, actually, to go back in my mind to</p> <p>4 see and I know the various issues that arose</p> <p>5 from the presence of internal control and when</p> <p>6 did I know, and I'm trying to recollect would</p> <p>7 it be at a time or would it be when I started</p> <p>8 residency and that been introduced in '97 or</p> <p>9 later on. I knew about internal controls at</p> <p>10 some point and I believe that was before Dr.</p> <p>11 Ejeckam's letter. But for whatever reason we</p> <p>12 didn't rely on internal control as a secondary</p> <p>13 control, and one of the reasons was at the</p> <p>14 time that while it stained, the benign breast</p> <p>15 stain, actually, if it's absence, if it's not</p> <p>16 there, you can still report based on your</p> <p>17 external control and that normal breast tissue</p> <p>18 does go in response to the menstrual cycle so</p> <p>19 you can have a variability and, you know, if</p> <p>20 it's not stained, it not necessarily have to</p> <p>21 stain, as such. But overall even through the</p> <p>22 training, as such, we were rely mostly on</p> <p>23 external control.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And so what were you taught in the context of</p>

<p style="text-align: right;">Page 41</p> <p>1 ER/PR external controls to look for in the 2 external control? 3 DR. DENIC: 4 A. That external control stains what we are 5 looking--that we should be looking, actually, 6 in our test tissue. So if you have external 7 control that the nuclei in external controls 8 are stained on that particular tumour, because 9 external controls are made of tumour that 10 would well express the antigen which would be 11 ER/PR and based on that you would make your 12 assessment or your test tissue. 13 COFFEY, Q.C.: 14 Q. So you were taught in your residency days in 15 St. John's that the external control you would 16 understand to be tumour tissue? Should 17 contain tumour tissue? 18 DR. DENIC: 19 A. That's correct. 20 COFFEY, Q.C.: 21 Q. And the nuclei of the tumour cell should stain 22 and that the control, external control would 23 be a strong expresser, a high expresser and 24 suggesting that a lot of nuclei should stain? 25 DR. DENIC:</p>	<p style="text-align: right;">Page 43</p> <p>1 asked to repeat. 2 COFFEY, Q.C.: 3 Q. Redo it, yeah. 4 DR. DENIC: 5 A. But in terms of the intensity, I don't think 6 that was the emphasis and put as a great 7 factor. 8 COFFEY, Q.C.: 9 Q. Doctor, every time you would reach for an 10 external control, ER and PR external control 11 slide, put it under the microscope, what were 12 you expecting to see? 13 DR. DENIC: 14 A. There is the staining of the tumour cells so 15 staining in the nuclei for the ER/PR. If it's 16 the other immunohistochemical stain, then you 17 know that some of them have a cytoplasmic 18 stains, some of them have membranous stains, 19 so. 20 COFFEY, Q.C.: 21 Q. You expected to see, I take it, a significant 22 number of the cells, tumour cells stained, and 23 did you expect generally to see that they be 24 stained intensely? 25 DR. DENIC:</p>
<p style="text-align: right;">Page 42</p> <p>1 A. That's correct. 2 COFFEY, Q.C.: 3 Q. Should be a lot of nuclei of the external 4 control tumour staining? 5 DR. DENIC: 6 A. That's correct. 7 COFFEY, Q.C.: 8 Q. Doctor, were you taught anything about what 9 you should, or what approach you should take 10 if the staining of the external control tissue 11 was not, there wasn't a lot of it, it was weak 12 or there wasn't very much of it at all, 13 stained weakly, as it were? Were you taught 14 anything about that as to what you should do? 15 And what significance at the time were you 16 taught, if anything? 17 DR. DENIC: 18 A. I don't believe the intensity of the stain did 19 play a role. I believe that checking the 20 control, you have to see that there's a 21 staining, as such. And intensity, I don't 22 recall that intensity played a role. 23 Obviously if the tissue come as a control and 24 does not stain and it's completely wrinkled or 25 washed off, you know, as a control, they were</p>	<p style="text-align: right;">Page 44</p> <p>1 A. But like anything else - 2 COFFEY, Q.C.: 3 Q. No, no. 4 DR. DENIC: 5 A. - you would probably like to be staining with 6 the full intensity to, as I said, to light up 7 as a Christmas tree, but not necessarily that 8 you would return external control if the 9 stains are intermediate staining, let's say, 10 intensity, but they stain a large number of 11 cells. 12 COFFEY, Q.C.: 13 Q. Doctor, in terms then of then the patient's 14 ER/PR slides, what were you taught then about- 15 -that you would look for nuclear staining. 16 And would you go beyond that, was there any 17 calculations you had to do? I'm thinking 18 particular percentages. 19 DR. DENIC: 20 A. You would look at the percentages, I think 21 there were two schools at the time of thoughts 22 and depends where you rotate. One was that 23 you should, you definitely look at the 24 percentages of the cells, you know. 25 COFFEY, Q.C.:</p>

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1 Q. Okay, so both schools agreed you'd do the
 2 calculation of percentages?
 3 DR. DENIC:
 4 A. That's right. And you do that in your head,
 5 you know, you look at certain number of fields
 6 and then you look entire tissue and try to
 7 estimate, really, how many cells are staining,
 8 eyeball.
 9 COFFEY, Q.C.:
 10 Q. Sure.
 11 DR. DENIC:
 12 A. Eyeball.
 13 COFFEY, Q.C.:
 14 Q. Eyeball, yes. Ten percent, 80 percent, you
 15 know, it's kind of whatever you're seeing
 16 there kind of the rough figure. And I take
 17 you're telling me in terms of eyeballing it
 18 that you wouldn't be surprised if you looked
 19 at a particular slide and called it 80 and one
 20 of your colleagues looked at the same slide
 21 and called it 90 and another colleague called
 22 it 70, you wouldn't be surprised by that at
 23 all?
 24 DR. DENIC:
 25 A. No.

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1 COFFEY, Q.C.:
 2 Q. Not at all. At the time would you have been
 3 surprised if you looked at the slide and
 4 called it ten and one of your colleagues
 5 called it 90?
 6 DR. DENIC:
 7 A. Yeah, I would be surprised.
 8 COFFEY, Q.C.:
 9 Q. Yeah, that's the sort of thing we're talking
 10 about here is is that--or somebody called it
 11 100 and you called it zero, that would be -
 12 DR. DENIC:
 13 A. That would be very significant -
 14 COFFEY, Q.C.:
 15 Q. Discrepancy, yeah, significant discrepancy.
 16 So, you're taught to do the calculation,
 17 understanding that it's a rough calculation of
 18 percentages. And you said there were two
 19 schools, so could you go on and tell the
 20 Commissioner about that? Again, you're back
 21 in your residency days at this point.
 22 DR. DENIC:
 23 A. I mean, in residency as much my recollection
 24 goes and while I cannot talk about certain
 25 pathologists and certain institutions, but I

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1 believe that people would do calculation and
 2 some of them would record as positive based on
 3 a criteria that Khalifa, at that time, put in
 4 one of his memos to the pathologists, which is
 5 30 percent. And so if they would see over 30
 6 percent, that they would say this is
 7 positive.; if they think that this is below,
 8 ten or 20, they can put negative. While on
 9 the other side there were pathologists that
 10 were just putting percentages.
 11 COFFEY, Q.C.:
 12 Q. Just -
 13 DR. DENIC:
 14 A. Seeing positive in 20 percent of the cells for
 15 estrogen or negative or zero of progesterone
 16 or something like that, so various
 17 combinations.
 18 COFFEY, Q.C.:
 19 Q. Doctor, and this has to do with reporting, in
 20 terms of how it would be reported. Do you
 21 recall--there were kind of two schools or two
 22 different approaches. Did particular
 23 institutions tend to have a particular
 24 approach?
 25 DR. DENIC:

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1 A. I know that the St. Clare's Mercy Hospital
 2 pathologists were reporting percentages. I
 3 can't claim for Health Sciences and the Grace
 4 Hospital. When I came on staff, I mean, when
 5 Dr. Cook approached me, they knew that they
 6 were reporting percentages, you know, so.
 7 COFFEY, Q.C.:
 8 Q. So you're--the Commissioner, look, there were
 9 two schools. St. Clare's fell into the
 10 percentage school?
 11 DR. DENIC:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. Reporting school. And the Grace and/or the
 15 General -
 16 DR. DENIC:
 17 A. They could kept going either way, depends on
 18 the pathologist, really.
 19 COFFEY, Q.C.:
 20 Q. So not only would it vary, in those places it
 21 might vary from institution to institution,
 22 but within the pathologists within the
 23 institution?
 24 DR. DENIC:
 25 A. That's correct.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And again in your training days were you ever</p> <p>3 aware that it might vary from day to day or</p> <p>4 week to week even with the same pathologist?</p> <p>5 DR. DENIC:</p> <p>6 A. No.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Okay. Your experience was any particular</p> <p>9 pathologist tended to report it in the same</p> <p>10 way?</p> <p>11 DR. DENIC:</p> <p>12 A. That would be my understanding. I mean,</p> <p>13 that's the way that I would do it, probably.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Okay. And, Doctor, as a resident would you</p> <p>16 actually be doing any of this reporting</p> <p>17 yourself?</p> <p>18 DR. DENIC:</p> <p>19 A. As a resident I would be looking into the</p> <p>20 slides and tell my attending, but my attending</p> <p>21 would have reported the slides because we</p> <p>22 didn't have a privileges signing out of cases.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. So, Doctor, you joined the staff of, St.</p> <p>25 Clare's staff in 1999. And I take it you</p>	<p>1 negative and zero, there could be cases where</p> <p>2 you -</p> <p>3 DR. DENIC:</p> <p>4 A. That's correct.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Doctor, I'm going to ask you now -</p> <p>7 THE COMMISSIONER:</p> <p>8 Q. Wait now, before you go to the next point.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. I apologise.</p> <p>11 THE COMMISSIONER:</p> <p>12 Q. So between the 30 percent and the zero -</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Oh, yes. Yeah, did you -</p> <p>15 THE COMMISSIONER:</p> <p>16 Q. How would you report that? If you had, the</p> <p>17 percentage was 15?</p> <p>18 DR. DENIC:</p> <p>19 A. I would say 15, I would tell 5, I would say</p> <p>20 three percent.</p> <p>21 THE COMMISSIONER:</p> <p>22 Q. Okay.</p> <p>23 DR. DENIC:</p> <p>24 A. Any positivity I would put in a percentage.</p> <p>25 THE COMMISSIONER:</p>
<p>1 adopted the reporting approach at St. Clare's?</p> <p>2 DR. DENIC:</p> <p>3 A. That's correct.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Just to use percentages. Did you ever use</p> <p>6 the--would you in reporting use the words</p> <p>7 "positive" or "negative"?</p> <p>8 DR. DENIC:</p> <p>9 A. I used the percentages and I think all the</p> <p>10 time when they are positive, but when they are</p> <p>11 negative, I might have used zero but I would</p> <p>12 have said negative, as such, meaning zero.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Okay, so at times you might--you're saying to</p> <p>15 the Commissioner, look, if you looked through</p> <p>16 all my pathology reports, you might find</p> <p>17 instances where I wrote simply negative?</p> <p>18 DR. DENIC:</p> <p>19 A. That's right.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Meaning zero?</p> <p>22 DR. DENIC:</p> <p>23 A. Meaning zero.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Or I wrote zero and zero means zero or I wrote</p>	<p>1 Q. Okay.</p> <p>2 DR. DENIC:</p> <p>3 A. Without making any distinctions of any</p> <p>4 cutoffs.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Okay, thanks. So cutoffs, except zero, zero</p> <p>7 and everything else, zero is the cutoff?</p> <p>8 DR. DENIC:</p> <p>9 A. That's right.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Anything above zero -</p> <p>12 DR. DENIC:</p> <p>13 A. That's right, if it's one percent, I would say</p> <p>14 one percent.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And you considered that, in a technical sense,</p> <p>17 positive, from a pathologist and clinically</p> <p>18 that was the oncologists' business?</p> <p>19 DR. DENIC:</p> <p>20 A. That's correct, because the thinking of that</p> <p>21 time is that we shouldn't be recommending what</p> <p>22 the oncologist should do and they should</p> <p>23 implement any number that people use in their</p> <p>24 practice and treat the patient based on the</p> <p>25 number received.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. So, Doctor, did you understand then that the</p> <p>3 number, and I appreciate it was an eyeball, to</p> <p>4 use your word, an eyeball approach, that the</p> <p>5 number, though, might have some significance?</p> <p>6 Like, there was a difference between saying</p> <p>7 ten and 90?</p> <p>8 DR. DENIC:</p> <p>9 A. Oh, yes.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Clinically, potentially there was a</p> <p>12 difference, you would have understood that?</p> <p>13 DR. DENIC:</p> <p>14 A. That's correct.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And do you think that generally amongst</p> <p>17 pathologists that you worked with that there</p> <p>18 was a general understanding that there is--</p> <p>19 there could be a difference between saying ten</p> <p>20 and 90? That might have some clinical -</p> <p>21 DR. DENIC:</p> <p>22 A. I think that would be commonsense, you know,</p> <p>23 because you report what you see and you</p> <p>24 wouldn't expect--pathologists pretty much have</p> <p>25 a good eye, you know, spending eight hours</p>	<p>1 DR. DENIC:</p> <p>2 A. Not about the clarification. The occasional</p> <p>3 call that I would have received, I think it</p> <p>4 was at the time one oncologist, in particular,</p> <p>5 who was asking for the ER/PR to be performed</p> <p>6 on the DCIS's.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. On DCIS?</p> <p>9 DR. DENIC:</p> <p>10 A. Yes.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. And I was going to ask you about that, but</p> <p>13 other than that in terms of--here's what I'm</p> <p>14 getting at, if you use the word "negative" in</p> <p>15 a particular case, and you did occasionally</p> <p>16 over the years, you wouldn't use the zero,</p> <p>17 were you ever contacted by an oncologist to</p> <p>18 ask you, you know, does negative mean zero, or</p> <p>19 does negative mean 10 or 5 or 20?</p> <p>20 DR. DENIC:</p> <p>21 A. Not that I can really recall, and I would</p> <p>22 probably recall if that frequent.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. If it ever happened, you're telling the</p> <p>25 Commissioner it would be very rare?</p>
<p>Page 54</p> <p>1 behind the oculars and looking for single</p> <p>2 cells. So, yes, I think that would be</p> <p>3 commonsense, but I wouldn't expect that broad</p> <p>4 range of difference.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. No, no, not only to see it, but in reporting</p> <p>7 it. At least in your own practice, your own</p> <p>8 personal practice, you understood that, look,</p> <p>9 in making this eyeball judgment, it's not</p> <p>10 enough for me to say kind of zero and anything</p> <p>11 else. In your own view, as best you could</p> <p>12 humanly possible, make the best estimate you</p> <p>13 could of the percentage because it could have</p> <p>14 --what the percentage was could have an effect</p> <p>15 in the oncologist's world?</p> <p>16 DR. DENIC:</p> <p>17 A. That's correct.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Doctor, in your own practice, and I'm going on</p> <p>20 beyond your residency days--in your residency</p> <p>21 days, but beyond that, do you ever recall</p> <p>22 getting any--being contacted by oncologists,</p> <p>23 one or more oncologist, about your reports on</p> <p>24 ER/PR and questions about them or</p> <p>25 clarifications?</p>	<p>Page 56</p> <p>1 DR. DENIC:</p> <p>2 A. Yes, that's right.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. How about your colleagues, did you ever call</p> <p>5 them talking about getting contacts or</p> <p>6 communications from oncologists looking for</p> <p>7 clarifications in terms of what was meant by</p> <p>8 negative or what was meant by positive?</p> <p>9 DR. DENIC:</p> <p>10 A. They probably tried to reach the particular</p> <p>11 person, I would say, but again --</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. I gather at St. Clare's, the people you</p> <p>14 generally practice with, they were using</p> <p>15 percentages?</p> <p>16 DR. DENIC:</p> <p>17 A. They were using percentages, that's right.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Did it ever come up anywhere that you know,</p> <p>20 like in tumour board rounds?</p> <p>21 DR. DENIC:</p> <p>22 A. I really can't recall that that was an issue.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Okay.</p> <p>25 DR. DENIC:</p>

<p style="text-align: right;">Page 57</p> <p>1 A. It could have been on individual basis that 2 the oncologist could have called a particular 3 person, but I can't say that I heard in a 4 general discussion. 5 THE COMMISSIONER: 6 Q. Just because it happens to be going through my 7 brain at this point, at the beginning of your 8 career, did you routinely do ER/PR or was that 9 at that stage the call of the surgeon or was 10 it the call of the pathologist, do you 11 remember? 12 COFFEY, Q.C.: 13 Q. Career, which -- 14 THE COMMISSIONER: 15 Q. We're talking about the beginning of his 16 career at St. Clare's. 17 COFFEY, Q.C.: 18 Q. When you first arrived here, who was doing -- 19 DR. DENIC: 20 A. I believe that was a routine order because 21 with the biochemical assay I know that the 22 surgeons were ordering that, but when I came 23 on staff, I believe that that became as a 24 routine for the estrogen progesterone order. 25 THE COMMISSIONER:</p>	<p style="text-align: right;">Page 59</p> <p>1 breast tissue would be sliced, and -- 2 COFFEY, Q.C.: 3 Q. How would you go about that at that time, was 4 there any particular method used? 5 DR. DENIC: 6 A. We refer to that as breadloafing, you know, 7 probably it's not the proper term, you know, 8 but section, you know, one or two centimetres 9 apart, but mostly you try as frequently to cut 10 the tissue to expose to the formalin because 11 the breast tissue is very soft and this is 12 really--if you can relate for cutting a loaf 13 of very fresh bread, you know, it's very 14 difficult sometimes to be equal cuts, you 15 know, it could be one centimetre one cut, the 16 other one could be 1.5 centimetres, you know, 17 but that would be the way the entire tissue is 18 being cut and left in a fixative for 24 hours 19 for the grossing. Then you would assess this 20 tissue the following day, and take samples 21 from the tissue, put it in cassettes. Those 22 cassettes would be given to the assistant, and 23 they would put the cassettes in a tissue 24 processor for overnight. 25 COFFEY, Q.C.:</p>
<p style="text-align: right;">Page 58</p> <p>1 Q. Thank you. 2 COFFEY, Q.C.: 3 Q. Doctor, you would have then when you obtained 4 staff privileges at St. Clare's began to order 5 --because certainly by 1999, it was routine 6 for pathologists doing a breast cancer case to 7 order ER/PR? 8 DR. DENIC: 9 A. I believe so. 10 COFFEY, Q.C.: 11 Q. Certainly by then, based upon what we've seen, 12 it was certainly the routine thing by 1999, or 13 at least it was a--I wouldn't say it was done 14 in every case, but it was certainly, I gather, 15 routine, expected. Doctor, what then would 16 happen? You know, beginning in 1999/2000, you 17 would order ER/PR. Perhaps you could just 18 take us--I'll ask you to back up a bit. At 19 that time, take us through kind of from your 20 perspective, a breast cancer case from your 21 perspective, your involvement? 22 DR. DENIC: 23 A. Breast specimen, on your day of rotation, you 24 would make sure that it came in to the proper 25 container with the formalin, and then the</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. Uh-hm. 2 DR. DENIC: 3 A. And the following day, the technologist would 4 continue with moving the tissue to the various 5 steps from the embedding stations and to the 6 stations of the cutting and staining, and the 7 final product would be your H & E glass slide 8 that would come to your desk. Then you would 9 look at the case, make assessment of the case 10 just to see first whether or not you have a 11 breast cancer, or there's any other lesion. 12 If you have the case of the breast--of the 13 cancer, then you would pick up the block that 14 you would think is more appropriate and send 15 that block for immunohistochemical staining. 16 COFFEY, Q.C.: 17 Q. So what criteria would be--at that time, did 18 you use, '99, 2000, 2001, to pick the 19 appropriate block or most appropriate block? 20 DR. DENIC: 21 A. The most appropriate block and trying to put 22 the region that is better differentiated to 23 tumour. The large number of the tumour 24 represented on the slide so that you can make 25 an evaluation of larger portion of the tumour.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. At that time, would you be looking to have</p> <p>3 internal control tissue there when you first</p> <p>4 started?</p> <p>5 DR. DENIC:</p> <p>6 A. When I first started--I might not have did in</p> <p>7 every single case.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Sure.</p> <p>10 DR. DENIC:</p> <p>11 A. For the single reason that the part of the</p> <p>12 practice that we learn as well from the</p> <p>13 biochemical assay, you want to have as much as</p> <p>14 possible tumour.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Yes.</p> <p>17 DR. DENIC:</p> <p>18 A. Because you're going to try to make that kind</p> <p>19 of assessment. The other thing is, yes, we</p> <p>20 relied a lot on external controls. We know</p> <p>21 that the external control is going to come,</p> <p>22 and sometimes it depends on the breast, you</p> <p>23 wouldn't even have the normal breast tissue</p> <p>24 around for the various reasons that by the way</p> <p>25 of sampling, which you cannot know when you</p>	<p>1 be a high grade tumour that's going to be your</p> <p>2 final probably in your diagnosis, you still</p> <p>3 are looking for a better differentiated</p> <p>4 portions of the tumour that you can submit for</p> <p>5 the estrogen and progesterone receptors, and</p> <p>6 reason being that this portion could be</p> <p>7 positive.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. So at least in the early days of your staff</p> <p>10 days at St. Clare's, are you telling the</p> <p>11 Commissioner that you might not have, in fact,</p> <p>12 been purposely, for example, like you might</p> <p>13 now look for internal control tissue, pay more</p> <p>14 attention to it? Back then you've indicated</p> <p>15 that perhaps that's not so, I wouldn't have.</p> <p>16 DR. DENIC:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. It may or may not have been there at the time?</p> <p>20 DR. DENIC:</p> <p>21 A. Yes, I think it's fair to say that.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Doctor, so you picked the most representative</p> <p>24 block, ordered the ER/PR. I take it that</p> <p>25 would be a requisition form?</p>
<p>Page 62</p> <p>1 sample the tissue whether you're going to have</p> <p>2 internal control. There's always the portion</p> <p>3 of tissue that has a fat tissue outside the</p> <p>4 tumour, and in the fat tissue, that's where</p> <p>5 your internal controls really would be your</p> <p>6 benign tissue situated, but not every breast</p> <p>7 tissue distribution of the normal tissue, it's</p> <p>8 not equally distributed around. So if you</p> <p>9 have that elderly lady, you know, so with the</p> <p>10 atrophy, you're always going to have all fat</p> <p>11 tissue around, so regardless of the sampling,</p> <p>12 but at the time when you take the sample, you</p> <p>13 cannot know that you have benign breast tissue</p> <p>14 inside. You can only assume that you might</p> <p>15 hit those ones.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Sure.</p> <p>18 DR. DENIC:</p> <p>19 A. But we did rely a lot, based on past</p> <p>20 experiences, that you need--as more tumour you</p> <p>21 get, and try to get the better differentiated</p> <p>22 tumour rather than the poorly differentiated</p> <p>23 portions of the tumour because within the</p> <p>24 sections you can see the various grades of the</p> <p>25 tumour. While the tumour can in one section</p>	<p>Page 64</p> <p>1 DR. DENIC:</p> <p>2 A. That's correct.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Filled out, and you'd circle the ER/PR?</p> <p>5 DR. DENIC:</p> <p>6 A. That's correct.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And the next thing you'd see is what? See the</p> <p>9 slide or slides?</p> <p>10 DR. DENIC:</p> <p>11 A. You finish your case at that time before--</p> <p>12 because you know that this is not going to</p> <p>13 happen overnight, and usually take four, five,</p> <p>14 seven days even, to get your slides back. So</p> <p>15 I would conclude my case so that clinicians</p> <p>16 know what they're dealing with, this is</p> <p>17 carcinoma, give them all parameters they've</p> <p>18 been looking for, for the margins, you know,</p> <p>19 the margins involved, so they can act upon and</p> <p>20 schedule the patient for sooner visits rather</p> <p>21 than later, and then I would receive the</p> <p>22 slides and I would report those slides, and</p> <p>23 issue the amended addendums.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Doctor, would you ever have to reorder the</p>

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<p>1 ER/PR test to be done? You know, you get the</p> <p>2 ER/PR slides, and you were unsatisfied with</p> <p>3 the first slides, would you ever have to</p> <p>4 reorder them?</p> <p>5 DR. DENIC:</p> <p>6 A. Yes, I did.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And what sorts of reasons would cause that?</p> <p>9 DR. DENIC:</p> <p>10 A. Most of the time reordering would be that</p> <p>11 tissue is not there, the tissue has been</p> <p>12 washed off. Most of the tumour is not there</p> <p>13 because that portion is washed off and then</p> <p>14 you have the tissue broken into pieces, and</p> <p>15 there would be occasion that you would order</p> <p>16 because it's a lot of brown staining that</p> <p>17 shouldn't be there on the tissue, so</p> <p>18 background would be very hard and overwhelming</p> <p>19 actually for interpretation. So those would</p> <p>20 be less rare than the first mentioned.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Yes, washing off the slide or broken up tissue</p> <p>23 on the slide was the most common problem?</p> <p>24 DR. DENIC:</p> <p>25 A. Yes.</p>	<p>1 DR. DENIC:</p> <p>2 A. That's correct because --</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. What caused --</p> <p>5 DR. DENIC:</p> <p>6 A. If you repeat it, you got it back, so you</p> <p>7 wouldn't think that what they're saying</p> <p>8 wouldn't be the right thing.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Doctor, we've heard references--the</p> <p>11 Commissioner has heard references to tissue</p> <p>12 reprocessing at St. Clare's. The idea of</p> <p>13 reprocessing tissue, in particular, breast</p> <p>14 tissue --</p> <p>15 DR. DENIC:</p> <p>16 A. There's been occasion that the tissue has been</p> <p>17 reprocessed and that came into play when the</p> <p>18 technologist would try to cut the tissue.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. That would be to make the slides?</p> <p>21 DR. DENIC:</p> <p>22 A. To make the slide because the tissue is</p> <p>23 embedded in the paraffin blocks and the next</p> <p>24 station would be cutting the tissue which</p> <p>25 there's a special cutting machine called</p>
Page 66	Page 68
<p>1 COFFEY, Q.C.:</p> <p>2 Q. That's a common problem.</p> <p>3 DR. DENIC:</p> <p>4 A. That's right, that is a common problem.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. What was your understanding as to what caused</p> <p>7 that?</p> <p>8 DR. DENIC:</p> <p>9 A. My understanding at that time, speaking to the</p> <p>10 technologist as well that tissue boils off</p> <p>11 because one--the part of the procedure is</p> <p>12 boiling the tissue, and obviously boiling the</p> <p>13 tissue, you can expect something as such.</p> <p>14 There's a different knowledge that they</p> <p>15 acquire now --</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. I appreciate that.</p> <p>18 DR. DENIC:</p> <p>19 A. Through all of these, the fixation could be</p> <p>20 the problem, the time, but I believe that's</p> <p>21 one of the explanation that I've been given.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Just simply that there's nothing here on the</p> <p>24 slide, why not, and you would be told, well,</p> <p>25 it boiled off?</p>	<p>1 microtome which cuts very fine slivers from</p> <p>2 the surface, cutting the wax and the tissue</p> <p>3 itself embedded in the wax. They will say we</p> <p>4 have a difficulty cutting this because tissue</p> <p>5 has more water inside because obviously the</p> <p>6 fixation didn't harden the tissue as much, but</p> <p>7 also means that the tissue has more water</p> <p>8 inside and probably the processing would have</p> <p>9 longer because the processing is not fixation.</p> <p>10 Processing is moving the tissue from the</p> <p>11 different grades of alcohol in order to</p> <p>12 extract the water because breast tissue is</p> <p>13 fatty tissue and fatty tissue contains water.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Doctor, so your understanding about tissue</p> <p>16 reprocessing--when you first arrived at St.</p> <p>17 Clare's as a staff person in 1999, was tissue</p> <p>18 reprocessing going on then at St. Clare's?</p> <p>19 DR. DENIC:</p> <p>20 A. I really can't tell you.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. You can't recall, but during your time</p> <p>23 certainly at St. Clare's, 1999, 2000, 2001,</p> <p>24 you became aware that tissue reprocessing at</p> <p>25 times occurred there?</p>

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<p>1 DR. DENIC: 2 A. At times, you know. 3 COFFEY, Q.C.: 4 Q. And -- 5 DR. DENIC: 6 A. But not as frequent. 7 COFFEY, Q.C.: 8 Q. And this is the explanation you got. What was 9 your understanding about what the effect of 10 reprocessing was? What was the advantage of 11 reprocessing and were there any disadvantages? 12 DR. DENIC: 13 A. What I understood at that time, the advantage 14 is, as I said, to make tissue easier to cut. 15 COFFEY, Q.C.: 16 Q. Okay. 17 DR. DENIC: 18 A. So that it can give you the full surface of 19 the tissue because if a tissue is still soft 20 in the block, you know, when the blade goes 21 over the surface, you know, the tissue can 22 give so you might not necessarily going to get 23 the full section, you can get the rim of the 24 tumour, but not the entire tumour. So that 25 was my understanding at the time, and again</p>	<p>1 Q. Did you ever make any inquiries about whether 2 there were any potential problems with 3 conducting tissue reprocessing? 4 DR. DENIC: 5 A. Frankly speaking at that time, no. 6 COFFEY, Q.C.: 7 Q. Have you since? 8 DR. DENIC: 9 A. Yes, I did. 10 COFFEY, Q.C.: 11 Q. And when did you do that, and whom did you 12 ask, and what did you learn? 13 DR. DENIC: 14 A. Through all of this preparing for the inquiry 15 and hearing about this stuff being said about 16 the process--I know even Dr. Ejeckam in his 17 memo did mention reprocessing can affect the 18 tissue. I tried to search the literature 19 myself and I couldn't find it really, to which 20 effect the tissue can sustain being 21 reprocessed, because again what the 22 reprocessing is, the tissue goes into the 23 alcohol, already gone to the formalin and to 24 the certain point have been fixed, and now 25 being exposed to alcohol, alcohol is a way</p>
<p>1 since the tissue reprocessing is not fixation 2 really, it's just making the tissue harder. 3 COFFEY, Q.C.: 4 Q. So your understanding is it had no effect on 5 fixation, the tissue reprocessing process 6 itself would not affect fixation one way or 7 the other? 8 DR. DENIC: 9 A. That's right, because it's already fixation 10 been finished at that point, finished on the 11 bench, and there's only one hour that still 12 tissue sits in the chamber with formalin in a 13 processor. If it's a weekend, then it's a 14 longer time it sits in the chamber with 15 formalin because I think it's even six hours 16 or so, and then start moving towards other 17 solutions. 18 COFFEY, Q.C.: 19 Q. Doctor, your understanding was that tissue 20 reprocessing process would have no effect on - 21 at least no negative effect on fixation of the 22 tissue? 23 DR. DENIC: 24 A. That's correct. 25 COFFEY, Q.C.:</p>	<p>1 that can also fix the tissue, it's a different 2 type of fixative as such, but through my 3 search of the literature I really couldn't 4 find just telling this is what is happening. 5 I did go through the manual for the 6 technologists which Sakura published, and I 7 think they even have their journals which is 8 again evidence-based as such. They are 9 recommending the way that you reprocess the 10 tissue, but I even couldn't find there that it 11 said don't reprocess the tissue if you want to 12 do immunohistochemistry. 13 COFFEY, Q.C.: 14 Q. The Sakura method, does that use formalin 15 fixative or alcohol fixative? 16 DR. DENIC: 17 A. I think Sakura is only--they reflect on the 18 practice, not necessarily on Sakura System as 19 such. They also reflect to the practice of 20 tissue reprocessing, so they're giving the 21 advice how to do it, but at the end of the day 22 I couldn't find evidence how it can affect it. 23 The only evidence I found in the article 2007, 24 just a comment that was written--the article 25 was written by Clive Taylor, Goldstine, and</p>

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<p>1 there's--a page of that article there was also 2 discussion about it, and in that article it 3 says that alcohol while it can be used as a 4 fixative, the only affect that it can have 5 could be giving a false positive result, but 6 nothing in terms of reprocessing I could find 7 in the literature. I'm not saying it doesn't 8 exist -- 9 COFFEY, Q.C.: 10 Q. But you, yourself -- 11 DR. DENIC: 12 A. But my efforts didn't bring anything to my 13 satisfaction. 14 COFFEY, Q.C.: 15 Q. Doctor, tissue reprocessing such as was 16 occurring at St. Clare's when you started on 17 staff and continued while you were on the 18 staff there, does that continue now, is there 19 any tissue reprocessing going on there now? 20 DR. DENIC: 21 A. There's no--processor is not any more at St. 22 Clare's. 23 COFFEY, Q.C.: 24 Q. So when did the processor move to the General? 25 DR. DENIC:</p>	<p>1 COFFEY, Q.C.: 2 Q. Within that--it's a small lab, so within that 3 --if it's going on, those people would know? 4 DR. DENIC: 5 A. It's a small group of people that's left 6 behind really. 7 COFFEY, Q.C.: 8 Q. They'd know. Doctor, so you would get then the 9 --we'd gotten to the point where you get the 10 slides back, when you might or might not have 11 to--when you might have to, the causes of 12 asking for a repeat, ER/PR. How frequently 13 would you have to ask for an ER/PR to be 14 repeated? Was it a very unusual incident or 15 not uncommon? 16 DR. DENIC: 17 A. It's difficult to extract on ones mind how 18 frequent ER/PR because we were dealing with 19 other immunochemistry stains and we were 20 asking them to be repeated too. 21 COFFEY, Q.C.: 22 Q. Uh-hm. 23 DR. DENIC: 24 A. So it's difficult for me, I can say, but I 25 would say, yes, it happened, but how</p>
<p>1 A. Moved in 2006. 2 COFFEY, Q.C.: 3 Q. 2006. So up to 2006, up to the time that the 4 processor left St. Clare's, was tissue 5 reprocessing from time to time going on at St. 6 Clare's? 7 DR. DENIC: 8 A. Occasionally. 9 COFFEY, Q.C.: 10 Q. And who would know how frequent it was? Who 11 at St. Clare's at the time would have known 12 how frequent that was? 13 DR. DENIC: 14 A. Technologist. 15 COFFEY, Q.C.: 16 Q. And who was that between, say, for example, 17 from 1999 through 2006, who was that? 18 DR. DENIC: 19 A. I mean, we have Mr. Ken Green and -- 20 COFFEY, Q.C.: 21 Q. So Mr. Green before he went to the General? 22 DR. DENIC: 23 A. Yes, before he went to the General, he was 24 moved at some point, and Catherine Parnell, 25 she came from the Grace Hospital as well.</p>	<p>1 frequently it happened -- 2 COFFEY, Q.C.: 3 Q. I take it, it wasn't something you were doing 4 every third day? 5 DR. DENIC: 6 A. No. 7 COFFEY, Q.C.: 8 Q. That kind of -- 9 DR. DENIC: 10 A. Actually, we haven't been ordering ER/PR every 11 third day because that would be probably once 12 or twice a month that I would be exposed to 13 that. 14 COFFEY, Q.C.: 15 Q. While we're on that topic, I'll ask you that, 16 how often would you order ER/PR tests, as a 17 staff person? I appreciate, again because it 18 might vary from month to month, week to week, 19 but how many ER/PR cases would you do a year? 20 DR. DENIC: 21 A. One to two cases a month. 22 COFFEY, Q.C.: 23 Q. So somewhere between 12 and 24 roughly a year, 24 12 to 25 a year? 25 DR. DENIC:</p>

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1 A. I think one of first years I probably did less
 2 because I started in half of the year. I
 3 would say that year was 12, but I think
 4 maximum that it went about 24 cases a year, so
 5 not frequently.
 6 COFFEY, Q.C.:
 7 Q. And, Doctor, at St. Clare's, were the cases
 8 kind of divided up equally amongst the
 9 pathologists generally?
 10 DR. DENIC:
 11 A. Not really. It depends what falls on your
 12 day.
 13 COFFEY, Q.C.:
 14 Q. Okay.
 15 DR. DENIC:
 16 A. So it might be the day during rotation you
 17 don't receive any breast tissue, or it could
 18 be the day that you receive two, but --
 19 COFFEY, Q.C.:
 20 Q. I appreciate that. In terms of would you--at
 21 the time, would you have thought, like, if I'm
 22 doing about two a month, 24 a year, would you
 23 have expected the pathologist in the office
 24 next to you to probably be doing around the
 25 same number per year throughout the year?

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1 DR. DENIC:
 2 A. That's right. I mean, every single specimen,
 3 not only breast, over the period of time they
 4 equalizes. So at the end of the year, I
 5 think, we would all be in the same ball park.
 6 COFFEY, Q.C.:
 7 Q. Doctor, just while we're on it, you started--
 8 you just mentioned 1999, half way through the
 9 year. You did, in fact, start on July 1,
 10 1999? I take it that's half way through.
 11 DR. DENIC:
 12 A. Yes, that's right.
 13 COFFEY, Q.C.:
 14 Q. Doctor, did you sit or attend--sit on the
 15 Medical Advisory Committee before your
 16 clinical chief days?
 17 DR. DENIC:
 18 A. Before I did as the President of the Medical
 19 Staff for one year.
 20 COFFEY, Q.C.:
 21 Q. And do you recall when that started, which
 22 year was that?
 23 DR. DENIC:
 24 A. Oh, when I was President of the Medical Staff,
 25 that's 2004/2005.

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1 COFFEY, Q.C.:
 2 Q. And, Registrar, if we could bring up, please,
 3 P-2447. Doctor, here there's--these are just
 4 the minutes of the MAC of September 9th, 2003,
 5 and the fourth column--I'm sorry, the third
 6 column, fourth name is yours?
 7 DR. DENIC:
 8 A. Yes, it is, 2003. At that time, I was Vice
 9 President of the--that's correct. I think as
 10 Vice President as well. Dr. Barry Rose, he
 11 was the President at that time.
 12 COFFEY, Q.C.:
 13 Q. Yes.
 14 DR. DENIC:
 15 A. So that's correct, I think at some point I
 16 started attending those ones as well with him.
 17 COFFEY, Q.C.:
 18 Q. And, in fact, when we look, your name appears
 19 on the October 8th minutes and the December
 20 10th minutes as well.
 21 DR. DENIC:
 22 A. Yes, so --
 23 COFFEY, Q.C.:
 24 Q. So the fall of '03?
 25 DR. DENIC:

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1 A. That's correct.
 2 COFFEY, Q.C.:
 3 Q. In your capacity as Vice President?
 4 DR. DENIC:
 5 A. That's right.
 6 COFFEY, Q.C.:
 7 Q. Of that organization, you would have attended
 8 these.
 9 DR. DENIC:
 10 A. That's correct.
 11 COFFEY, Q.C.:
 12 Q. Doctor, at the MAC meetings, do you recall
 13 whether or not at times the topic of reporting
 14 of adverse events or guidelines on disclosure
 15 of adverse events and clinical errors was
 16 discussed, and I will show you, Doctor, this
 17 is the same meeting, page three of this
 18 exhibit, paragraph nine, second bullet,
 19 guidelines on disclosure of adverse events and
 20 clinical errors, "A discussion was held at a
 21 recent clinical chief's meeting on guidelines
 22 on disclosure of adverse events and clinical
 23 errors", and it goes on to talk about that,
 24 "MAC is asked to review documents", and so on.
 25 This does appear a number of times afterward,

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<p>1 references to this. I just wanted to ask you, 2 in 2003, as a member of the MAC, were you 3 exposed to this? 4 DR. DENIC: 5 A. If it was discussed and I was there, 6 obviously, you know, I would have been aware 7 of, you know, and bringing the memories back, 8 I can't recall exactly what was discussed 9 about it and what document produced. 10 COFFEY, Q.C.: 11 Q. Doctor, in relation to ER and PR, we've heard 12 from Dr. Ejeckam about his experience in the 13 fall of 2002 when he first arrived in St. 14 John's, and he was on the General Hospital 15 staff, and then about what happened in early 16 2003. Doctor, do you ever recall in 1999, 17 2000, 2001, 2002, into 2003, before Dr. 18 Ejeckam's memo, do you ever recall any 19 discussion amongst the pathologists in St. 20 John's about ER/PR and any problems? 21 DR. DENIC: 22 A. No. 23 COFFEY, Q.C.: 24 Q. In terms of, you know, there's a problem with 25 the ER/PR slides?</p>	<p>1 DR. DENIC: 2 A. That's correct. 3 COFFEY, Q.C.: 4 Q. And they would be held how often? 5 DR. DENIC: 6 A. They were supposed to be happening on a 7 monthly basis, but I can't be certain that 8 they happened on a monthly basis, so they 9 could be on and off. 10 COFFEY, Q.C.: 11 Q. And they would normally be held where? 12 DR. DENIC: 13 A. At the Health Sciences. 14 COFFEY, Q.C.: 15 Q. And the purpose of those meetings was what? 16 DR. DENIC: 17 A. The purpose of this meeting is to discuss any 18 operational issues that the program overall 19 might have, and give any additional 20 information that you can convey to your staff. 21 COFFEY, Q.C.: 22 Q. Doctor, do you ever recall at any of those 23 meetings back, you know, up to at least April, 24 2003, any concerns being expressed about 25 immunohistochemistry stains?</p>
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<p>1 DR. DENIC: 2 A. No, not in any general discussions as such. 3 COFFEY, Q.C.: 4 Q. Doctor, did you ever attend routinely, for 5 example, in 2002 or 2003, would you be 6 routinely attending meetings of pathologists 7 at the General Hospital, like, kind of group 8 meetings? 9 DR. DENIC: 10 A. They had a meeting that occurred only for the 11 General Hospital pathologists, which I 12 wouldn't attend, but there were like program 13 meetings in place that they were -- 14 COFFEY, Q.C.: 15 Q. I'm sorry, what kind of meetings? 16 DR. DENIC: 17 A. Program meetings. 18 COFFEY, Q.C.: 19 Q. Program meetings, okay. 20 DR. DENIC: 21 A. That I would attend, the entire group of 22 pathologists. 23 COFFEY, Q.C.: 24 Q. And these program meetings would be--all 25 pathologists would be invited?</p>	<p>1 DR. DENIC: 2 A. Not until Ejeckam's letter really, that I can 3 recall. 4 COFFEY, Q.C.: 5 Q. And if we could look, please, at Exhibit P- 6 0113. Doctor, this is--page one is Dr. 7 Ejeckam's memo of April 4, 2003. You would 8 have received this back in April, 2003? 9 DR. DENIC: 10 A. I would have. 11 COFFEY, Q.C.: 12 Q. You did. Doctor, this refers, of course, not 13 only to ER/PR, but a number of antibodies, six 14 other antibodies, and were you aware before 15 April 4th of 2003 of these sort of problems 16 that Dr. Ejeckam is referring to here? 17 DR. DENIC: 18 A. No, not in my practice. 19 COFFEY, Q.C.: 20 Q. And you received this, and what was your 21 reaction to it? 22 DR. DENIC: 23 A. The first thing you relate to your own 24 practice as such, and I couldn't talk about 25 high molecular rate keratin which was utilized</p>

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<p>1 in prostate biopsies because St. Clare's 2 doesn't do prostate. The other ones, the 3 stain used in lymphomas or these are 4 malignancy of the lymph nodes - 5 COFFEY, Q.C.: 6 Q. There are four of those? 7 DR. DENIC: 8 A. There are four of them, CD3, CD5, CD20, CD79A, 9 and CA was the marker, epithelial marker. 10 It's very non-specific, and then we have 11 ER/PR, of course. 12 COFFEY, Q.C.: 13 Q. The ones that concerned you at the time? 14 DR. DENIC: 15 A. It wasn't any of the great concern because he 16 was talking about durability, sensitivity, 17 specificity. To me, while we probably did 18 have some discussions at St. Clare's, 19 unofficial discussions about it, we were 20 taking this as pretty much he would like to 21 not these stains - 22 COFFEY, Q.C.: 23 Q. I'm sorry - 24 DR. DENIC: 25 A. Because the stains were working--I know that</p>	<p>1 in your own practice would at times have 2 ordered them? You were utilizing the lymphoma 3 markers yourself? 4 DR. DENIC: 5 A. Yeah, we were utilizing that, but not just 6 them, as you understand. 7 COFFEY, Q.C.: 8 Q. There were others, and I'll be talking to you 9 more about that, but CEA, you utilized that in 10 your practice? 11 DR. DENIC: 12 A. We did, but occasional. 13 COFFEY, Q.C.: 14 Q. And the ER/PR you utilized in your practice 15 occasionally - 16 DR. DENIC: 17 A. That's right, once or twice - 18 COFFEY, Q.C.: 19 Q. Once or twice a month, probably about 20/25 20 times a year you would have utilized that. A 21 statement "unreliable"--it doesn't say "just 22 are", it says, "have remained", which suggests 23 past tense, gone on for a period of time. 24 "Have remained unreliable, erratic, and 25 unhelpful for diagnostic purposes". In this</p>
<p>1 CD3, CD5, CD79A, and, you know, I didn't have 2 a problem. Every now and then pathologist is 3 going to come and tell you I would like this 4 stain to be stronger, and when we sit behind 5 the microscope and look even today at 6 immunohistochemical stains and you're dealing 7 with the various tumours, sometimes expression 8 is not there to that extent that you would 9 probably be more confident to do. So it was 10 taken as a quality assurance process, that 11 he's going to try to tweak (phonetic) the 12 stains. 13 COFFEY, Q.C.: 14 Q. Now i.e. make them stronger or more intense? 15 DR. DENIC: 16 A. More intense, more crispier, outlined exact 17 number of the cells because some of these 18 lymphoma markers, they stain geographical 19 areas in the lymphoid tissue, you know. So 20 maybe that geographical area was--in one 21 portion was stronger, and as it goes to the 22 periphery becomes a little bit weaker. So 23 that's the way it's perceived. 24 COFFEY, Q.C.: 25 Q. So the four lymphoma markers, you, yourself,</p>	<p>1 context in terms of the other six stains, they 2 are used for diagnostic reasons, aren't they? 3 DR. DENIC: 4 A. Be careful about diagnostic as well. We make 5 a diagnosis on H & E. 6 COFFEY, Q.C.: 7 Q. H & E, yes. 8 DR. DENIC: 9 A. And these are pretty much the sub-classified, 10 the lesion, you know, tumour, whether it's 11 staining, population stain CD20 because 12 they're used for a number of -- 13 COFFEY, Q.C.: 14 Q. They're used for sub-classifications? 15 DR. DENIC: 16 A. Exactly. 17 COFFEY, Q.C.: 18 Q. But the ER and PR are not used for diagnostic 19 or sub-classification, they're used for 20 treatment? 21 DR. DENIC: 22 A. That's right, they're prognostic. 23 COFFEY, Q.C.: 24 Q. They're the two out of the eight? 25 DR. DENIC:</p>

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<p>1 A. That's correct.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Prognostic. Was there discussion, informal</p> <p>4 discussions at St. Clare's about this? This</p> <p>5 originated at the General Hospital, and this</p> <p>6 is where all these slides are being made.</p> <p>7 DR. DENIC:</p> <p>8 A. It might have been, but nobody was alarmed</p> <p>9 about it. I don't remember that anybody was</p> <p>10 alarmed. We knew that Dr. Ejeckam has</p> <p>11 interest in immunohistochemistry and this is a</p> <p>12 part that he took over in order to make the</p> <p>13 stains really better in every sense.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And where had you gotten the understanding</p> <p>16 that Dr. Ejeckam was assuming this role? You</p> <p>17 wouldn't have known Dr. Ejeckam before he came</p> <p>18 in 2002?</p> <p>19 DR. DENIC:</p> <p>20 A. No, I wouldn't, I wouldn't know. I think Dr.</p> <p>21 Cook might have told us about Dr. Ejeckam has</p> <p>22 interest and he's a point person for</p> <p>23 immunohistochemistry, just overseeing it.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And Doctor Khalifa, we understand, left St.</p>	<p>1 alarm raised over this?</p> <p>2 DR. DENIC:</p> <p>3 A. Then.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. At that time, yes.</p> <p>6 DR. DENIC:</p> <p>7 A. That's correct.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Now, Doctor, if you were to receive--you go</p> <p>10 back to your office this afternoon or tomorrow</p> <p>11 and to receive a memo like this now, I take it</p> <p>12 utilizing this sort of language, it would</p> <p>13 raise alarms?</p> <p>14 DR. DENIC:</p> <p>15 A. Oh, certainly would. I mean, I would--I would</p> <p>16 --first I would probably ask for the meaning</p> <p>17 on all of this, and probably look at those</p> <p>18 slides that he referred to and just to see</p> <p>19 what he's referring to as such today.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Yeah. Why, Doctor, whomever you got the memo</p> <p>22 from--if it was, for example, Dr. Ford Elms,</p> <p>23 as the current Director of</p> <p>24 Immunohistochemistry was to write to you now</p> <p>25 and say in respect of any stains and he named</p>
<p>1 John's, I believe, in 1999?</p> <p>2 DR. DENIC:</p> <p>3 A. That's correct.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And Dr. Ejeckam arrived in the fall of 2002.</p> <p>6 In the period between 1999, Dr. Khalifa's</p> <p>7 leaving, and 2002, was there any pathologists</p> <p>8 who you would have associated particularly</p> <p>9 with immunohistochemistry?</p> <p>10 DR. DENIC:</p> <p>11 A. Not to this extent that you have a single</p> <p>12 person with a interest in</p> <p>13 immunohistochemistry, but it was my</p> <p>14 understanding that during that gap when Dr.</p> <p>15 Khalifa left until Dr. Ejeckam took over, that</p> <p>16 that was the role and duties of the site</p> <p>17 chief.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. At the General?</p> <p>20 DR. DENIC:</p> <p>21 A. At the General.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Doctor, you told the Commissioner now looking</p> <p>24 back in April of 2003, this did not alarm us,</p> <p>25 for whatever reason at Clare's, there was no</p>	<p>1 them that they have remained unreliable,</p> <p>2 erratic, and unhelpful for diagnostic</p> <p>3 purposes, you would take it up with Dr. Elms</p> <p>4 right away, wouldn't you?</p> <p>5 DR. DENIC:</p> <p>6 A. I would, and we did in the past with one other</p> <p>7 stain and we stopped the stain.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Yes.</p> <p>10 DR. DENIC:</p> <p>11 A. And we are not doing it until it's validated.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. So was there any discussion, Doctor, at the</p> <p>14 time in 2003 that you recall about--well, what</p> <p>15 about the slides that were produced before</p> <p>16 April 4th? Was there any discussion about the</p> <p>17 slides we got back in the beginning of April,</p> <p>18 March, February, January?</p> <p>19 DR. DENIC:</p> <p>20 A. No, definitely not.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And, Doctor, yourself at the time, did it</p> <p>23 cross your mind to question or think about,</p> <p>24 well, what about my ER/PR slides or my CEA</p> <p>25 slides, my lymphoma slides, that I've been</p>

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<p>1 getting before we got this memo?</p> <p>2 DR. DENIC:</p> <p>3 A. No, Mr. Coffey, the way that it works, you</p> <p>4 received the memo, you have the pathologists</p> <p>5 behind all of this who is handling this kind</p> <p>6 of stuff, and then making decisions based on</p> <p>7 it. You rely that he's going to make any kind</p> <p>8 of judgment call at that time. You go back at</p> <p>9 a time--I mean, this memo comes to your desk,</p> <p>10 you read it, you process the information, you</p> <p>11 move on in your regular day routine because--</p> <p>12 while what we know today and we all look at</p> <p>13 this with a retrospectoscope, as the people</p> <p>14 would say, you know, maybe some other things</p> <p>15 would have been done at that time, but lot of</p> <p>16 these stains that are mentioned here, they are</p> <p>17 using them as part of the batteries of the</p> <p>18 stains, all those lymphomas. So you don't use</p> <p>19 only one, CD3 and CD5, then you use the</p> <p>20 various other methods which are more sensitive</p> <p>21 than this, like floctometry, high molecular</p> <p>22 rate kerotin is one of these things that now</p> <p>23 becomes almost obsolete because we are using</p> <p>24 various better sensitive stains and batteries</p> <p>25 of three or four stains are replacing it. So</p>	<p>1 information and wants to bring it to your</p> <p>2 attention, and there's--the Commissioner has</p> <p>3 been through this a number of times.</p> <p>4 Witnesses have taken her through it. At the</p> <p>5 time, Doctor, how did you view the purpose of</p> <p>6 this memo, what did you understand or take</p> <p>7 from it other than to tell you, look, the</p> <p>8 ER/PR is up and running again?</p> <p>9 DR. DENIC:</p> <p>10 A. I think it's very informative memo. He</p> <p>11 brought back to the attention to all</p> <p>12 pathologists about immunohistochemistry really</p> <p>13 in general, not only about ER/PR, and the</p> <p>14 flagging really, what are the factors that we</p> <p>15 should look into it, what are the factors that</p> <p>16 can affect immunohistochemical stains, and I</p> <p>17 think that was the purpose of this memo.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Ongoing educational --</p> <p>20 DR. DENIC:</p> <p>21 A. Educational, I would say.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. And Doctor, was there discussion at St.</p> <p>24 Clare's, amongst pathologists there, about</p> <p>25 this, do you recall?</p>
<p>1 I believe that at the time nobody was alarmed.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. And you're telling the Commissioner at the</p> <p>4 time it didn't cross your mind--at the time in</p> <p>5 April when I got this, it didn't occur to me</p> <p>6 to think, well, I reported cases in March or</p> <p>7 February or January of 2003, ER/PR results</p> <p>8 that oncologists are relying upon?</p> <p>9 DR. DENIC:</p> <p>10 A. No, it didn't, because between ER and PR</p> <p>11 results, it would be hundreds of different</p> <p>12 cases as such, and you don't keep a track</p> <p>13 really on one or two cases, especially if you</p> <p>14 see them rare.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Doctor, the second page of the exhibit, which</p> <p>17 is the May 2nd, 2003 memorandum from Dr.</p> <p>18 Ejeckam, did you receive a copy of this?</p> <p>19 DR. DENIC:</p> <p>20 A. Yes, I did.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And this is a three page memo and he speaks of</p> <p>23 having rectified the difficulties related to</p> <p>24 the immunostain of ER/PR and will resume</p> <p>25 requests, and he then provides the following</p>	<p>1 DR. DENIC:</p> <p>2 A. Not that I can recall in any formal sense.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. How about in an informal sense, that you can</p> <p>5 recall?</p> <p>6 DR. DENIC:</p> <p>7 A. It could have been. I mean, if we received</p> <p>8 the memos and people said "did you receive Dr.</p> <p>9 Ejeckam's memo?" or something like that.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Was there--looking at it, and you've had, I</p> <p>12 take it, since 2005, looked at this at least</p> <p>13 once, and perhaps more than once since, since</p> <p>14 2005, looking at it now more recently, is</p> <p>15 there anything that strikes you now as "look,</p> <p>16 that was the first time I learned something,"</p> <p>17 particular certain things? And you can take</p> <p>18 your time and look through it. I'll get you</p> <p>19 control of the mouse, if you like. Anything</p> <p>20 in particular in the memo at the time that was</p> <p>21 new to you?</p> <p>22 DR. DENIC:</p> <p>23 A. He did mention the tissue reprocessing as</p> <p>24 such, again emphasizing on that again, this is</p> <p>25 the information that I couldn't substantiate</p>

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1 myself. I'm not saying that it doesn't exist
 2 somewhere, probably the experts, that can
 3 shine the light to that better than I do.
 4 Optimal fixation, he was talking about 18 to
 5 24 hours that most of the tissue actually
 6 being fixed, but some of them might have been
 7 fixed over 24 hours, although we know that
 8 even over 24 hours today, it's not a problem
 9 even if it go over 48 hours. So this is -
 10 COFFEY, Q.C.:
 11 Q. Checking the buffered formalin?
 12 DR. DENIC:
 13 A. Yes, I think that's something that I was not
 14 aware of, about the formalin. This wasn't a
 15 part of our--it was a part of our practice,
 16 because a tissue has to come into a formalin,
 17 and you know the specifics of the formalin as
 18 such, but this is something that really was
 19 technical and left for the technical people to
 20 make sure that the formalin is the formalin
 21 and whatever is in a container is the
 22 formalin.
 23 COFFEY, Q.C.:
 24 Q. And the idea that ER/PR false negative results
 25 increase -

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1 DR. DENIC:
 2 A. Increase in core biopsies, I would say this
 3 was the new information for me, although doing
 4 ER and PR on a core biopsy was extremely rare,
 5 and but it was quite logical, when you think
 6 about it, because core biopsy doesn't
 7 represent a large portion of the tissue, and
 8 that you may go through the portion of the
 9 tissue which contains ER negative clone.
 10 He said to check normal breast acini in a
 11 section, internal controls. This is a second
 12 level control, as he said, and that was
 13 something that I had been taught at that time.
 14 Nuclear staining in normal breast tissue is
 15 heterogeneous and varies with the menstrual
 16 cycle. So he pretty much confirmed what I
 17 knew about it, that it varies, and if it's not
 18 there, that not necessarily means that you
 19 shouldn't rely. He doesn't necessarily say do
 20 not report the case.
 21 COFFEY, Q.C.:
 22 Q. If for example, the -
 23 DR. DENIC:
 24 A. If you don't have internal controls positive.
 25 COFFEY, Q.C.:

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1 Q. If there's internal control tissue, normal
 2 tissue there, and it hasn't stained, but the
 3 tumour has stained, the tumour itself has
 4 stained and the external control has stained
 5 appropriately -
 6 DR. DENIC:
 7 A. Then you would take that as such. But that
 8 you can see that we know that in our practice,
 9 especially in our recent practices as well, we
 10 know that it is a possibility that tumour
 11 stains and the negative control stains. We
 12 also learn through all of this that we have a
 13 certain number of cases that have a positive
 14 internal control on our slides and they still
 15 had converted from zero to Mount Sinai. So
 16 that brings the complexity of internal
 17 controls as a secondary level of controls.
 18 COFFEY, Q.C.:
 19 Q. Having received this memo and read paragraph
 20 three, did it change your practice in any way,
 21 your approach?
 22 DR. DENIC:
 23 A. I think it re-emphasized, that I become more
 24 cognitive about it, I would say yes. But
 25 again, having in mind that there are

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1 variations.
 2 COFFEY, Q.C.:
 3 Q. Sure.
 4 DR. DENIC:
 5 A. And in the practice of the pathologists that
 6 do one or two cases a month, I don't know how
 7 all of this would play out.
 8 COFFEY, Q.C.:
 9 Q. And Doctor, the information in paragraph four,
 10 in terms of most PR tumour, positive tumours,
 11 are also ER positive, ten percent of--he says
 12 at the time, ten percent of PR positive
 13 tumours are ER negative, appreciate this is
 14 being written in April of 2003. I mean, this
 15 sort of information about the relative rarity
 16 or commonness of combinations of
 17 positive/negatives?
 18 DR. DENIC:
 19 A. I think that's additional one, information
 20 that he re-emphasized. I seen those numbers,
 21 I seen the numbers reading through the
 22 literature about it, but just give it to the
 23 scope of the practice of the pathologist again
 24 who see one or two cases a month, ten percent
 25 of the cases, you never know when you look at

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<p>1 a case, that one of the case that you see 2 wouldn't fall in a ten percent. What we 3 anecdotally say about immunohistochemistry and 4 the tumours in general, they don't read the 5 books, and they don't behave in a way that's 6 written, but certainly it is a good 7 information that he put there for that we 8 should be aware of.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Did it change your practice or approach, do 11 you recall? Because we have seen, and there 12 are references when you look at the Mount 13 Sinai retest results, bearing in mind the 14 original results, that there are significant 15 number of ER, originally ER negative PR 16 positive tumours that became ER positive and 17 PR positive, but arithmetically, and you were 18 aware of this, I take it, Doctor, that 19 arithmetically, there are more ER negative PR 20 positive tumours than there should have been?</p> <p>21 DR. DENIC:</p> <p>22 A. If I can elaborate on that, Mr. Coffey? Yes, 23 I'm aware, looking through the database that 24 was compiled by Dr. Mullen, and actually, 25 recently I had more time, because this summer,</p>	<p>1 articles. So what does that mean? That in 2 the let's say 2700 tests that we performed 3 over the years, while we didn't examine all of 4 those, because the other ones had obviously ER 5 and PR positivity or ER at least positivity, 6 the number that was presented falls to two 7 percent on all population of the tests that 8 had been done, and tells you that, in a 9 practice of one of the pathology, because when 10 you see the cases here and there, you might 11 very well have a case which is--ten cases 12 which are ER and PR positive or at least ER 13 positive, and then it would be the case that 14 you have ER negative PR positive. So it's not 15 something that would have been picked up. So 16 based on the calculation, I think even NLCHI 17 did it in their review, this number, based on 18 entire population of the tests which 19 literature does it, looking entire population, 20 is two percent.</p> <p>21 So yes, when we look in this cohort that 22 was taken out, I agree with you. It really 23 sticks out. But in overall group, it blends 24 in and falls within the level of published.</p> <p>25 COFFEY, Q.C.:</p>
<p>Page 102</p> <p>1 for whatever reason, the OR was--certain 2 number OR was closed, so the service at one 3 period of time wasn't that busy, so I went 4 back and just look all of this, and there are 5 a certain number of these cases that show ER 6 negative PR positivity, and I think, through 7 the statistics that have been done through 8 NLCHI, I think this percentage is around eight 9 percent.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. And the Commission will be hearing more about 12 that. But I'm -</p> <p>13 DR. DENIC:</p> <p>14 A. If I can just -</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Sure -</p> <p>17 DR. DENIC:</p> <p>18 A. - finish this off for where I'm going with all 19 of this. This is done on the population, only 20 of the tests that had been reviewed. The 21 statistics that's given in the literature 22 about the percentages of PR negative--PR 23 positive and ER negative is based on the 24 population, an entire cohort of the patient 25 that have been reviewed and published in the</p>	<p>Page 104</p> <p>1 Q. Doctor, really what I'm getting at here is 2 this, is that having received this memo at the 3 time, in 2003, did it affect your approach in 4 individual cases in terms of your--you know, 5 when I look at a slide or slides and I'm 6 calling it in a particular way, ER negative, 7 PR positive, this is a one in ten according to 8 Dr. Ejeckam's memo, this is one in ten 9 situation, just as lobular invasives, if you 10 call those negatives, it's a one in 20 or a 11 one in ten, depending upon which stat you use. 12 The point being, Doctor, is did you apply 13 that, do you think, can you tell the 14 Commissioner, after having received this? Did 15 you change your approach in any manner to 16 that, that you can recall?</p> <p>17 DR. DENIC:</p> <p>18 A. I mean, I would change overall practice in a 19 way. You can still see ER/PR, ER negative and 20 PR positive, but again, then you would again 21 based of what he wrote as well, you would 22 include your external controls. You would 23 probably look your internal controls as well, 24 and put all this in a blend now. So not just 25 based on this statement I would change, but I</p>

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<p>1 would say I would change my practice based of 2 consultations of what Dr. Ejeckam would have 3 written. 4 COFFEY, Q.C.: 5 Q. Doctor, paragraph five refers to the reporting 6 approach. I appreciate what's written here. 7 Did this, in any way, change your reporting 8 approach? 9 DR. DENIC: 10 A. This is something that we've been reporting 11 and I've been reporting percentages, so I 12 would report one percent, five, ten. 13 COFFEY, Q.C.: 14 Q. I take it the answer is no, it didn't change 15 your approach? 16 DR. DENIC: 17 A. It didn't. 18 COFFEY, Q.C.: 19 Q. Didn't affect you, and you made a note of 20 this, paragraph six, this higher staining 21 intensity does not reflect better results and 22 you referred to that earlier. Were you aware 23 of this? 24 DR. DENIC: 25 A. Yes.</p>	<p>1 A. Lobular, and that's what I'm trying now just 2 to let you know. 3 COFFEY, Q.C.: 4 Q. Okay. 5 DR. DENIC: 6 A. I wasn't aware of lobular carcinomas for the 7 reason being the Royal College of Physicians 8 and Surgeons recommended textbook in 9 pathology, which is Rosai Ackerman. The two 10 editions that I know of were one when I 11 started the residency training program, I 12 think it was in '96 edition. There's another 13 one in 2004. They state, based on the source 14 the textbook is referring to, that there's no 15 statistical difference between ductal 16 carcinoma and lobular carcinoma expressing 17 estrogen receptor. But also states that it's 18 known that the mucinous carcinoma expressed 19 more estrogen receptor and one of the 20 carcinoma that we wouldn't expect to express 21 estrogen receptor was the medullary carcinoma. 22 It was really a textbook that I was utilizing 23 a lot and it was my Bible, and when I came out 24 from the residency program, people used to 25 claim that I knew by heart.</p>
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<p>1 COFFEY, Q.C.: 2 Q. Before the memo? 3 DR. DENIC: 4 A. Yes. 5 COFFEY, Q.C.: 6 Q. The ER positive tumours is the way he refers 7 to this here, there are four listed here, and 8 Dr. Ejeckam has told us there was a fifth 9 lobular that he should have included. Were 10 you aware that these particular four types of 11 tumours are generally thought to be ER 12 positive? 13 DR. DENIC: 14 A. I was aware about the mucinous carcinomas and, 15 if I can just touch bases on the positive 16 tumours. 17 COFFEY, Q.C.: 18 Q. So you were aware of one? Just before you go 19 on. 20 DR. DENIC: 21 A. Mucinous. 22 COFFEY, Q.C.: 23 Q. You were aware of, and were you aware yourself 24 of lobular? 25 DR. DENIC:</p>	<p>1 Then, the numbers of the lobular 2 carcinoma, I seen the various numbers and the 3 book of Dr. Tabassoli and it's breast 4 pathology, and she's a well known pathologist. 5 Her book states that positivity rate in 6 lobular carcinomas ranged against--then, based 7 on the statistics presented by the various 8 authors, from 70 to 92. So it's a broad range 9 as such. 10 I didn't know about papillary carcinomas. 11 I knew about low grade ductal carcinoma 12 because lower the grade, you would expect 13 these to stain. 14 COFFEY, Q.C.: 15 Q. And the text you refer to, the second text, 16 you would have seen that when? The second 17 text you just referred to, the one that did 18 refer to lobulars and the range from 70 to 92. 19 DR. DENIC: 20 A. That book is old book as well, you know, so 21 this is the book that we had in our 22 department. I can't tell you what edition it 23 is, but - 24 COFFEY, Q.C.: 25 Q. That goes back to your residency days?</p>

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<p>1 DR. DENIC: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. Okay, yes, so you would have been exposed to 5 the idea that certainly - 6 DR. DENIC: 7 A. That it could go up to 90 percent, but it 8 could be 70 percent. So it still give you the 9 broad range of positivity really, because 30 10 percent of the cases, if you take the lower 11 level. If you take the higher, 92, then you 12 say almost every single case would be 13 positive. 14 COFFEY, Q.C.: 15 Q. And Doctor, so again, in terms of this, at the 16 time, paragraph seven, and I appreciate you 17 already knew about mucinous, but these other 18 three, again did this change your approach? 19 DR. DENIC: 20 A. It gave me extra knowledge, but these are the 21 tumours that you see very rarely really. Even 22 lobular carcinomas are rare, between one to 15 23 percent. It depends again of the stats 24 published in the literature. Mucinous are 25 rare. Ductal carcinoma low grade are not that</p>	<p>1 you knew about or understood about expected 2 positivity rates, relative rarity of negative 3 tumours? Do you ever remember the knowledge 4 that you referred to, you either had or picked 5 up in 2003, causing you then to actually 6 question something? 7 DR. DENIC: 8 A. I can't be certain, you know. It's a lot of 9 things going through our desk, and you know, I 10 really cannot be certain. Maybe I have not. 11 I might have in very rare instances, but most 12 of the time I would not. 13 COFFEY, Q.C.: 14 Q. Doctor, in relation to these two memos, the 15 April 4th and the May 2nd one, have you ever 16 received any memo similar in tone or content 17 to the April 4th memo, in terms of telling you 18 "we're suspending - 19 DR. DENIC: 20 A. No. 21 COFFEY, Q.C.: 22 Q. - testing, unreliable, erratic." So you've 23 been here in St. John's on staff almost a 24 decade now. 25 DR. DENIC:</p>
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<p>1 rare, but some of them we call tubular, what 2 you see on the top. 3 COFFEY, Q.C.: 4 Q. Doctor, paragraph eight, low grade, the 5 contents of this, were you aware of this 6 before April of 2003? 7 DR. DENIC: 8 A. I was aware of that. 9 COFFEY, Q.C.: 10 Q. You were? 11 DR. DENIC: 12 A. Yeah. 13 COFFEY, Q.C.: 14 Q. And so that wouldn't have changed your 15 approach? 16 DR. DENIC: 17 A. No. 18 COFFEY, Q.C.: 19 Q. Doctor, did you ever have occasion, in your 20 practice, to question the result, an ER/PR, 21 what you were seeing on the slide or at least 22 thought you were seeing on the slide and 23 cause, for example, inquiries to be made or 24 the test to be rerun because what you were 25 seeing on the slide did not accord with what</p>	<p>1 A. That's correct. 2 COFFEY, Q.C.: 3 Q. Nine years, and this is the only time in your 4 career that that sort of memo, that you've 5 received one anyway like that, the April 4th 6 one? 7 DR. DENIC: 8 A. No. I mean, not any other memos, except for 9 these, these two. 10 COFFEY, Q.C.: 11 Q. And in terms of the, you know, in terms of the 12 second memo, the May 2nd one, the sort of 13 educative memo, informative memo, have you 14 ever received one like that? And it could be 15 in respect of any sort of--it could be 16 prostate, it could be lung, I don't know, or 17 any other stains. I'm just asking you. 18 DR. DENIC: 19 A. There were certain memos that Dr. Khalifa sent 20 around, but if you will ask me what was in the 21 memo, and I know it was educational, he was 22 informing - 23 COFFEY, Q.C.: 24 Q. So Dr. Khalifa would, in his time, at times 25 send around educative memos.</p>

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<p>1 DR. DENIC: 2 A. Would there be anybody else? 3 COFFEY, Q.C.: 4 Q. That you recall? 5 DR. DENIC: 6 A. I don't recall, Mr. Coffey. 7 COFFEY, Q.C.: 8 Q. So the point I'm making with you, Doctor, is 9 if--I'm not suggesting that you're going to-- 10 you're telling the Commissioner that there 11 were no others, there could have been others? 12 DR. DENIC: 13 A. There could have been others. 14 COFFEY, Q.C.: 15 Q. But it was relatively rare, this sort of 16 educative memo? 17 DR. DENIC: 18 A. Yes, yes, I would say relatively rare. 19 THE COMMISSIONER: 20 Q. Mr. Coffey, it's well past the time to have a 21 break. 22 COFFEY, Q.C.: 23 Q. One final question, if I could, Commissioner, 24 on this? And in terms then of that, Doctor, I 25 take it then that you did not--you don't</p>	<p>1 only assume because knowing Dr. Ejeckam that 2 he would follow this through, and that they 3 would have been validated. 4 COFFEY, Q.C.: 5 Q. And did you ever receive an explanation, seek 6 one or receive one, as to what the problem had 7 been in 2003? 8 DR. DENIC: 9 A. No. 10 COFFEY, Q.C.: 11 Q. Thank you, Commissioner. Break. 12 THE COMMISSIONER: 13 Q. We'll take 15 minutes. 14 (BREAK) 15 THE COMMISSIONER: 16 Q. Please be seated. Mr. Coffey. 17 COFFEY, Q.C.: 18 Q. Thank you. P-0113, please, again. Doctor, 19 the third of Dr. Ejeckam memos is June 19th, 20 2003, addressed to Mr. Gulliver, and it's 21 copied to a number of individuals. You're not 22 listed amongst them. Were you aware of the 23 existence of that June 19th memo? 24 DR. DENIC: 25 A. Of this one, at that time?</p>
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<p>1 recall any real discussion about, for example, 2 the educative memo? It didn't occasion like 3 discussion in any semi-formal way? 4 DR. DENIC: 5 A. This memo in particular? 6 COFFEY, Q.C.: 7 Q. Yes. 8 DR. DENIC: 9 A. Not that I remember. 10 COFFEY, Q.C.: 11 Q. If I could just push it a little bit further, 12 one--a little bit further, Commissioner. The 13 final sentence - 14 THE COMMISSIONER: 15 Q. (inaudible) Mr. Coffey. 16 COFFEY, Q.C.: 17 Q. - "we are working on the remaining antibodies, 18 and hopefully all normal immunostains will 19 resume soon." What happened with the 20 remaining antibodies, do you recall? Because 21 there were six others and what do you recall 22 about what happened with them? 23 DR. DENIC: 24 A. I don't think so that we ever received that 25 they were back online at a time, but I can</p>	<p>1 COFFEY, Q.C.: 2 Q. Yes. 3 DR. DENIC: 4 A. No. 5 COFFEY, Q.C.: 6 Q. Not at that time. When did you first become 7 aware of this yourself? 8 DR. DENIC: 9 A. Became aware, I think it was May 2007 when 10 Premier - 11 COFFEY, Q.C.: 12 Q. Referred to it in the House of Assembly? 13 DR. DENIC: 14 A. - referred to that in the House of Assembly. 15 COFFEY, Q.C.: 16 Q. So Doctor, then in terms of the, kind of the 17 overall approach then to ER/PR, your own 18 experience with it, you've described your 19 training in the late 90s and your 20 introduction, what you did as a staff person 21 beginning in '99. You've indicated that at 22 some point, and probably before Dr. Ejeckam's 23 memo, by the time of Dr. Ejeckam's memo, you 24 were aware of internal controls as a subject 25 matter involving ER/PR. You say not so much</p>

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1 the significance that you would now accord to
 2 them, but the idea of utilizing internal
 3 controls, you were aware of?
 4 DR. DENIC:
 5 A. That's right, not only for the ER/PR, but for
 6 the other antibodies too.
 7 COFFEY, Q.C.:
 8 Q. Sure, and Doctor, because some pathologists
 9 have told the Commissioner that until they got
 10 this memo, they weren't aware of it, but in
 11 your case, you were aware of internal controls
 12 as an approach?
 13 DR. DENIC:
 14 A. As an approach.
 15 COFFEY, Q.C.:
 16 Q. And then you got this memo, saw it as--or
 17 didn't view the first memo, the April 4th, one
 18 with alarm. Didn't raise any alarms. The May
 19 2nd one, it was an educative memo.
 20 DR. DENIC:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. You've told the Commissioner that "some things
 24 were new to me. I integrated them into my
 25 approach."

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1 DR. DENIC:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. And then you continued to do ER/PRs?
 5 DR. DENIC:
 6 A. That's correct.
 7 COFFEY, Q.C.:
 8 Q. And the next time then that ER/PR as a subject
 9 matter was brought to your attention, in terms
 10 of directly as a concern, was when?
 11 DR. DENIC:
 12 A. It was concern when I think that was 2005.
 13 COFFEY, Q.C.:
 14 Q. Okay, and when in 2005?
 15 DR. DENIC:
 16 A. I would say some time in the summer of 2005
 17 that -
 18 COFFEY, Q.C.:
 19 Q. Okay, so this is when it was really the
 20 retesting has started or they were thinking
 21 about it?
 22 DR. DENIC:
 23 A. That's right, the thinking.
 24 COFFEY, Q.C.:
 25 Q. I'll get to that then in a bit, but so in

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1 between then, kind of the only time then
 2 between 1999 and summer of 2005 that ER/PR was
 3 kind of on your radar as a concern, and it
 4 wasn't a big concern at the time, was Dr.
 5 Ejeckam's memos?
 6 DR. DENIC:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. And other than that, you don't recall any
 10 discussion about problems with ER/PR staining
 11 or concerns about any--here's why I'm asking
 12 about that, Doctor. I'll just ask, Exhibit P-
 13 1913? Doctor, this is minutes of the site
 14 chiefs and divisional manager, division of
 15 anatomic pathology meeting, March 31st, 2004,
 16 and you're not in attendance, okay. But you
 17 were, at the time, sort of the person who
 18 filled in for Dr. Cook on occasion at St.
 19 Clare's, okay.
 20 DR. DENIC:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. You had performed--and had been doing that for
 24 a while before this, and on page two, under
 25 new business, paragraph 4.2, there's new

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1 technology. "The immunoperoxidase stainer
 2 appears to be working generally well," and we
 3 understand otherwise that that would be the
 4 Ventana.
 5 DR. DENIC:
 6 A. That's correct.
 7 COFFEY, Q.C.:
 8 Q. And then it says "however, there continues to
 9 be some problems with estrogen and
 10 progesterone receptors." So Doctor, I take it
 11 from what you've told the Commissioner, that
 12 as you have no conscious memory of ever having
 13 that sort of concern about there continuing to
 14 be some problems with estrogen and
 15 progesterone being brought to your attention?
 16 DR. DENIC:
 17 A. No. No, definitely not.
 18 COFFEY, Q.C.:
 19 Q. If we could, and I'll just pick another one,
 20 P-1876? And this is a bit earlier, Doctor, in
 21 your career on staff at St. Clare's, but these
 22 are minutes of a meeting of site chiefs and
 23 divisional managers, division of pathology,
 24 April 25, 2001. There are number of present.
 25 They don't include, of course, yourself at

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1 that time. "Business arising: quality control
 2 of immunoperoxidase staining. Generally, the
 3 immunos appear to be very good. There appears
 4 to be some problems with the estrogen and
 5 progesterone receptors. Positive controls are
 6 checked daily by a pathologist. However,
 7 these need to be documented. Dr. Parai is
 8 going to follow up on that." And they talk
 9 about the heavy utilization of immuno
 10 services. But here, Doctor, the assertion in
 11 the minutes that "there appears to be some
 12 problems with the estrogen and progesterone
 13 receptors," this was again, about two years
 14 into your staff life at St. Clare's, again,
 15 you don't recall this, it ever being brought
 16 to your attention?
 17 DR. DENIC:
 18 A. No.
 19 COFFEY, Q.C.:
 20 Q. Now Doctor, and that's not the only one.
 21 There are one or two others. I'm not going to
 22 take you to them, but during the time you were
 23 on staff. The Commissioner has seen
 24 references to them in the minutes of various
 25 meetings or groups. Doctor, reflecting upon

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1 it now, okay, would it have been helpful, do
 2 you think, if there were concerns about
 3 estrogen and progesterone receptors amongst
 4 the management, this is Doctors Cook, Parai,
 5 Haegert, Mr. Gulliver, and we looked at the
 6 exhibit we just had up there, Registrar,
 7 please, the one just before this? Oh yes,
 8 this one, Doctor, and this is '04. Again,
 9 Doctors Cook, Parai and Robb and Mr. Dyer, oh,
 10 Mr. Dyer is not present here, but Doctors
 11 Cook, Parai and Robb. Would it have been
 12 helpful, do you think, Doctor, as a staff
 13 pathologist, to have been kind of kept
 14 apprised of if there are concerns about
 15 estrogen and progesterone stains, and whatever
 16 they might be? To at least be alerted to it?
 17 DR. DENIC:
 18 A. Well, I cannot comment exactly. They say
 19 there's some problems about it. I can tell
 20 you what's my current practice.
 21 COFFEY, Q.C.:
 22 Q. No, and I -
 23 DR. DENIC:
 24 A. And that may answer some of the questions
 25 because -

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1 COFFEY, Q.C.:
 2 Q. Okay. Well, if there were problems now, what
 3 would be your approach?
 4 DR. DENIC:
 5 A. That's what I'm saying. But if you have a
 6 problem, that's why the director of
 7 immunohistochemistry, he has his report to
 8 give on the joint program and the discipline
 9 meeting. So this would be the venue that all
 10 pathologists been apprised for any kind of
 11 issues that may arise, that would be the venue
 12 that pathologists would express the issue of
 13 any general concerns. So while I cannot
 14 comment on at the time, I can just tell you
 15 what's my practice now, and -
 16 COFFEY, Q.C.:
 17 Q. Your practice as clinical chief and now as
 18 director or chief of the lab?
 19 DR. DENIC:
 20 A. That's right.
 21 COFFEY, Q.C.:
 22 Q. Is to make sure that if there are problems
 23 with immunohistochemistry stains, brought to
 24 your attention by Dr. Elms, the director?
 25 DR. DENIC:

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1 A. That's correct.
 2 COFFEY, Q.C.:
 3 Q. That the staff pathologists are told from time
 4 to time what's going on?
 5 DR. DENIC:
 6 A. That's correct. And Dr. Elms has his standing
 7 on my meetings and he give the report.
 8 THE COMMISSIONER:
 9 Q. Are you referring then to the regular meeting
 10 of pathologists?
 11 DR. DENIC:
 12 A. That's right.
 13 THE COMMISSIONER:
 14 Q. All right.
 15 COFFEY, Q.C.:
 16 Q. And this regular meeting of pathologists, had
 17 that been going on in one form or another all
 18 the way back to 1999?
 19 DR. DENIC:
 20 A. Yes, they were going on from the -
 21 COFFEY, Q.C.:
 22 Q. Over the years?
 23 DR. DENIC:
 24 A. Over the years, that's right.
 25 COFFEY, Q.C.:

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

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1 DR. DENIC:
2 A. That's correct. And was -
3 COFFEY, Q.C.:
4 Q. That continued right up until the time you -
5 DR. DENIC:
6 A. That's right. Whenever he's away, he -
7 COFFEY, Q.C.:
8 Q. You took over for him, okay. Doctor, look,
9 please, at Exhibit P-1918? Again, this is
10 October 7, 2004, it's to all pathologists from
11 Dr. Cook. It's involving estrogen and
12 progesterone receptors. And it says, "I'd
13 like to remind everyone that estrogen and
14 progesterone receptors should be ordered
15 automatically on all excisional biopsies."
16 And he goes on to talk about the other types
17 of specimens. "It has come to my attention
18 that these receptors are not being ordered on
19 a number of cases." Do you remember receiving
20 this memo?
21 DR. DENIC:
22 A. I believe so.
23 COFFEY, Q.C.:
24 Q. And at the time, and I appreciate it's
25 addressed to all pathologists, which would

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1 include yourself?
2 DR. DENIC:
3 A. That's correct.
4 COFFEY, Q.C.:
5 Q. But did you actually think it was directed at
6 yourself, were you ordering ER/PRs before
7 this?
8 DR. DENIC:
9 A. Yes, I was.
10 COFFEY, Q.C.:
11 Q. Okay, so if some staff were not doing it -
12 DR. DENIC:
13 A. Didn't affect my practice. It would be on
14 occasion it had been picked up people finish
15 the case, they report the case, give
16 everything ready and just slip through their
17 mind to order estrogen and progesterone
18 receptor, you know, so the oncologist would
19 call and ask for the results.
20 COFFEY, Q.C.:
21 Q. Doctor, again, before you became interim
22 clinical chief, I'm going to ask you about
23 quality assurance activities as a site--I'm
24 sorry, as a site, as a staff pathologist at
25 the St. Clare's site, what, if any, quality

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

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<p>1 exchanged the knowledge between the 2 clinicians. The rounds, type of quality 3 control rounds we had the surgical rounds. 4 Those rounds would be held once a week where 5 the cases of interest, and not necessarily 6 great difficulties, but those ones, too, would 7 have been shown to the pathologists and asked 8 for their opinion. And we found those very 9 valuable to assure that the good quality of 10 reports are going out, that everybody is on 11 the same page and that we can provide the best 12 care for the patients.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Okay. Anything else, Doctor? The idea of 15 here is an example, okay, like, for example, 16 have somebody randomly check a case that you 17 had done or you check somebody else's case, 18 like in effect an audit of some sort or 19 another -</p> <p>20 DR. DENIC:</p> <p>21 A. Not at that time.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Not at that time. Doctor, do you recall 24 whether it was ever discussed back then, the 25 idea of, between '99, say, and before the</p>	<p>1 Fontaine raised, at the General Hospital site, 2 and it wouldn't--I believe you wouldn't have 3 been in attendance, the idea of a request by 4 Dr. Carter to have her be able to see all the 5 ER/PR cases, the slides? She wouldn't report 6 them, but she wanted just to see them because 7 she's breast pathologist. Were you aware that 8 Dr. Carter, in 2004, was interested in kind of 9 looking at all slides, all ER/PR slides?</p> <p>10 DR. DENIC:</p> <p>11 A. No.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Okay. It wasn't -</p> <p>14 DR. DENIC:</p> <p>15 A. No. That was discussed, obviously, at the 16 General Hospital site.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And within St. Clare's itself, because she was 19 at St. Clare's at that time.</p> <p>20 DR. DENIC:</p> <p>21 A. You know, but I don't recall that was 22 discussed. Dr. Carter was there and her 23 services were anyhow utilized by the 24 pathologists.</p> <p>25 COFFEY, Q.C.:</p>
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<p>1 summer of 2005, the idea of--did it ever come 2 up, that you recall, of having randomized 3 audits, not directed at any one individual, 4 but just to assure everyone that, look, things 5 are being done properly?</p> <p>6 DR. DENIC:</p> <p>7 A. I cannot recollect it. It might have been 8 among Dr. Cook or Dr. Haegert or -</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. In terms--yeah, but I'm asking about in terms 11 that you were aware of?</p> <p>12 DR. DENIC:</p> <p>13 A. That I am aware of -</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. You're not -</p> <p>16 DR. DENIC:</p> <p>17 A. No, that I can recall. Maybe it was 18 mentioned. So many things been mentioned in 19 the last ten years. But not that any great 20 initiatives was put in it, but was it 21 discussed, I believe it might have been, but I 22 don't have a knowledge of it.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Doctor, we've seen a reference to an exhibit, 25 it's September, 2004 minutes where Dr.</p>	<p>1 Q. Yes.</p> <p>2 DR. DENIC:</p> <p>3 A. At the St. Clare's.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And it was put in the note that we've seen, in 6 effect, not that people were consulting her so 7 much as she just wanted to keep her skills 8 sharp and she would want to see, just because 9 of the sheer volume, would have liked to see 10 more ER/PR slides?</p> <p>11 DR. DENIC:</p> <p>12 A. That's right.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. But that expression of interest on her part, 15 you weren't aware of that?</p> <p>16 DR. DENIC:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. All right. Doctor, before I get right down to 20 the ER/PR itself, beginning in 2005, I 21 understand that you were involved in the 22 pathology working group? Because you're 23 certainly referred to in their minutes, and 24 I'll just bring it up here, or have the 25 Registrar do it, P-0922? Doctor, this is who</p>

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1 attendees are, you're listed second there.
 2 DR. DENIC:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. Doctors. Pardon me?
 6 DR. DENIC:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. Yes. And this is the first meeting of the
 10 group referred to under the general
 11 introduction. And the Commissioner again has
 12 seen a number of exhibits related to this
 13 already. But I'm just going to ask you
 14 generally about your involvement, if you could
 15 describe the nature of your involvement on
 16 behalf of pathologists generally in relation
 17 to the issue of compensation, remuneration and
 18 working conditions?
 19 DR. DENIC:
 20 A. I took my position in December, 2004 as
 21 president of Newfoundland Association of
 22 Pathologists. I was elected by the members of
 23 the group. And one of the first initiatives
 24 that I saw in my goals is to bring up the
 25 issue of pathology and the pathologists in

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

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1 COFFEY, Q.C.:
 2 Q. Yeah. So, Doctor, just while we're on this
 3 point, and I want to clarify this for the
 4 Commissioner, people, you used the word
 5 "people" okay, so I take it don't understand
 6 what you do or appreciate what you do and
 7 perhaps without an educational effort, they
 8 couldn't be expected to?
 9 DR. DENIC:
 10 A. That is correct.
 11 COFFEY, Q.C.:
 12 Q. You're off to yourselves. People in this
 13 context would include, I take it, the health
 14 authorities administration?
 15 DR. DENIC:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. Government civil servants, bureaucrats?
 19 DR. DENIC:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. Politicians?
 23 DR. DENIC:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. Members of the public at large?
 2 DR. DENIC:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. Patients?
 6 DR. DENIC:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. Clinicians who are not pathologists?
 10 DR. DENIC:
 11 A. That's correct, too.
 12 COFFEY, Q.C.:
 13 Q. Yeah. It also includes your fellow physicians
 14 but the ones who are not in the lab with you?
 15 DR. DENIC:
 16 A. Exactly.
 17 COFFEY, Q.C.:
 18 Q. Okay. So I just wanted to clarify that. So
 19 when you say "people" this is, you know, this
 20 is not directed at any one group, this is the
 21 world at large, in effect, from your
 22 perspective?
 23 DR. DENIC:
 24 A. That's correct, that's absolutely correct.
 25 COFFEY, Q.C.:

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1 Q. Okay, go ahead, Doctor, I'm sorry. So you--
 2 something had to be done?
 3 DR. DENIC:
 4 A. Something had to be done. So the meeting was
 5 organized by, at that time they called them
 6 Physician Service Liaison Committee. That
 7 was in March. I did prepare a presentation,
 8 and I designated the part of my presentation
 9 to Dr. Fontaine and I brought Dr. Ford Elms
 10 with me, as well as--in case any other
 11 questions and to got involved with this. And
 12 I believe at the time Dr. Elms was sitting on
 13 one of the committees for the salaried
 14 physicians to NLMA, so any kind of input that
 15 he had. So we brought this presentation
 16 forward to the government officials, and at
 17 the time that was Mr. John Abbott, Dr. Ed Hunt
 18 from the government that I remember. And
 19 there were the members, as well, from the NLMA
 20 and Dr. John Haggee and Dr. Susan King and Mr.
 21 Ritter was there. Probably was some more
 22 people there, as well. So we brought that up
 23 as a presentation, but the presentation was
 24 set up really to describe what the pathology
 25 is all about, what are we dealing with and

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1 what is our role and specialty in delivering
 2 the patient care and in particular the cancer
 3 patient care. We were talking about the
 4 workloads. We presented some of the numbers.
 5 And we were talking about the problems about
 6 all of these starting from the, again, people
 7 not knowing, including even under grads did
 8 not know what we do and it is difficult to
 9 attract somebody. But the argument, as well,
 10 is under grads know what the pathologists do,
 11 but they also know how much they are paid for
 12 it. They also know how much effort you have
 13 to put into it in order to get into the
 14 speciality, which is not recognized, on the
 15 top, we don't see patients and maybe that's
 16 not attractive for the physicians because, you
 17 know, if you say medicine, automatically
 18 connected to patients. But we were talking
 19 about overworked pathologists, what does that
 20 mean, what does it mean to be burned out and
 21 how that can affect the patient care when
 22 tired pathologists are reading the slides and
 23 making the diagnosis based on which the
 24 treatment depends. So -
 25 COFFEY, Q.C.:

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1 Q. You made your presentation. And what was the
 2 result, initially?
 3 DR. DENIC:
 4 A. I think it was well taken, it was well taken.
 5 And I did have a few conversations after that
 6 with Mr. Abbott at the time and he was very
 7 receptive, I must say, for whatever we said.
 8 He didn't know what to do because when you say
 9 pathologists, people are thinking these people
 10 are autopsy only and the autopsies was less
 11 than .5 percent of our workload.
 12 COFFEY, Q.C.:
 13 Q. Yeah.
 14 DR. DENIC:
 15 A. So this is something that we almost didn't do.
 16 And -
 17 COFFEY, Q.C.:
 18 Q. So where did it go from there, Doctor? You
 19 got a sympathetic ear and -
 20 DR. DENIC:
 21 A. The government at the time decided they would
 22 like to bring this back to the physician
 23 service, or medical service committee where
 24 the various representatives including the
 25 medical directors across the region would have

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1 been involved in order to give their opinion.
 2 And the pathology working group was struck, as
 3 you can see on the screen.
 4 COFFEY, Q.C.:
 5 Q. That would be in the middle of June?
 6 DR. DENIC:
 7 A. That was in the middle of June.
 8 COFFEY, Q.C.:
 9 Q. 2005.
 10 DR. DENIC:
 11 A. And we produced, actually, we met twice, I
 12 believe so.
 13 COFFEY, Q.C.:
 14 Q. Yeah.
 15 DR. DENIC:
 16 A. And we produced a document.
 17 COFFEY, Q.C.:
 18 Q. The Commissioner has seen that document.
 19 DR. DENIC:
 20 A. Yes, the document that really explain
 21 everything that I said now and the seriousness
 22 of situations and -
 23 COFFEY, Q.C.:
 24 Q. Exhibit P-1286? That's the document that
 25 you're talking about?

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<p>1 DR. DENIC: 2 A. That's the document. 3 COFFEY, Q.C.: 4 Q. Yes. And so, Doctor, the group kind of 5 diligently works away, produces this document. 6 Who did you present it to and what was the 7 reaction? 8 DR. DENIC: 9 A. This document was presented by Dr. Williams, I 10 think he passed back to the government 11 officials obviously around September, as such. 12 And there was no, actually, there was no, any 13 kind of feedback from government based on 14 this. Although the document itself was very 15 strong and showed the support across the 16 board, not only that the pathologist were 17 involved but the medical directors, too. 18 COFFEY, Q.C.: 19 Q. Yeah. There are letters of support attached, 20 appended to this report here. 21 DR. DENIC: 22 A. That's right, there are some letters of 23 support that we received from the Cancer 24 Centre signed by Dr. Laing and Dr. P.K. 25 Ganguly.</p>	<p>1 safely reported by each pathologist. The 2 current workload is not sustainable. 3 Continuing to practice under present 4 circumstances would jeopardize patient care, 5 pathology practice standards." And you go on 6 to explain that you do not expect the decision 7 will have an adverse effect on patient care, 8 however, increased turnaround times could 9 occur over certain specimens. 10 DR. DENIC: 11 A. That's correct. 12 COFFEY, Q.C.: 13 Q. Now, Doctor, I take it then that two questions 14 in this regard. At that point, in December of 15 '05 it existed, I take it, a current shortfall 16 of pathologists at that time? 17 DR. DENIC: 18 A. That's correct. 19 COFFEY, Q.C.: 20 Q. And it was province wide? 21 DR. DENIC: 22 A. That's correct. 23 COFFEY, Q.C.: 24 Q. Had that existed for a period of time? 25 DR. DENIC:</p>
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<p>1 COFFEY, Q.C.: 2 Q. I take it, Doctor, that there was no immediate 3 positive response in the sense of the concerns 4 that were expressed there were not immediately 5 addressed? 6 DR. DENIC: 7 A. That's correct. 8 COFFEY, Q.C.: 9 Q. Okay. If I could, please, Exhibit P-1338? 10 Doctor, this is a letter of--it's from 11 yourself to Mr. Ritter, Dr. Williams and Mr. 12 Abbott, December 7th, 2005, it's called "Joint 13 Statement, Newfoundland Association of 14 Pathologists and Laboratory Directors, Chiefs 15 of Pathology Departments." 16 DR. DENIC: 17 A. That's correct. 18 COFFEY, Q.C.: 19 Q. And it's from yourself in your capacity as 20 president of the Newfoundland Association of 21 Pathologists. You write, "Due to the current 22 shortfall of pathologists in Newfoundland and 23 Labrador and significant increase in workload 24 and demand, it is our decision to restrict the 25 daily maximum number of specimens that can be</p>	<p>1 A. That existed through all of this time. 2 COFFEY, Q.C.: 3 Q. And that's what I'm getting at. So this 4 wasn't something that happened in November of 5 '05, this had gone on for a period of time? 6 DR. DENIC: 7 A. That's correct, that's - 8 COFFEY, Q.C.: 9 Q. First thing, so there was a shortage of 10 pathologists. You report, in fact, in 11 September, in fact, refers to that, I think, 12 and workload issues and so on. 13 DR. DENIC: 14 A. Actually, the report in March. 15 COFFEY, Q.C.: 16 Q. Yes, in the first one, but then the one we 17 just looked at - 18 DR. DENIC: 19 A. That's correct. 20 COFFEY, Q.C.: 21 Q. - then a couple of moments ago. So, Doctor, 22 you're pointing out in your view, at least, 23 the current workload is not sustainable. 24 Doctor, what then happened? I take it you 25 wrote this because there was no, in effect, no</p>

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<p>1 practical reaction to what you had done up to 2 this point in time?</p> <p>3 DR. DENIC: 4 A. That's right.</p> <p>5 COFFEY, Q.C.: 6 Q. Your concerns were not addressed.</p> <p>7 DR. DENIC: 8 A. I mean, we had to--I mean, the purpose is to 9 tell the official how bad situation is, to 10 tell them that without reacting on this we are 11 jeopardizing the patient care, but we don't 12 want to take the blame on it. We are just 13 ringing the bells and just tell you this is 14 definitely going to affect the patient care 15 and while we know that we're going to give 16 everything that this doesn't happen, that yes, 17 we're going diminish the number of cases, but 18 we're going to be still working with the 19 urgent cases. So this was the whole point of 20 this, trying to protect the, firstly, to 21 protect the patients because minimizing your 22 workload you dedicating your time more to the 23 patients slides rather than to rush them 24 through. And secondly, protecting the 25 profession as such, again, having burned out</p>	<p>1 It's a letter of May 16, 2006, Doctor. I 2 think you'll recognize it.</p> <p>3 DR. DENIC: 4 A. I do.</p> <p>5 COFFEY, Q.C.: 6 Q. It's addressed to Mr. Osborne and Mr. 7 Sullivan. And it's from yourself and Mr. 8 Ritter. Signed it right there, last page?</p> <p>9 DR. DENIC: 10 A. That's correct.</p> <p>11 COFFEY, Q.C.: 12 Q. Okay. So what do you recall about how it came 13 to be that this letter was written?</p> <p>14 DR. DENIC: 15 A. I think Dr. Ritter--Dr. Ritter, Mr. Ritter 16 received a call or the information came from 17 the government they're not going to react upon 18 our demands unless the workloads being 19 conducted.</p> <p>20 COFFEY, Q.C.: 21 Q. A workload?</p> <p>22 DR. DENIC: 23 A. For the pathologists.</p> <p>24 COFFEY, Q.C.: 25 Q. So I take it -</p>
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<p>1 pathologists. So that was the purpose of this 2 document. What happened after that is that 3 Dr. Don Cook, Dr. Williams and Mr. Gulliver, 4 they start working on outsourcing the, some of 5 the tissue out.</p> <p>6 COFFEY, Q.C.: 7 Q. Um-hm.</p> <p>8 DR. DENIC: 9 A. And they found the agency in Ottawa is called 10 Gama Dynacare and they struck the deal with 11 them. I wasn't quite certain about the other 12 regions, what they have done, and I was told 13 that they're going to pursue as we agreed, so 14 obviously they did, I think I spoke to Dr. 15 Neil at that time, that they did curb the 16 number of specimens that the pathologists 17 going to see over the course of a day.</p> <p>18 COFFEY, Q.C.: 19 Q. Now, Doctor, what then happened? Again, you 20 know, not necessarily in a minute-by-minute -</p> <p>21 DR. DENIC: 22 A. I mean, nothing didn't happen at that time 23 until again around May of 2006.</p> <p>24 COFFEY, Q.C.: 25 Q. Exhibit P-1372, please? I said 172, 1372.</p>	<p>1 DR. DENIC: 2 A. Workload study.</p> <p>3 COFFEY, Q.C.: 4 Q. And when we bring--and the Commissioner again 5 has seen the contents of this.</p> <p>6 DR. DENIC: 7 A. Okay.</p> <p>8 COFFEY, Q.C.: 9 Q. Already. At least, I don't know if she's had 10 it all read to her, but she's had portions of 11 it read out here. It just begins, "We are 12 writing in follow-up on our recent request 13 that the government implement a new annual 14 bonus commensurate with existing oncology 15 bonus for all pathologists practising in 16 Newfoundland and Labrador." And it goes on 17 from there. And it does refer to the, if we 18 look at page 3, the second--the last paragraph 19 it begins, "We are not opposed to a workload 20 review." So -</p> <p>21 DR. DENIC: 22 A. That is correct.</p> <p>23 COFFEY, Q.C.: 24 Q. Workload review had come up by this point in 25 time. This is addressing it and saying, look,</p>

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

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1 province." And you then conclude the whole of
 2 the letter by saying, "In the best interests
 3 of all concerned we respectfully ask to meet
 4 with you at your earliest convenience so this
 5 crucial matter may be addressed without
 6 further delay." I take it there was -
 7 DR. DENIC:
 8 A. There was a meeting.
 9 COFFEY, Q.C.:
 10 Q. - meeting. And what was the outcome of the
 11 meeting?
 12 DR. DENIC:
 13 A. The outcome of the meeting is that I think
 14 Minister Sullivan, he understood the issue and
 15 but still he wanted the workload review to be
 16 done. He was thinking that this is the only
 17 way that the government can address this
 18 issue.
 19 COFFEY, Q.C.:
 20 Q. And Mr. Sullivan at the time was the Minister
 21 of Finance?
 22 DR. DENIC:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. The workload review was conducted by Dr. -

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1 DR. DENIC:
 2 A. Raymond Maung.
 3 COFFEY, Q.C.:
 4 Q. Maung. And again, the Commissioner has seen
 5 the report as an exhibit here. I take it that
 6 you and your fellow pathologists participated
 7 in that review?
 8 DR. DENIC:
 9 A. That's correct.
 10 COFFEY, Q.C.:
 11 Q. We know if you were interviewed, you
 12 cooperated in that? Dr. Maung's report was
 13 filed, I believe, in early 2007?
 14 DR. DENIC:
 15 A. It was filed in January, 2007.
 16 COFFEY, Q.C.:
 17 Q. 2007. And in summary he recommended what?
 18 DR. DENIC:
 19 A. In summary he recommended the extra staff.
 20 Even what we had on the books wasn't
 21 sufficient for something where tertiary care
 22 institution should go.
 23 COFFEY, Q.C.:
 24 Q. I was going to ask you to expand upon that.
 25 I'm sorry, would you just repeat that, Doctor?

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

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<p>1 A. - they can't get a locum?</p> <p>2 DR. DENIC:</p> <p>3 A. That's right. So the pathology, who's going</p> <p>4 to take on that workload until they find a</p> <p>5 locum position and somebody to, replacement</p> <p>6 for that period of time they are absent.</p> <p>7 Also, the part of having more people is to get</p> <p>8 involved in more of cancer patient treatment,</p> <p>9 you know, secondary reviews of the cases, you</p> <p>10 know, that can come to the Cancer Centre, as</p> <p>11 such. So this is necessary to have a full</p> <p>12 compliment even more in order to properly</p> <p>13 function.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. As a tertiary care --</p> <p>16 DR. DENIC:</p> <p>17 A. As a tertiary care institution.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Institution, in the context of Newfoundland?</p> <p>20 DR. DENIC:</p> <p>21 A. That's correct.</p> <p>22 THE COMMISSIONER:</p> <p>23 Q. So right now--I want to make sure that I</p> <p>24 understand. Your reading of Dr. Maung's</p> <p>25 report was that the number that was there</p>	<p>1 physicians occupying 18 positions, so that we</p> <p>2 had--so in ten years time you had almost 80</p> <p>3 percent of turnover. So this was--that</p> <p>4 eventually we took a term "revolving door"</p> <p>5 from Dr. Banerjee's report, "syndrome", and</p> <p>6 based on the high turnover, you cannot sustain</p> <p>7 the quality of service that we all cherish.</p> <p>8 We want subspecializers because I think that's</p> <p>9 the way to go, and to deliver the best service</p> <p>10 for the patients.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Doctor, he filed this report or made it</p> <p>13 available in January of 2007. What then</p> <p>14 happened?</p> <p>15 DR. DENIC:</p> <p>16 A. In 2007, nothing happened except that I</p> <p>17 started receiving again resignations.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. So by this point in time--I'll be coming back</p> <p>20 to that, but you're clinical chief by this</p> <p>21 time?</p> <p>22 DR. DENIC:</p> <p>23 A. That's right, and in 2006, just to back up a</p> <p>24 little bit, we recruited four residents from</p> <p>25 our program, which we found a nice influx of</p>
<p>Page 154</p> <p>1 would be sufficient for the institutions in</p> <p>2 which they worked, but not take into account</p> <p>3 the role of the institution as a tertiary care</p> <p>4 facility, is that --</p> <p>5 DR. DENIC:</p> <p>6 A. That's correct, that's correct, and he</p> <p>7 designated extra number of pathologists. Even</p> <p>8 for Corner Brook, there's a certain point of</p> <p>9 FTE, given even to Carbonear, and so forth.</p> <p>10 So almost every single centre was, based on</p> <p>11 his report, given additional support.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. So he filed his report. Did he say anything</p> <p>14 about compensation in the report?</p> <p>15 DR. DENIC:</p> <p>16 A. He also said that the compensation in the</p> <p>17 report has to be addressed, that they cannot</p> <p>18 allow just keeping the level of compensation</p> <p>19 as such because they're not going to recruit</p> <p>20 anybody, and subspecializing, he also put in</p> <p>21 his report as the way that we should go, but</p> <p>22 in order to subspecialize, you have to have</p> <p>23 manpower, and how you're going to have</p> <p>24 manpower when you have a 30 percent turnover,</p> <p>25 and in a ten year period of time, 34</p>	<p>Page 156</p> <p>1 fresh blood, the people that we trained, the</p> <p>2 people that we can trust, and by March of</p> <p>3 2007, they were all gone.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. So you had recruited them coming out of--</p> <p>6 finishing up LSATS?</p> <p>7 DR. DENIC:</p> <p>8 A. We invested in them, spend the time -</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. So they had been residents here?</p> <p>11 DR. DENIC:</p> <p>12 A. That's correct.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. They were finished their residency in '06?</p> <p>15 DR. DENIC:</p> <p>16 A. That's correct.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. I'm sorry, go ahead, and by March of '07?</p> <p>19 DR. DENIC:</p> <p>20 A. By March of 2007, all four were gone, and I</p> <p>21 think I even forwarded a letter to Mr. Abbott,</p> <p>22 a copy actually of the letter of one of our</p> <p>23 former residents and who was on our staff who</p> <p>24 left in December of 2006 where he expresses</p> <p>25 his opinion about the entire system. So I did</p>

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1 write the letter to Mr. Abbott at the time. I
 2 might have cc'd it to some other people, and
 3 if you have the exhibit --
 4 COFFEY, Q.C.:
 5 Q. And, Doctor, so the point being that Dr.
 6 Maung's report came in. It was commissioned
 7 by the government, they wanted it. You
 8 participated in it?
 9 DR. DENIC:
 10 A. That's correct.
 11 COFFEY, Q.C.:
 12 Q. As a group. The report came in and there was
 13 no immediate positive response by the
 14 government to it?
 15 DR. DENIC:
 16 A. No.
 17 COFFEY, Q.C.:
 18 Q. In the sense of implementing the
 19 recommendations?
 20 DR. DENIC:
 21 A. No. I get a telephone conversation with Mr.
 22 Abbott sometime in March, and he told me that
 23 the department is supporting it, meaning the
 24 Department of Health.
 25 COFFEY, Q.C.:

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1 Q. Yes, and Mr. Abbott has been here and
 2 described for the Commissioner, in fact, that
 3 that's, in fact, how he felt and that's what
 4 he did?
 5 DR. DENIC:
 6 A. And I believe he was very supportive all
 7 along.
 8 COFFEY, Q.C.:
 9 Q. So what then happened, Doctor?
 10 DR. DENIC:
 11 A. Then I think--in the same period of time, I
 12 think it's March, I delivered another letter.
 13 At that time, Dr. Carter was looking for
 14 position somewhere else, I think in BC. She
 15 approached me asking to be a reference because
 16 she realized as well that she was underrated
 17 here and being a high professional as she was,
 18 so I filed another letter to Mr. Abbott.
 19 COFFEY, Q.C.:
 20 Q. Exhibit P-0201, please. This is March 8th,
 21 2007, Doctor. It's certainly one of the
 22 letters, anyway.
 23 DR. DENIC:
 24 A. Yeah.
 25 COFFEY, Q.C.:

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1 Q. Is this one of the letters you would be
 2 speaking about?
 3 DR. DENIC:
 4 A. I think it is another one after that. There's
 5 another one that--again this is the time that
 6 even Dr. Fontaine was supposed to leave at
 7 that time, and he was--his main interest was
 8 in cytopathology and actively involved and
 9 losing him as well would jeopardize the
 10 cervical screening program.
 11 COFFEY, Q.C.:
 12 Q. Exhibit P-1695, please. A letter of March
 13 27th, 2007, addressed to Mr. Abbott from
 14 yourself, copied to Ross Wiseman, the
 15 Minister, and Dr. Howell, VP Medical.
 16 DR. DENIC:
 17 A. That's right.
 18 COFFEY, Q.C.:
 19 Q. And there's an enclosure letter from Dr. B.
 20 Carter and a job advertisement. I take it
 21 this is the letter to Mr. Abbott?
 22 DR. DENIC:
 23 A. To Mr. Abbott, that's right.
 24 COFFEY, Q.C.:
 25 Q. Referring to the problem you were facing with

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1 Dr. Carter's imminent departure?
 2 DR. DENIC:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. Doctor, in relation to this, I want to ask you
 6 about something you've written here. Mr.
 7 Abbott at the time was the Deputy Minister of
 8 Health, and, in fact, you understood from your
 9 dealings with him that he was supportive of
 10 implementing at least certain aspects of Dr.
 11 Maung's report?
 12 DR. DENIC:
 13 A. Definitely. He was supportive along the way
 14 and all the way really. Whenever we spoke, he
 15 would say here's my favourite pathologist, now
 16 I know, and I tell the other people what you
 17 guys do. So I knew from--that he was very
 18 supportive.
 19 COFFEY, Q.C.:
 20 Q. Doctor, here in the second paragraph you
 21 write, "I cannot stress enough that after all
 22 the fiasco with ER and PR testing and
 23 interpretation, the loss of this pathologist
 24 will greatly jeopardize the future of breast
 25 pathology practice in our province. She is

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<p>1 currently the leader of the newly formed 2 breast subspecialty task group at Eastern 3 Health and an invaluable resource for 4 pathology and oncology practice in 5 Newfoundland and Labrador", and you go on to 6 point out, "She's an acting chair for the 7 breast disease site group for the provincial 8 cancer centre coordinator for educational 9 events for NAP and Eastern Health and the 10 director of a quality management program for 11 pathology, and you conclude by saying, "As 12 stated so many times before, I hope that you 13 and Minister Wiseman bring this serious issue 14 to all those who care for the patients of this 15 province and bring a resolution to pathology 16 problems immediately". So I take it you 17 looking from Mr. Abbott and Mr. Wiseman a 18 resolution of this? 19 DR. DENIC: 20 A. That's correct. 21 COFFEY, Q.C.: 22 Q. And in the context here, you've said to them, 23 "I can't stress enough after all the fiasco 24 with ER and PR testing". Now I take it that 25 that's a somewhat colourful way of referring</p>	<p>1 of there being any positive in the sense of 2 we're going to get this done next week or next 3 month? 4 DR. DENIC: 5 A. No, it was until--it was sometime in May. 6 COFFEY, Q.C.: 7 Q. And we'll get to that in a moment, but one 8 other thing I wanted to ask you about, Doctor, 9 is this, do you know if this problem and a 10 resolution of this was ever raised with the 11 Board of Trustees of Eastern Health around 12 this time? 13 DR. DENIC: 14 A. It might have been by Mr. Tilley. 15 COFFEY, Q.C.: 16 Q. Okay. 17 DR. DENIC: 18 A. I remember that Dr. Howell and Mr. Tilley told 19 me that they're going to bring this issue to 20 the Board. 21 COFFEY, Q.C.: 22 Q. Okay, so you weren't there if it was raised? 23 DR. DENIC: 24 A. No. 25 COFFEY, Q.C.:</p>
<p>1 to the ER/PR problem that was identified in 2 2005 and what happened afterwards? 3 DR. DENIC: 4 A. That's right, yes. 5 COFFEY, Q.C.: 6 Q. And in the context here, "In light of the 7 problems with ER/PR testing and 8 interpretation", you're saying, look, here we 9 are, we're about to lose the only breast 10 pathologist we have? 11 DR. DENIC: 12 A. This is correct. 13 COFFEY, Q.C.: 14 Q. And this is what she's doing for us. Doctor, 15 what was the response to that, initial 16 response to that March 21st letter? 17 DR. DENIC: 18 A. I think he just acknowledged -- 19 COFFEY, Q.C.: 20 Q. Receipt of it. 21 DR. DENIC: 22 A. Received the letter, and I don't remember 23 anything else happened. 24 COFFEY, Q.C.: 25 Q. I take it that you don't have any recollection</p>	<p>1 Q. But you were advised that it was going to be 2 brought to the board? 3 DR. DENIC: 4 A. That's right. 5 COFFEY, Q.C.: 6 Q. With a view--you would have understood that 7 the Board of Trustees or someone from them 8 would try and get something done about it? 9 DR. DENIC: 10 A. That's right, you know. 11 COFFEY, Q.C.: 12 Q. So when is the next you heard about this? 13 DR. DENIC: 14 A. I heard about this on the news. 15 COFFEY, Q.C.: 16 Q. What did you hear? 17 DR. DENIC: 18 A. But that was in May. Frankly speaking, I was 19 very disappointed that I have to find out 20 about this, that oncology's bonus going to be 21 given to the pathologists, it was a news cast 22 from the House of Assembly and I believe that 23 Lorraine Michael was - 24 COFFEY, Q.C.: 25 Q. So you heard about it because of a news cast</p>

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1 involving the procedures in the House of
 2 Assembly?
 3 DR. DENIC:
 4 A. News cast, but I believe I was the last one to
 5 find out officially.
 6 COFFEY, Q.C.:
 7 Q. Doctor, while I'm on the topic, I'll ask you
 8 this. Doctor, so the oncology--payment of
 9 what's known or referred to as the oncology
 10 bonus -
 11 DR. DENIC:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. - was indicated in May of 2007, that
 15 pathologists in this province would be
 16 receiving that?
 17 DR. DENIC:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. In terms of the matter of workload and
 21 increasing the number of positions,
 22 particularly at the tertiary care institute
 23 that Dr. Maung referred to, has any--has that
 24 been addressed at all?
 25 DR. DENIC:

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1 A. No. That hasn't been addressed. I was told
 2 in some of the conversations with Dr. Cathi
 3 Bradbury, as well, let's first fill these
 4 positions and then we're going to look after
 5 at the additional ones.
 6 COFFEY, Q.C.:
 7 Q. Okay, fill the current ones?
 8 DR. DENIC:
 9 A. Yes, fill the current ones and then we're
 10 going to see what we're going to do about it,
 11 but it's not that were given upfront.
 12 COFFEY, Q.C.:
 13 Q. And Doctor, again, the Commissioner has heard
 14 some evidence concerning announcements of
 15 improved compensation since May of 2007, since
 16 that announcement about the oncology bonus,
 17 improved compensation for pathologists in
 18 Newfoundland and Labrador. What can you tell
 19 us about your knowledge about that?
 20 DR. DENIC:
 21 A. This new compensation, as you refer to, again
 22 that came into the light during the tremendous
 23 strain that pathology was still under and in
 24 light of new resignations. Dr. Carter, again,
 25 submitted her resignation and this time was

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1 quite firm resignation and without any
 2 possibility of retraction.
 3 COFFEY, Q.C.:
 4 Q. In fact, she has since gone.
 5 DR. DENIC:
 6 A. And since then she's gone, and she's gone
 7 since June. That obviously provoked a lot of
 8 media attention because of the ER/PR and I
 9 think even I had an interview at that time.
 10 Then there was another impending resignation
 11 from Dr. Fontaine that he was my divisional
 12 chief of cytopathology and in my agreement
 13 with him, I gave him a full responsibility and
 14 a full-time job down there in cytopathology so
 15 that he can dedicate his knowledge and efforts
 16 in cervical screening and cytology at all. He
 17 was very actively involved in provincial
 18 cervical screening program. So losing two
 19 people of this calibre, I think it was very
 20 tough for me, because I found myself
 21 responsible for delivering the service without
 22 people.
 23 COFFEY, Q.C.:
 24 Q. Without the bodies to do it.
 25 DR. DENIC:

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1 A. And I think that's where the media attention
 2 came into play.
 3 COFFEY, Q.C.:
 4 Q. So Doctor, and again, there has been reference
 5 to, the Commissioner has heard evidence, in a
 6 general way, about what happened in terms of
 7 the announcement of the enhanced compensation
 8 for pathologists. Was this something, Doctor,
 9 I mean, were you asked for your input into
 10 that or was this something you were just told,
 11 finally, "look, this is what we're going to
 12 do, we, the government, are going to do."
 13 DR. DENIC:
 14 A. We had input in that. I started, again,
 15 interaction with government officials,
 16 especially the Minister Wiseman, and I met him
 17 in a few occasions as well, that we discussed
 18 various issues. On one occasion that we met,
 19 we discussed the issue of Dr. Carter leaving,
 20 and what we are going to do about it. On one
 21 occasion, we discussed the issue how we
 22 immediately going to resolve this issue, and
 23 there was a third instance as well that I met
 24 with Minister Wiseman as well, discussing on
 25 all of this, asking for resolution. NLMA was

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1 also involved.
 2 And the way I saw that this had been
 3 resolved is to compare our self with Ontario,
 4 because all the losses were to Ontario, most
 5 of them, and some of them to Alberta. So we
 6 were not competing any more with PEI, New
 7 Brunswick and everything else. And the only
 8 resolution that I thought at that time, to
 9 compare our package with the package with
 10 Ontario, which was already well written and
 11 implemented as such. Even then, before all of
 12 this is done, when we were losing our
 13 pathologists, they would be making over
 14 \$100,000 more, at least, to Ontario.
 15 So being foreign medical grads, which
 16 most of the pathology residents are, including
 17 myself, having no ties to Newfoundland,
 18 obviously staying here for weather and the
 19 whales and the puffins wouldn't be so much
 20 attraction, so they would be leaving the
 21 province, because there are no ties. There's
 22 nothing to keep them, and we were all starting
 23 our second life at a later age. So in order
 24 to provide the basic necessities for the
 25 families as well. When I started, I was

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1 already 40. When I started back in
 2 Yugoslavia, I was 23. It's quite a huge
 3 difference. So these people would leave.
 4 COFFEY, Q.C.:
 5 Q. So you were telling Mr. Wiseman and his
 6 officials, "look, if we're going to get these
 7 people to stay," or at least perhaps convince
 8 them to stay, "you have to match Ontario,
 9 Alberta, those sorts of numbers"?
 10 DR. DENIC:
 11 A. That's right.
 12 COFFEY, Q.C.:
 13 Q. And packages, and I take it then that what
 14 then happened finally?
 15 DR. DENIC:
 16 A. Finally, we were delivered--we submitted our
 17 requests. Among the requests were that
 18 Ontario package should be implemented. There
 19 was also included a request for the CME
 20 activities. Before, we had a one-week of CME
 21 activities guaranteed with \$2,000 given for us
 22 for the CME activities, which are quite
 23 insufficient.
 24 COFFEY, Q.C.:
 25 Q. That had been long--that had been all the time

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1 you'd been on staff?
 2 DR. DENIC:
 3 A. That had been all the time. So we were asking
 4 for two weeks and a \$5,000 increase. But we
 5 were also asking for additional money to be
 6 given to the clinical chief for the various
 7 educational activities that I can organize in
 8 the department and the other clinical chiefs
 9 actually in the other regions. We were also
 10 asking for additional package equal to 18
 11 months of fellowship training for the
 12 pathologists because we have even now new
 13 residents that are willing to go and do
 14 fellowship trainings of six months to a year.
 15 COFFEY, Q.C.:
 16 Q. That's after their basic residency?
 17 DR. DENIC:
 18 A. After residency, because a fellowship
 19 training, you want to go on fellowship
 20 training in the subspecialty of the breast,
 21 then you go somewhere else. If you want to go
 22 in prostate biopsies, you go somewhere else,
 23 or genitourinary subspecialty training. That
 24 we can utilize that budget, that we can send
 25 them away and bring them back, and they should

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1 be obliged to give at least two or three years
 2 of return of service.
 3 COFFEY, Q.C.:
 4 Q. So that's what you're looking for?
 5 DR. DENIC:
 6 A. That's what we were looking for, and
 7 eventually, we received the package in the
 8 mail, really, that did reflect some of this
 9 stuff. So we were given the remuneration
 10 level as of Ontario. We were given CME
 11 activity for two weeks and \$5,000 which was a
 12 part--all of this is a part of that package,
 13 the money figure that you've seen. We were
 14 given \$21,000 for educational activities, only
 15 it was given to Eastern Health. It wasn't
 16 given for any other regions, which I already
 17 utilized a portion of it bringing one of the
 18 expert for the workshop in June. Dr. Srigley
 19 was just talking about prostate biopsies. We
 20 were not given any additional money for the
 21 fellowship trainings, because we were talking
 22 to the government, we need to subspecialize.
 23 We need to have the people. We're going to
 24 send them away, they come back and bring it,
 25 and build the group around these people. You

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1 don't necessarily have to send everybody out.
 2 So this hasn't been done yet. So this package
 3 was delivered individually.
 4 COFFEY, Q.C.:
 5 Q. To each pathologist?
 6 DR. DENIC:
 7 A. To each pathologist, and -
 8 COFFEY, Q.C.:
 9 Q. When was that, Doctor?
 10 DR. DENIC:
 11 A. I believe that's May sometime.
 12 COFFEY, Q.C.:
 13 Q. Of 2008?
 14 DR. DENIC:
 15 A. Yes, of 2008.
 16 COFFEY, Q.C.:
 17 Q. Doctor, again, your sense of the effect on
 18 morale of that package has been what?
 19 DR. DENIC:
 20 A. It was well taken. You can say about it,
 21 everybody was pleased from the staff, but it
 22 was like a peers victory, as you know what I
 23 refer. We won, but in all these years, we
 24 were beaten down to the ground. At the end,
 25 when you receive it, you know, yes, you

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1 appreciate receiving it, and we are thankful
 2 for that, no doubt about that. But it just,
 3 you know, take time to build up all of this
 4 back to the normal.
 5 COFFEY, Q.C.:
 6 Q. Doctor, if we could then--I'm going to take
 7 the Doctor up on where they are right now with
 8 that, just after lunch, Commissioner, if I
 9 could?
 10 THE COMMISSIONER:
 11 Q. All right then, we'll meet again at 2:15.
 12 COFFEY, Q.C.:
 13 Q. Thank you, Commissioner.
 14 (LUNCH BREAK)
 15 THE COMMISSIONER:
 16 Q. Mr. Coffey.
 17 COFFEY, Q.C.:
 18 Q. Thank you, Commissioner. Dr. Denic, just
 19 before we broke for lunch, you were telling
 20 the Commissioner about the developments in
 21 relation to compensation for pathologists.
 22 DR. DENIC:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. And I take it then that each of the

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1 pathologists received this offer and you've
 2 described, you know, your understanding of
 3 their--certainly your own, and the reactions
 4 overall to it. What has the--what's the
 5 current situation, in terms of, from your
 6 perspective, in terms of recruitment, the
 7 effect, if any, it has had yet, at least up to
 8 date on recruitment and you anticipate it
 9 might have? Because I take it, as the chief,
 10 you are responsible for recruitment?
 11 DR. DENIC:
 12 A. That's correct. All application would come,
 13 or to Dr. John Guy, who is the medical
 14 director or would come to me, but we would
 15 exchange all applications and move the process
 16 forward. So with the recruitment and
 17 retentions since this occurred, that we were
 18 given a better package, we substantially
 19 increased the number of applicants applying
 20 for these positions, and I think that the
 21 current status of those that applied, I would
 22 say in the range of over 20 at this point of
 23 time.
 24 COFFEY, Q.C.:
 25 Q. For how many positions right now?

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1 DR. DENIC:
 2 A. As of September, I'm going to be five
 3 positions short for the adult pathology
 4 service.
 5 COFFEY, Q.C.:
 6 Q. For the what?
 7 DR. DENIC:
 8 A. Adult pathology service.
 9 COFFEY, Q.C.:
 10 Q. Yes.
 11 DR. DENIC:
 12 A. Because why it is to the adult pathology
 13 service, which always been and has been
 14 actually short, and then we have one
 15 neuropathology and one pediatric pathologist,
 16 which is a part of the Child and Women's
 17 Health Program. So five positions short out
 18 of 17, and unfortunately, I received another
 19 resignation of one of our newcomers. As you
 20 remember, there were two pathologists that
 21 were coming as of summer of this year. One of
 22 them did a fellowship in molecular markers in
 23 UK, and another pathologist, she came from the
 24 States and she had a fellowship in
 25 hematopathology. So this pathologist is

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1 leaving as end of November, the reason being
 2 family reasons in particular, and nothing
 3 else. She has a family in Montreal and while
 4 she was applying here, she applied in Montreal
 5 and so she first received the job application
 6 for Newfoundland, but since the family is
 7 still in Montreal, she is going back for
 8 family reasons, up to Montreal, so just as
 9 part of explanation. Somebody may ask why she
 10 is leaving so soon.
 11 COFFEY, Q.C.:
 12 Q. That's for personal reasons.
 13 DR. DENIC:
 14 A. That's right.
 15 COFFEY, Q.C.:
 16 Q. And Doctor, in terms of you say you are now
 17 five short?
 18 DR. DENIC:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. And the person that's relocating to Montreal
 22 would be the sixth?
 23 DR. DENIC:
 24 A. As of November.
 25 COFFEY, Q.C.:

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1 Q. As of November, and you have currently
 2 approximately 20 applicants?
 3 DR. DENIC:
 4 A. 20 what?
 5 COFFEY, Q.C.:
 6 Q. 20 applicants.
 7 DR. DENIC:
 8 A. Oh yes, I have 20 applicants, that's correct.
 9 COFFEY, Q.C.:
 10 Q. Doctor, can you tell us, please -
 11 THE COMMISSIONER:
 12 Q. Excuse me, Dr. Denic, this morning when you
 13 were talking, I believe, about the report of
 14 Dr. Maung -
 15 DR. DENIC:
 16 A. That's correct.
 17 THE COMMISSIONER:
 18 Q. - you were talking about the number of
 19 positions and his recommendation that there
 20 certain be an augmentation in the number of
 21 positions because of the fact that you were
 22 working in a tertiary care institution.
 23 DR. DENIC:
 24 A. That's correct.
 25 THE COMMISSIONER:

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1 Q. So when you talk about the 17, that is not
 2 including the two extra?
 3 DR. DENIC:
 4 A. That is correct, because these two positions
 5 have never been given officially to us.
 6 THE COMMISSIONER:
 7 Q. Okay.
 8 DR. DENIC:
 9 A. We were told let's first fill up all the
 10 positions, then we're going to talk about it.
 11 COFFEY, Q.C.:
 12 Q. And the 17 are at St. Clare's, the Grace -
 13 DR. DENIC:
 14 A. No Grace.
 15 COFFEY, Q.C.:
 16 Q. St. Clare's, the General, Carbonear and
 17 Clarenville?
 18 DR. DENIC:
 19 A. No, I'm just talking about St. John's.
 20 COFFEY, Q.C.:
 21 Q. Oh, St. John's, so -
 22 DR. DENIC:
 23 A. Because Carbonear and Clarenville, they have
 24 their positions filled. They have two
 25 positions assigned to Clarenville, and they

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1 have two pathologists, and one position for
 2 Carbonear and they have one. This is just for
 3 the St. John's.
 4 COFFEY, Q.C.:
 5 Q. So 17 currently, the approved positions in St.
 6 John's, there are 17, and in Eastern Health,
 7 there are 20, which is the other--total, 17
 8 plus -
 9 DR. DENIC:
 10 A. When Department of Health counts and when we
 11 count the pathology service, we count also the
 12 neuropathologist and pediatric pathologist as
 13 well.
 14 COFFEY, Q.C.:
 15 Q. Okay.
 16 DR. DENIC:
 17 A. But they don't provide adult pathology
 18 service, which is most vulnerable. While
 19 they're still vulnerable because they are just
 20 single practitioners as such, you know, so
 21 overall it would be 21 positions for Eastern
 22 Health, but 17 adult serving pathologists for
 23 the adult pathology for St. John's, plus
 24 neuropathologist, plus pediatric pathologist
 25 for St. John's, plus two for Clarenville, plus

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<p>1 one for Carbonear.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. 17, 19.</p> <p>4 DR. DENIC:</p> <p>5 A. It's 21.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. 21, actually, I believe that's 22.</p> <p>8 THE COMMISSIONER:</p> <p>9 Q. 22?</p> <p>10 DR. DENIC:</p> <p>11 A. Oh, there are 22.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. 22, okay, so it's 17 plus the two -</p> <p>14 DR. DENIC:</p> <p>15 A. 17 plus two, 19 -</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Plus two.</p> <p>18 DR. DENIC:</p> <p>19 A. That's right. That's correct.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Okay. Doctor, can you tell us please then, in</p> <p>22 relation to breast pathology, so you've told</p> <p>23 us already Dr. Carter has left, and I take it</p> <p>24 she was the only breast pathologist here for--</p> <p>25 while she was here, she was the only one?</p>	<p>1 the rotation through the breast pathology, and</p> <p>2 he also received additional training through</p> <p>3 the workshop before he came here in breast</p> <p>4 pathology in London, UK. His track record in</p> <p>5 regards to breast research and interest is</p> <p>6 very long and of high quality. He spent even</p> <p>7 some times in BC Cancer Centre working with</p> <p>8 some of the people who are well known in</p> <p>9 breast pathology and immunohistochemistry,</p> <p>10 such as Dr. Gilks, Blake Gilks. So he has a</p> <p>11 relationship with the BC Cancer Centre. So</p> <p>12 putting all of this in perspective, I think I</p> <p>13 have a good person to work with and the person</p> <p>14 who can provide the quality of service.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Is he in St. John's right now?</p> <p>17 DR. DENIC:</p> <p>18 A. He is in St. John's and he's currently</p> <p>19 practising.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And where is he located?</p> <p>22 DR. DENIC:</p> <p>23 A. He's located at St. Clare's Mercy Hospital.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Doctor, in relation to then breast pathology</p>
<p>Page 182</p> <p>1 DR. DENIC:</p> <p>2 A. That's correct.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. In the sense of breast pathologists, in the</p> <p>5 sense of, you know, was fellowship trained in</p> <p>6 that regard. What's the situation in relation</p> <p>7 to that now?</p> <p>8 DR. DENIC:</p> <p>9 A. As of July of this year, our former resident,</p> <p>10 Dr. Nick Makretsov, he finished his fellowship</p> <p>11 in molecular biology of the breast working on</p> <p>12 the biological markers, which include ER/PR</p> <p>13 and HER2/neu of the breast, in United Kingdom,</p> <p>14 Cambridge, where he spent a full year. He has</p> <p>15 a great interest in the breast pathology. He</p> <p>16 is a Royal College of Physicians and Surgeons</p> <p>17 of Canada certified, but he is also certified</p> <p>18 by the European Board of Pathology, and he got</p> <p>19 certified while he was there during fellowship</p> <p>20 training. The part of his training in here,</p> <p>21 while he was a resident, although he was a</p> <p>22 fully trained pathologist in his own country</p> <p>23 and came as such, he received some of the</p> <p>24 training from Dr. Beverley Carter as a part of</p> <p>25 newly established concordment (phonetic) of</p>	<p>Page 184</p> <p>1 service, what are your plans right now, in</p> <p>2 relation to that?</p> <p>3 DR. DENIC:</p> <p>4 A. Let me just back up where we were when Dr.</p> <p>5 Carter left. Obviously there was a gap in the</p> <p>6 service, and at that time, I was looking to</p> <p>7 out source certain number of breast tissue to</p> <p>8 Sunnybrook Hospital. Not all breast tissue,</p> <p>9 but the tissue that could give a problems to</p> <p>10 the general pathologists, such as needle</p> <p>11 localization biopsies and needle core biopsies</p> <p>12 of the breast. So we were working on creation</p> <p>13 of the contract with Sunnybrook, but in all of</p> <p>14 this period of time, we never managed actually</p> <p>15 to complete it because it was going between</p> <p>16 the lawyers, hospital lawyer, Sunnybrook</p> <p>17 lawyers and actually, that came to effect when</p> <p>18 Dr. Makretsov started to work. But after</p> <p>19 that, we didn't need it.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Okay.</p> <p>22 DR. DENIC:</p> <p>23 A. During that gap, I was reporting myself all</p> <p>24 the needle localization biopsies and core</p> <p>25 biopsies of the breast. We were sending still</p>

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1 ER/PR because I stopped ER/PR in May, 23rd, I
 2 think of May, that was my memo that came out
 3 telling that we are stopping testing in house
 4 because we didn't have a breast team any more.
 5 So from then, all ER/PR continued to go to
 6 Mount Sinai. So the breast service, in terms
 7 of diagnostic, its character, I agreed with
 8 Dr. Nick Makretsov's suggestion that he takes
 9 on all cases of the breast, which he currently
 10 is doing.
 11 COFFEY, Q.C.:
 12 Q. So all cases means right from the diagnostic
 13 that it is breast cancer?
 14 DR. DENIC:
 15 A. Breast cancer. Not necessarily have to be
 16 breast cancers, you know, any lumpectomies,
 17 needle localizations, any mastectomies that
 18 have been done, needle core biopsies. So
 19 every specimen that has the word breast in it,
 20 really, he's going to be looking into it.
 21 COFFEY, Q.C.:
 22 Q. Okay.
 23 DR. DENIC:
 24 A. To ensure the quality of the services as such,
 25 all of these cases in review on our quality

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1 assurance rounds the following week. So he
 2 brings them all and we review them. Also,
 3 every now and then, he brings the cases to me
 4 and consult me, and still if he have some
 5 problems, we are sending these cases out for
 6 external review and diagnosis.
 7 COFFEY, Q.C.:
 8 Q. So I take it that you, at least for the
 9 foreseeable future, intend to utilize him as
 10 the source around which to structure the
 11 breast pathology service?
 12 DR. DENIC:
 13 A. A core.
 14 COFFEY, Q.C.:
 15 Q. Core group.
 16 DR. DENIC:
 17 A. That is correct, and I think it's a good core.
 18 The plan is I'm waiting for Dr. Cook to come
 19 back from his leave and that's going to be in
 20 the middle of September, although he's going
 21 to be on ease back for a period of time, and
 22 he's going to join the group, and in terms of
 23 reporting, when he's ready, we're going to--
 24 I'm planning to restart ER and PR and
 25 reporting is going to be done by two people by

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1 consensus and Dr. Ford Elms is also going to
 2 join them as director of immunohistochemistry,
 3 so that he can monitor the quality and
 4 reproducibility of the results. So that's the
 5 plan.
 6 COFFEY, Q.C.:
 7 Q. So that ER/PR, ER and PR testing, testing in
 8 the sense of the slides that will be
 9 interpreted has not been performed in St.
 10 John's since May of 2008?
 11 DR. DENIC:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. And when do you anticipate that it will
 15 actually start again, like in the sense that
 16 they will prepare slides here locally in St.
 17 John's, or intended to be actually used and
 18 read by pathologists?
 19 DR. DENIC:
 20 A. As I said, I'm just waiting for Dr. Cook to
 21 come back and which is the middle of
 22 September, to give him some time to get back
 23 into a program, and so we can say some time in
 24 October.
 25 COFFEY, Q.C.:

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1 Q. And Dr. Elms has been--has testified here, and
 2 he has told the Commissioner that he referred
 3 to the fact that they discontinued ER/PR in
 4 '08 temporarily and he said, well, even in
 5 restarting it, that it would have to be -
 6 DR. DENIC:
 7 A. He has to validate the test.
 8 COFFEY, Q.C.:
 9 Q. - revalidate it, that was it, yes, revalidate
 10 it again. So again, that will take -
 11 DR. DENIC:
 12 A. A week.
 13 COFFEY, Q.C.:
 14 Q. - a week, certain amount of time, so and I
 15 take it that that won't be done until there's
 16 an actual date when you anticipate that Dr.
 17 Medved (sic), I'm sorry his name is?
 18 DR. DENIC:
 19 A. Makretsov.
 20 COFFEY, Q.C.:
 21 Q. Makretsov, I apologize, Dr. Makretsov and Dr.
 22 Cook are both in the building working?
 23 DR. DENIC:
 24 A. That's right, and we're going to make--any
 25 decision of such nature is going to be made

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1 together, and when Dr. Cook comes back, Dr.
 2 Elms is any how still at St. Clare's Hospital,
 3 I'll be applying to move him out to Health
 4 Sciences, but this is--that discussion is
 5 going to occur and we're going to start from
 6 there.
 7 COFFEY, Q.C.:
 8 Q. Doctor, and I will come back and revisit some
 9 of that toward the end of your testimony.
 10 Doctor, I'd like to return now to the spring
 11 and summer of 2005. I asked you about when
 12 you'd first heard about this, kind of what has
 13 turned out to be ER/PR problem, I'll describe
 14 it generally that way, in you think the summer
 15 of 2005.
 16 DR. DENIC:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. Doctor, I'm just going to ask you then, what
 20 did you--what's your recollection of who you
 21 first heard about this from, what you heard
 22 and then what you knew as time went on? So
 23 who'd you first hear -
 24 DR. DENIC:

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1 A. I heard this from Dr. Don Cook. And this was
 2 more like hallway talk, really. Because Dr.
 3 Cook and I, we practice at the same
 4 department, although our offices are little
 5 bit remote, there's a group of offices
 6 separated from mine, actually, I'm a little
 7 bit more separated from the others, but
 8 basically within 20 metres. So this was a
 9 hallway talk that he told me there is a case
 10 that the results changed, actually using the
 11 words converted from estrogen negative to
 12 positive and that he had been informed by
 13 oncologist that it happened and that the
 14 oncologist actually consulted somebody in the
 15 States, some of the oncologist in regards to
 16 that patient, trying to help out the patient
 17 and that they were told that this was a
 18 lobular carcinoma so it should have been
 19 positive. So that's as far as it went at that
 20 time.
 21 COFFEY, Q.C.:
 22 Q. In terms of what you were told?
 23 DR. DENIC:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. So he told you about what turns out would be
 2 Peggy Deane's case, presumably?
 3 DR. DENIC:
 4 A. Correct. I didn't know Peggy Deane at the
 5 time and I didn't know her relation, be the
 6 husband--I didn't even know of her husband.
 7 COFFEY, Q.C.:
 8 Q. So he just, Dr. Cook was just telling you
 9 about her case, as it turns out?
 10 DR. DENIC:
 11 A. That's right.
 12 COFFEY, Q.C.:
 13 Q. Would have been Ms. Deane's case. And at the
 14 time the explanation was that, well, it was a
 15 lobular cancer and should have been positive
 16 or would be expected to be positive and that
 17 had resulted in the retest?
 18 DR. DENIC:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. Did Dr. Cook tell you at that time what he
 22 proposed to do, if anything?
 23 DR. DENIC:
 24 A. I don't know that he told me at that time.
 25 But, you know, again, it would be probably

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1 uninformative formalization that they're going
 2 to retest some of the additional cases just to
 3 see the scope of the problem.
 4 COFFEY, Q.C.:
 5 Q. Doctor, had you before Dr. Cook mentioned this
 6 to you, you know, and I gather he used the
 7 word "conversion" at least you've indicated
 8 that's the word he used, going from ER
 9 negative, it converted to ER positive?
 10 DR. DENIC:
 11 A. That's correct.
 12 COFFEY, Q.C.:
 13 Q. He used the word "conversion". In the entire
 14 time you'd been in St. John's before that, had
 15 anyone ever told you about an ER negative
 16 converting to positive that you're -
 17 DR. DENIC:
 18 A. No.
 19 COFFEY, Q.C.:
 20 Q. Okay. And I ask that because there has been
 21 evidence that the Commissioner has seen in
 22 some pathology reports back, in particular,
 23 2003, that for whatever reason they were
 24 retested and it went from, certainly from what
 25 has been described as clinically negative to

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<p>1 clinically positive and--the ER status. And I</p> <p>2 gather if that did happen, you certainly</p> <p>3 weren't aware of it?</p> <p>4 DR. DENIC:</p> <p>5 A. I wasn't aware.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Made aware of it. Had you ever, up to that</p> <p>8 point Dr. Cook spoke to you about this</p> <p>9 conversion, had you ever heard of ER cases,</p> <p>10 not only in St. John's, but anywhere,</p> <p>11 converting? Were you aware of--were you</p> <p>12 familiar with the concept of ERs on retesting</p> <p>13 converting?</p> <p>14 DR. DENIC:</p> <p>15 A. I would say no.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Okay. And I take it then that you, at that</p> <p>18 time you wouldn't have been familiar with Dr.</p> <p>19 Rhodes' papers in the UK in 2001, 2002, that</p> <p>20 time period? You'd know what I'm talking</p> <p>21 about now?</p> <p>22 DR. DENIC:</p> <p>23 A. I know what you're talking about. I mean,</p> <p>24 that was paper that would be probably more of</p> <p>25 interest to the people who just do breast and</p>	<p>1 Q. Okay. Doctor, at the time Dr. Cook spoke to</p> <p>2 you and after the conversation ended, you</p> <p>3 understood or had the understanding that if</p> <p>4 there was a problem, whose responsibility was</p> <p>5 it to address it or to investigate it? And I</p> <p>6 appreciate Ms. Deane's case was not yours, I</p> <p>7 appreciate that. But you understood, Dr. Cook</p> <p>8 tells you about this and kind of walk--you</p> <p>9 both go your separate ways. You understood he</p> <p>10 was--if anybody was going to do anything about</p> <p>11 it, look further into it -</p> <p>12 DR. DENIC:</p> <p>13 A. You mean at that time or -</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. At that time, at that time or in the day or</p> <p>16 two or three afterward when you started to</p> <p>17 talk about retesting, who was responsible for</p> <p>18 dealing with this, from your perspective?</p> <p>19 DR. DENIC:</p> <p>20 A. But even today I would be responsible to start</p> <p>21 dealing with it.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Okay. So it would be the clinical chief, he</p> <p>24 in his capacity as clinical chief?</p> <p>25 DR. DENIC:</p>
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<p>1 -</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Yes, I appreciate that.</p> <p>4 DR. DENIC:</p> <p>5 A. - directly specialized service, you know, but</p> <p>6 not necessarily that I would dig through that</p> <p>7 literature at that time.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. So at the time, because in those papers they</p> <p>10 do talk about what they had found in their</p> <p>11 studies, in their surveys and they talk about</p> <p>12 conversions, I believe, or words to that</p> <p>13 effect. So the idea of conversions, ER</p> <p>14 converting was not something that before Dr.</p> <p>15 Cook spoke to you about really was something</p> <p>16 you were familiar with in this context of ER?</p> <p>17 DR. DENIC:</p> <p>18 A. What I know now and the literature obviously</p> <p>19 it was written before and been a global</p> <p>20 problem.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. But at the time you weren't aware of that?</p> <p>23 DR. DENIC:</p> <p>24 A. No.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 A. Clinical chief, that's right.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. What then did you next hear about this?</p> <p>4 DR. DENIC:</p> <p>5 A. Not much happened, actually, because I went</p> <p>6 back with the impression that this could be</p> <p>7 isolated case.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Um-hm.</p> <p>10 DR. DENIC:</p> <p>11 A. And you go back to your daily routine and you</p> <p>12 deal with this regular surgical workload.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And when did you next then hear about ER/PR?</p> <p>15 DR. DENIC:</p> <p>16 A. I think was sometimes through the media or</p> <p>17 could have been even again that maybe from Dr.</p> <p>18 Cook before the media that they retested the</p> <p>19 additional number of patients.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Yes.</p> <p>22 DR. DENIC:</p> <p>23 A. And they found additional numbers of patients</p> <p>24 that converted.</p> <p>25 COFFEY, Q.C.:</p>

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1 Q. And did he tell you, do you recall was he
 2 telling you this kind of as hallway chat or -
 3 DR. DENIC:
 4 A. It's a hallway chat, it's nothing more than a
 5 hallway chat.
 6 COFFEY, Q.C.:
 7 Q. Not like he sat down the group of you and -
 8 DR. DENIC:
 9 A. No.
 10 COFFEY, Q.C.:
 11 Q. - told you formally?
 12 DR. DENIC:
 13 A. No.
 14 COFFEY, Q.C.:
 15 Q. What then happened in terms of just again,
 16 looking back on it from your perspective?
 17 DR. DENIC:
 18 A. I think the next development, if I can recall,
 19 was that it was the memo issued by Dr. Cook
 20 stating that we're going to stop testing
 21 ER/PR.
 22 COFFEY, Q.C.:
 23 Q. Okay.
 24 DR. DENIC:
 25 A. And -

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1 COFFEY, Q.C.:
 2 Q. Go ahead, Doctor.
 3 DR. DENIC:
 4 A. That ER/PR is going to be sent away for
 5 retesting.
 6 COFFEY, Q.C.:
 7 Q. Now, the Commissioner has heard evidence that
 8 certainly that Dr. Cook was engaged in a
 9 number of activities around that time and in
 10 fact, as well, that Dr. Carter was certainly
 11 in June and July of 2005. Were you aware of--
 12 that Dr. Carter had been asked to--or had
 13 suggested that she undertake a review, a
 14 large-scale review in July of 2005 and had
 15 been told by Dr. Cook to go ahead and do it,
 16 were you aware of that?
 17 DR. DENIC:
 18 A. I mean, I knew that it happened, but I don't
 19 want to mislead you at that period of time.
 20 COFFEY, Q.C.:
 21 Q. Yes.
 22 DR. DENIC:
 23 A. I cannot be certain. I might, I might not
 24 have had that kind of knowledge, because I
 25 know subsequently I had that knowledge that

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

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1 neuropathologist.
 2 COFFEY, Q.C.:
 3 Q. So you'll see over here it's a meeting of
 4 pathologists?
 5 DR. DENIC:
 6 A. Okay.
 7 COFFEY, Q.C.:
 8 Q. There's been evidence that there was a meeting
 9 of pathologists and there was discussion at
 10 the time about concerns expressed about the
 11 current problem, including some of our
 12 suggestions about how to approach this. They
 13 talk about an ongoing study and ensuring no
 14 bias is introduced into it. Assume that the
 15 pathologist reported the original test
 16 correctly. "Persons conducting the study do
 17 not need to know which pathologist signed the
 18 report originally." I'm skipping over some of
 19 it. "Anything else is an audit of the
 20 individual pathologists and if that is the
 21 aim, that is not the proper procedure for an
 22 audit. This is not the proper procedure for
 23 an audit of a pathologist's performance." And
 24 it goes on to refer to some generalized
 25 statements, critical statements that suggests

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1 pathologists were, or at least some were
 2 hearing. Now, were you aware, first of all,
 3 that such a meeting had occurred?
 4 DR. DENIC:
 5 A. I wasn't even present for -
 6 COFFEY, Q.C.:
 7 Q. No, you weren't present, but were you aware
 8 that it occurred?
 9 DR. DENIC:
 10 A. No.
 11 COFFEY, Q.C.:
 12 Q. Now this is August 5th, 2005 and that memo
 13 suspending, advising pathologists suspending
 14 is being--testing is being suspended is August
 15 8th, 2005. So what I wanted to ask you about
 16 is at the end of July and early August, 2005,
 17 this seems to suggest that certainly a number
 18 of pathologists were fairly aware of the fact
 19 that there was an ongoing study, they were
 20 viewing it as a potential audit, expressing
 21 concerns about, talking about what would be
 22 negative statements or certainly negative
 23 statements that were being overheard about
 24 pathologists' work. Were you aware of that in
 25 the summer of, like in late July, early

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1 August, 2005?
 2 DR. DENIC:
 3 A. I mean, I'm trying to remember why I wasn't at
 4 that meeting, really, because--and that's
 5 something that's difficult to go back. I take
 6 usually my vacations in the end of July and
 7 August, so I could have been on vacation.
 8 COFFEY, Q.C.:
 9 Q. Yeah. But not only so much the meeting as the
 10 subject matter, what they're talking about,
 11 were you informed -
 12 DR. DENIC:
 13 A. Eventually did, eventually. I mean, this is
 14 something that conveyed all of a--even up to
 15 these dates, you know, about pathologists
 16 being concerned about how many cases they've
 17 been involved, what are the consequences of
 18 all of this. I mean, it wouldn't surprise me,
 19 it's only the context of all of these
 20 documents. But I haven't seen this document
 21 and I wasn't on this meeting.
 22 COFFEY, Q.C.:
 23 Q. Sure. But then as the summer of 2005 went on,
 24 is it your recollection that it began to
 25 become more and more a topic of conversation

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1 amongst pathologists?
 2 DR. DENIC:
 3 A. I remember that because, as I said, concerns
 4 mostly.
 5 COFFEY, Q.C.:
 6 Q. Yes. With that in mind were the staff
 7 pathologists, and I'll call you that because
 8 you were one of them at the time, were you
 9 being kept apprised of what was going on? And
 10 aside from a hallway chat now, I'm talking
 11 about as a group were you being apprised or
 12 being kept informed?
 13 DR. DENIC:
 14 A. I'm trying to remember did it come up on any
 15 of the meetings, really, that we had, and I
 16 cannot recall such thing.
 17 COFFEY, Q.C.:
 18 Q. Ever coming up?
 19 DR. DENIC:
 20 A. I won't say it never happened, but I cannot
 21 recall. I don't know are there any minutes of
 22 the meetings at that time. But I don't
 23 believe that officially we were apprised until
 24 a certain time.
 25 COFFEY, Q.C.:

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1 Q. And this is what I'm really getting at,
 2 Doctor, is this, is that as a staff
 3 pathologist at the time and looking back on
 4 it, your fellow staff pathologists which you
 5 observed at the time, was the lack of
 6 information disconcerting?
 7 DR. DENIC:
 8 A. I mean -
 9 COFFEY, Q.C.:
 10 Q. I'm not asking you to be critical of Dr. Cook
 11 -
 12 DR. DENIC:
 13 A. - in general -
 14 COFFEY, Q.C.:
 15 Q. - I'm just asking you -
 16 DR. DENIC:
 17 A. In general the lack of information, obviously
 18 not only the pathologists, I think in the
 19 general world where we live the lack of
 20 information could have a negative effect. In
 21 regards to this, obviously eventually we find
 22 out that they are doing testing, they're going
 23 to be sending out, more than a concern. And I
 24 wasn't quite sure did Dr. Cook had all the
 25 informations about it, did he know the full

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

9 COFFEY, Q.C.:

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

16 DR. DENIC:

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

19 COFFEY, Q.C.:

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

25 DR. DENIC:

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

8 COFFEY, Q.C.:

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

13 DR. DENIC:

14 A. That's correct.

15 COFFEY, Q.C.:

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

17 DR. DENIC:

18 A. That's correct.

19 COFFEY, Q.C.:

20 Q. In Mount Sinai. And to retest?

21 DR. DENIC:

22 A. That's correct.

23 COFFEY, Q.C.:

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

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1 about what's going on?

2 DR. DENIC:

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

11 COFFEY, Q.C.:

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

24 DR. DENIC:

25 A. It looks familiar, I believe I did.

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1 COFFEY, Q.C.:

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

7 DR. DENIC:

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

10 COFFEY, Q.C.:

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

13 DR. DENIC:

14 A. Yes, I think so.

15 COFFEY, Q.C.:

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

20 DR. DENIC:

21 A. Um-hm.

22 COFFEY, Q.C.:

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

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<p>1 about what they were finding in this review? 2 Because you understood by this point in time, 3 by the end of July you would have understood 4 that there's a big investigation going on into 5 ER and PR, and now you're getting a memo 6 dealing with ordering and reporting ER status. 7 And this is a how-to list. So did you have 8 any thoughts at the time as to what, if 9 anything, they were finding in their review? 10 DR. DENIC: 11 A. No, I would say no. 12 COFFEY, Q.C.: 13 Q. Okay. We've heard, Doctor, that there were 14 external reviews conducted, reviewers were 15 brought in, and I'll ask you about those in a 16 moment. But after the suspension of testing, 17 and you were advised of that in early August, 18 and the retesting effort, what do next 19 remember happening in terms of what you knew 20 next? 21 DR. DENIC: 22 A. I think that was October, probably, that the 23 story broke in the newspaper. 24 COFFEY, Q.C.: 25 Q. Okay. And that's -</p>	<p>1 A. I think Dr. Cook at one point in one of 2 program meetings, he read Dr. Banerjee's 3 report. 4 COFFEY, Q.C.: 5 Q. He read the report--all the report, or at 6 least a portion of it? 7 DR. DENIC: 8 A. I can't tell, but I know that he read the 9 report. It could be the entire report. 10 COFFEY, Q.C.: 11 Q. Do you recall when that was? 12 DR. DENIC: 13 A. I can't exactly. It could have been December 14 or - 15 COFFEY, Q.C.: 16 Q. Of 2005? 17 DR. DENIC: 18 A. Of 2005. 19 COFFEY, Q.C.: 20 Q. And did he show the report to anybody at that 21 meeting? I take it, it was at a meeting. 22 DR. DENIC: 23 A. He was reading from report. 24 COFFEY, Q.C.: 25 Q. Yes, I'm sorry.</p>
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<p>1 DR. DENIC: 2 A. Looking back. 3 COFFEY, Q.C.: 4 Q. - from looking back on it, that's the next 5 thing really that you recall? 6 DR. DENIC: 7 A. That's right. 8 COFFEY, Q.C.: 9 Q. This being brought to your attention? 10 DR. DENIC: 11 A. That's correct. 12 COFFEY, Q.C.: 13 Q. Doctor, Dr. Banerjee was here in September of 14 2005, as was Trish Wegrynowski. Did you know 15 that they were coming to St. John's? 16 DR. DENIC: 17 A. I believe we were told that they are coming or 18 Dr. Cook said, but I never met them. 19 COFFEY, Q.C.: 20 Q. Doctor, they were here, they were debriefed, 21 exit interviews were conducted and then the 22 reports were filed in October and then 23 November of 2005. Were you told anything 24 about what they found? 25 DR. DENIC:</p>	<p>1 DR. DENIC: 2 A. But he didn't hand around the report. 3 COFFEY, Q.C.: 4 Q. Did anyone ask him in your presence for a copy 5 of the report? 6 DR. DENIC: 7 A. No, I think he told us right from the get go 8 that reports protected peer review documents, 9 and that he's going to read it to us. 10 COFFEY, Q.C.: 11 Q. Okay. He could read it to you, but couldn't 12 give you a copy, and hope that no one had a 13 recording device, I take it. That's what 14 happened--okay, you're describing what 15 happened. 16 DR. DENIC: 17 A. (Inaudible) but that happened during my 18 tenure, I know. 19 COFFEY, Q.C.: 20 Q. And, Doctor, how about Trish Wergynowski's 21 report? 22 DR. DENIC: 23 A. No. 24 COFFEY, Q.C.: 25 Q. Okay. Doctor, up to the point where Dr. Cook</p>

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1 was reading some or all of Dr. Banerjee's
 2 initial report to you, and you think it was
 3 probably December of 2005, up to that point
 4 had Dr. Cook, Carter, or anyone else told you
 5 what Dr. Cook and Carter themselves had
 6 observed in their review in the summer of
 7 2005?
 8 DR. DENIC:
 9 A. I can't say then, but I know eventually I
 10 heard about it, so would it be that period of
 11 time, as I said, it's difficult with somebody
 12 who has current knowledge about entire
 13 situation to go back and say did I know. I
 14 think I would mislead you if I said yes or no.
 15 COFFEY, Q.C.:
 16 Q. Perhaps I'll put it--come at this way. Doctor
 17 Cook has testified, as has Dr. Carter here,
 18 that in their review in the summer of 2005,
 19 they noticed that there were problems with
 20 internal controls, either they weren't in the
 21 tissue or they were there and weren't stained,
 22 there were fixation problems with the slides
 23 they were looking at --
 24 DR. DENIC:
 25 A. That's correct.

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

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1 that Dr. Cook and Carter have told the
 2 Commissioner that in the summer of 2005, they
 3 realized, and looking at the mass of slides
 4 they did, there were fixation problems and
 5 problems with internal controls. When Dr.
 6 Cook read Dr. Banerjee's report out to you and
 7 referred to these three things, was that news
 8 to you at the time, was that the first time
 9 you heard that? You're sitting there and
 10 listening to this for the first time. Was
 11 that really news to you at the time or did you
 12 already know this because of something that
 13 you learned from Dr. Cook or Dr. Carter?
 14 DR. DENIC:
 15 A. That's why I'm saying, Mr. Coffey, it's a
 16 difficult to know--he read this, so that's
 17 knowledge that I definitely received at that
 18 time, and as much you can assimilate the
 19 knowledge that somebody is reading you the
 20 text rather than to have--to look into the
 21 text and to analyze yourself. So that makes a
 22 big difference in terms of any kind of
 23 recollection, but as I said, he could have
 24 said to me or anybody else that some of the
 25 problems could be the fixation, internal

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1 controls, and I know definitely that over all
 2 this period of time he said that so many
 3 times. So whether this was done before he
 4 read the report or not --
 5 COFFEY, Q.C.:
 6 Q. Or afterwards.
 7 DR. DENIC:
 8 A. I cannot be absolutely certain.
 9 COFFEY, Q.C.:
 10 Q. Doctor, where were you when the report was
 11 read to you? Where was that done, at St.
 12 Clare's?
 13 DR. DENIC:
 14 A. That was at a meeting--we usually had a
 15 meeting at the Health Science Centre.
 16 COFFEY, Q.C.:
 17 Q. Oh, this was this kind of monthly program
 18 meeting?
 19 DR. DENIC:
 20 A. That's right.
 21 COFFEY, Q.C.:
 22 Q. Okay, so it was --
 23 DR. DENIC:
 24 A. With a group of people.
 25 COFFEY, Q.C.:

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

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

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1 DR. DENIC:
 2 A. If you can move it--there's a few --
 3 COFFEY, Q.C.:
 4 Q. This is paragraph three, and there appears to
 5 be inadequate attention paid by the
 6 pathologists to the thickness of tissue
 7 slices.
 8 DR. DENIC:
 9 A. We can analyze one by one if you want with me.
 10 COFFEY, Q.C.:
 11 Q. Sure. What I'm getting at is this, and I
 12 appreciate that, and I'll come back to that
 13 overall --
 14 DR. DENIC:
 15 A. Okay.
 16 COFFEY, Q.C.:
 17 Q. But what I'm asking--because at the time, as
 18 you just told the Commissioner, look, this is
 19 just being read to me and --
 20 DR. DENIC:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. It's difficult to keep track of --
 24 DR. DENIC:
 25 A. That's right.

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

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<p>1 seen the report. You would have seen the</p> <p>2 report since?</p> <p>3 DR. DENIC:</p> <p>4 A. Yes.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. And you would agree that certainly most of her</p> <p>7 comments are directed at the technologist end</p> <p>8 of things?</p> <p>9 DR. DENIC:</p> <p>10 A. That's correct.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. That would be a fair comment.</p> <p>13 DR. DENIC:</p> <p>14 A. That's correct.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. So here, Doctor, in paragraph--what's numbered</p> <p>17 number 7 here, I want to ask you about this,</p> <p>18 about the pitfalls of IHC, the importance of</p> <p>19 quality control and interpretation of IHC</p> <p>20 results. He's suggesting better education</p> <p>21 required for technologists, pathologists, and</p> <p>22 clinicians about the pitfalls of IHC, the</p> <p>23 importance of quality control, and the</p> <p>24 interpretation of IHC results. I want to ask</p> <p>25 you this. Up to the point that this was read</p>	<p>1 Rosai Ackerman, you have there the basics of</p> <p>2 immunohistochemistry. In the basics of</p> <p>3 immunohistochemistry, there's a few lines</p> <p>4 about false negatives. I think it's a small</p> <p>5 paragraph about it.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Uh-hm.</p> <p>8 DR. DENIC:</p> <p>9 A. I think part of--ten sentences, just a part of</p> <p>10 one column, and there's another part about</p> <p>11 false positives, which at the time for the</p> <p>12 immunohistochemistry at all, not about ER/PR,</p> <p>13 I'm just talking in general, they think that</p> <p>14 false positives are the bigger problem.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. In immunohistochemistry?</p> <p>17 DR. DENIC:</p> <p>18 A. In immunohistochemistry as such, that overall</p> <p>19 any stains--they don't talk about ER/PR, and</p> <p>20 that--so that the pitfalls were addressed just</p> <p>21 in general of immunohistochemistry as such, so</p> <p>22 nothing to any greater extent. As I said,</p> <p>23 even for the exam, we just had to know the</p> <p>24 basic principles; antigen antibodies</p> <p>25 attachment, secondary antibodies, and with the</p>
<p>Page 222</p> <p>1 to you, at that point, December of '05, how</p> <p>2 attuned were you, how alert were you to the</p> <p>3 idea that there are pitfalls with IHC, and</p> <p>4 quality control is very important with IHC</p> <p>5 because of the nature of the test, and the</p> <p>6 interpretation of IHC, in particular in</p> <p>7 relation to ER/PR requires particular</p> <p>8 attention to internal controls? How aware of</p> <p>9 IHC as a problematic subject--if not done very</p> <p>10 carefully and properly, how aware were you of</p> <p>11 that before this, or was IHC just another test</p> <p>12 that, you know, stain as ordered?</p> <p>13 DR. DENIC:</p> <p>14 A. At the beginning, and as such, it was</p> <p>15 considered as another test. Most of the</p> <p>16 pathologists, I believe, in talking to--while</p> <p>17 I know through Dr. Ejeckam's letter and later</p> <p>18 on when I saw what he wrote to Mr. Gulliver,</p> <p>19 as such, he said this is not another test, but</p> <p>20 the way that that immunohistochemistry was</p> <p>21 presented to the pathology at that time in</p> <p>22 training, and based on the literature, and</p> <p>23 again I can go back to the same surgical</p> <p>24 pathology book recognized by the Royal College</p> <p>25 of Physicians and Surgeons as a textbook,</p>	<p>Page 224</p> <p>1 chromogen, then how to get the stains, and</p> <p>2 just very basic about pitfalls, false</p> <p>3 positive, negatives, and as I said, it was</p> <p>4 more written about positive, but there is a</p> <p>5 sentence there that states pathologists</p> <p>6 shouldn't rely on immunohistochemistry if you</p> <p>7 have your tumour which is negative, you should</p> <p>8 go after what you see on your H & E slides.</p> <p>9 S o t h e r e w a s l i m i t a t i o n i n</p> <p>10 immunohistochemistry as such, and I think that</p> <p>11 --</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. This is immunohistochemistry at large?</p> <p>14 DR. DENIC:</p> <p>15 A. But we are talking what the pathologists were</p> <p>16 trained about immunohistochemistry as such,</p> <p>17 and this is as much that we were trained, we</p> <p>18 had to know this is not done on a wet bench,</p> <p>19 you know, just that you have somebody showing</p> <p>20 you, oh, this went wrong on this case, this</p> <p>21 was a false negative, this was a false</p> <p>22 positive, because of this kind of stuff.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Okay.</p> <p>25 DR. DENIC:</p>

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1 A. So it was very basic training that we knew of,
 2 and for the long time we would think it is a
 3 technical procedure that observed and done by
 4 the technologist. You receive your slides and
 5 you report what you see on the slide.
 6 COFFEY, Q.C.:
 7 Q. Doctor --
 8 THE COMMISSIONER:
 9 Q. Before you leave this, Mr. Coffey, on the
 10 subject of--let's go back to this, yes, better
 11 education, paragraph seven here, "Required for
 12 technologists, pathologists, and clinicians
 13 about the pitfalls of ICH". Who's
 14 responsibility is it to identify for a
 15 clinician a pitfall or pitfalls of IHC?
 16 DR. DENIC:
 17 A. That has to be done mutually, but should
 18 address the issue of--like, we have the issue
 19 of cutoffs, that we can say, okay, we
 20 recognize the cutoff is one percent in our
 21 lab, and that's why we think this should be
 22 done. This is one of the--so the oncologists
 23 probably would know where the lab stands from
 24 that perspective. Maybe--I would say maybe we
 25 can--as a pathologist, we can say none of the

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1 tests has to be taken at face value because
 2 every single test has build up false positive
 3 and negative in its procedure, so it has to be
 4 taken in a clinical context and probably
 5 queried, but the oncologists and clinicians,
 6 they would know for the most of the time that
 7 no tests ever done in medicine is 100 percent
 8 sensitive, 100 percent specific. So it goes
 9 both ways. I would say it goes both ways in
 10 terms of education and--it could have played a
 11 role, but they had a role to educate
 12 themselves as well.
 13 THE COMMISSIONER:
 14 Q. Well, it just seems to me that, just as an
 15 observation from somebody completely outside
 16 of your profession, at least from the material
 17 that's been coming in here, that the lines of
 18 communication are not optimal, shall we say.
 19 A number of people say things like, well, so
 20 and so would know that, and the other one says
 21 I wouldn't know that. It just seems that on
 22 both ends of the spectrum you are assuming
 23 that the other person to whom you are sending
 24 information knows the limitations of the
 25 information and knows the content of the

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1 information. Your point about cutoffs is a
 2 good one because a number of the test results
 3 would say positive or negative, and just that,
 4 no percentages. Now if you send a percentage,
 5 and I see those pathologists who have come
 6 here and said it is my practice to give a
 7 percentage, and I understand that in that case
 8 you are being clear to the clinician who is
 9 receiving the information that this is your
 10 opinion as to what the percentage is, and it's
 11 then for the clinician taking that percentage
 12 to decide how to put that in the mix and what
 13 treatments to offer in the case of ER done for
 14 the purpose of treatment to a patient, but if
 15 what's being sent is a straight positive or
 16 negative, particularly in the years 2001,
 17 2002, then the opportunity for confusion is
 18 there, and it would seem from the material
 19 that we received, there was confusion in
 20 respect of some of the persons involved. So
 21 I, frankly, am somewhat concerned about the
 22 communication between the pathologist and the
 23 clinician, and are there gaps--is it just that
 24 in medicine everybody assumes that everybody
 25 else knows the purpose of the test that you're

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1 giving and the limitations of the test so that
 2 when you send it off outside of your lab, then
 3 there will be no doubt from the person who is
 4 receiving your information as to what you are
 5 saying, or is there a role here anywhere for
 6 people to start talking to each other about
 7 exactly what that means?
 8 DR. DENIC:
 9 A. I agree with you. I mean, the communication
 10 could have been the problem, although I
 11 believe that Dr. Khalifa, I think, carried
 12 through this 30 percent cutoff value based on
 13 the literature. It was literature and
 14 evidence-based that he delivered to the
 15 oncologists as well. So that not completely--
 16 in terms of some stuff, like, it says pitfall
 17 of immunohistochemistry, I don't expect that
 18 the oncologists should know about--should know
 19 about fixation, that's not the scope of their
 20 --I shouldn't expect the oncologist know about
 21 internal control. They could know through
 22 their general knowledge, but to ask me and
 23 call me, Nash, did you look at internal
 24 control, I--that would be the same as I would
 25 call Dr. Laing and say --

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<p>1 THE COMMISSIONER:</p> <p>2 Q. But do you really think that that's what's</p> <p>3 being referred to by Dr. Banerjee here? He's</p> <p>4 not really talking about your telling them</p> <p>5 about internal controls.</p> <p>6 DR. DENIC:</p> <p>7 A. No, no, but the pitfalls in</p> <p>8 immunohistochemistry have broad area, and as</p> <p>9 you said, with the communication in terms of</p> <p>10 cutoff, you know, probably could have been</p> <p>11 better communicated and pathologist should</p> <p>12 have been first on the same page.</p> <p>13 THE COMMISSIONER:</p> <p>14 Q. Uh-hm.</p> <p>15 DR. DENIC:</p> <p>16 A. And I think we were not on the same page, and</p> <p>17 obviously through high turnover of the</p> <p>18 pathologists and oncologists, nobody--we</p> <p>19 didn't have a chance to be on the same page at</p> <p>20 some point.</p> <p>21 THE COMMISSIONER:</p> <p>22 Q. Are there better methods of communication in</p> <p>23 your view now than there were in 2001, 2003,</p> <p>24 etc?</p> <p>25 DR. DENIC:</p>	<p>1 Q. And then all of a sudden, you went to IHC, and</p> <p>2 the same kind of mentality about the results</p> <p>3 got in the mix, and maybe that shouldn't have</p> <p>4 been the mentality, and I'm wondering is the</p> <p>5 problem that groups are not talking to each</p> <p>6 other, is it that clinicians should be</p> <p>7 educated better in terms of what a pathologist</p> <p>8 does and what use you can make of particular</p> <p>9 tests, or is it something else? Just sort of</p> <p>10 help me with the lines of division here and</p> <p>11 who talks to whom to make sure that there is</p> <p>12 no confusion when somebody is trying to make a</p> <p>13 decision about the treatment of a patient?</p> <p>14 DR. DENIC:</p> <p>15 A. I mean, the lines of communications, I</p> <p>16 believe, they were there, maybe not to the</p> <p>17 strength as we have it today.</p> <p>18 THE COMMISSIONER:</p> <p>19 Q. Uh-hm.</p> <p>20 DR. DENIC:</p> <p>21 A. But never been broken--we were always</p> <p>22 communicating our results and available to the</p> <p>23 clinicians, not only oncologists, to</p> <p>24 everybody. So the line of communications were</p> <p>25 there. We're realizing through all of this</p>
<p>Page 230</p> <p>1 A. Yes, definitely there are better, and as I</p> <p>2 said, we are now meeting over the breast</p> <p>3 disease site group, not only pathologists, but</p> <p>4 oncologists, surgeons, geneticists, and</p> <p>5 everybody involved in patient care of the</p> <p>6 breast patients, and we discuss the various</p> <p>7 stuff, we are developing policies and</p> <p>8 procedures and guidelines of the treatment.</p> <p>9 We are all involved, so this was one of the</p> <p>10 initiatives that maybe--the issues in the</p> <p>11 future of similar natures can be addressed.</p> <p>12 THE COMMISSIONER:</p> <p>13 Q. Uh-hm, and for example, if there is within</p> <p>14 your world, and obviously in the world of a</p> <p>15 pathologist, you would be expected to know, I</p> <p>16 presume, the limitation on the use of a</p> <p>17 particular test. Would it be--I'm thinking</p> <p>18 particularly of when the switch occurred and</p> <p>19 you went from the bio assay method, which as I</p> <p>20 understand it, somebody sent numbers to</p> <p>21 somebody and they kind of took those numbers</p> <p>22 and they were the gospel.</p> <p>23 DR. DENIC:</p> <p>24 A. That's right.</p> <p>25 THE COMMISSIONER:</p>	<p>Page 232</p> <p>1 there was obviously a link here and there</p> <p>2 missing in the lines of communications, but in</p> <p>3 the lab we performed so many tests, I think,</p> <p>4 11 million tests are coming out--lab general,</p> <p>5 blood work, and everything else that have been</p> <p>6 done, and if new test is present in the lab or</p> <p>7 we are changing certain values of reporting,</p> <p>8 we send that information to the clinicians.</p> <p>9 Most of the tests that--you think that the</p> <p>10 clinicians when they receive the results, they</p> <p>11 have to process themselves, they have--</p> <p>12 everything has to be put in a clinical</p> <p>13 content. That's why some of these patients</p> <p>14 with even low ER were treated because they put</p> <p>15 the various parameters in the content, and</p> <p>16 they prove that through their practice. So to</p> <p>17 answer on your question is I agree with you</p> <p>18 that obviously we have to work on</p> <p>19 strengthening--I'm not say that there's never</p> <p>20 been a communication, and I would disagree</p> <p>21 with that, but obviously when something goes</p> <p>22 wrong, then you go back and you try to find</p> <p>23 the weak points, and that's where we are now.</p> <p>24 THE COMMISSIONER:</p> <p>25 Q. And you think that the breast site group is</p>

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1 the answer to communications in respect of at
 2 least this issue?
 3 DR. DENIC:
 4 A. I think it's one--one of very good answers,
 5 and again I said interaction between these two
 6 groups is very tight, and I think that we have
 7 the vehicle to address any future issues.
 8 THE COMMISSIONER:
 9 Q. Okay. Sorry, Mr. Coffey, I interrupted.
 10 COFFEY, Q.C.:
 11 Q. And in a wider vein in that regard, I take it,
 12 the breast site group--and I take it the plan
 13 is certainly to have other disease site groups
 14 as well as time and resources permit?
 15 DR. DENIC:
 16 A. As times goes on.
 17 COFFEY, Q.C.:
 18 Q. And resources permit. Doctor, one thing in
 19 terms of education, I'll ask you about
 20 education--you would now be, I take it, in
 21 charge of education for technologists?
 22 DR. DENIC:
 23 A. Ultimately.
 24 COFFEY, Q.C.:
 25 Q. Ultimately, yes.

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1 DR. DENIC:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. So who, in practice, is in charge of it?
 5 DR. DENIC:
 6 A. It's going to be Mr. Gulliver, and the
 7 managers, and also there's going to be a great
 8 influence of the new Regional Quality
 9 Management Manager, Ms. Lynn Wade.
 10 COFFEY, Q.C.:
 11 Q. Okay, we'll come to that then, and in terms of
 12 pathologists, I take it that--you've indicated
 13 that it's going to be limited, at least breast
 14 pathology is anticipated in the future to be
 15 limited to a small group within Eastern
 16 Health?
 17 DR. DENIC:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. And I take it that either to get made a member
 21 of that group, you would be expected to know
 22 something about breast pathology more than the
 23 average pathologist?
 24 DR. DENIC:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. Doctor, in terms of residents, I want to ask
 3 you about this, because you kind of summarized
 4 to--the Commissioner was asking you about, and
 5 not so much even as breast pathology as IHC
 6 and wider scope, this wider scope, what's the
 7 situation right now in the residency training
 8 program for pathologists in terms of their
 9 education about IHC?
 10 DR. DENIC:
 11 A. Nothing official yet.
 12 COFFEY, Q.C.:
 13 Q. So if I could then, it hasn't changed from the
 14 day that you were a resident, in the sense of
 15 officially it hasn't changed?
 16 DR. DENIC:
 17 A. In the sense of official.
 18 COFFEY, Q.C.:
 19 Q. I apologize, go ahead.
 20 DR. DENIC:
 21 A. Because again through all of this, what we are
 22 going through, every single pathologist is
 23 aware of all of this what we were talking
 24 about, about possible factors influencing and
 25 affecting IHC testing. So again when you work

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1 with residents and looking into the IHC
 2 stains, you're going through all of this with
 3 them, and recently we started initiative and
 4 it's going to be very soon, that the residents
 5 spend couple of weeks rotating through the
 6 immunohistochemistry.
 7 COFFEY, Q.C.:
 8 Q. So the actual business end of creating the
 9 slides and at least why slides are being
 10 created?
 11 DR. DENIC:
 12 A. Just to see in's and out's of
 13 immunohistochemistry and go from one station
 14 to another and review the slides and--various
 15 slides and go through the validation of the
 16 process, optimization of the process. So
 17 that's going to be Dr. Elms' job, and the
 18 residency training program directors,
 19 (unintelligible) job.
 20 COFFEY, Q.C.:
 21 Q. Doctor, you've indicated that at the meeting
 22 where you were first read this report by Dr.
 23 Cook, I take it there wasn't at least
 24 immediately in the room at the time much
 25 reaction from the pathologists?

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

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1 about the fact that they were being retested?
 2 Had you been aware --
 3 DR. DENIC:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. You weren't aware of that?
 7 DR. DENIC:
 8 A. No.
 9 COFFEY, Q.C.:
 10 Q. We understand based upon some exhibits we've
 11 seen that the first of Dr. Mullins retest
 12 results came back, arrived in St. John's
 13 probably in the evening of September 26, 2005.
 14 Dr. Cook had them in the morning, September
 15 27th, and then--there were quite a number of
 16 them that day and a couple of days after that.
 17 AS the fall of 2005 then went on, were you
 18 told anything about what the results were?
 19 DR. DENIC:
 20 A. No.
 21 COFFEY, Q.C.:
 22 Q. In terms of the conversions, how many there
 23 were?
 24 DR. DENIC:
 25 A. No.

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1 COFFEY, Q.C.:
 2 Q. Nothing at all. I take it then that if you
 3 weren't told--you work in the same office
 4 complex that Dr. Cook did and Dr. Carter did,
 5 certainly Dr. Cook did, that you had no reason
 6 to believe anyone else was told either,
 7 pathologists?
 8 DR. DENIC:
 9 A. I don't know if they were told, but I was not
 10 told.
 11 COFFEY, Q.C.:
 12 Q. It wasn't the topic of conversation?
 13 DR. DENIC:
 14 A. No.
 15 COFFEY, Q.C.:
 16 Q. Was it a topic of conversation amongst
 17 pathologists wondering about, well, what are
 18 the results?
 19 DR. DENIC:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. People were wondering. Do you know if Dr.
 23 Cook was asked, you know, "Don, are you going
 24 to tell us what the results were"?
 25 DR. DENIC:

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1 A. He might have been asked as well, and I
 2 remember one point of conversation, but again
 3 it's difficult to put a timeline of this one,
 4 that he might have said that large number of
 5 pathologists or almost everybody, that kind of
 6 word, is involved.
 7 COFFEY, Q.C.:
 8 Q. Is involved, and you would have taken the word
 9 "involved" to mean have had one or more
 10 conversions?
 11 DR. DENIC:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. In terms of their own caseload?
 15 DR. DENIC:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. The point being, I take it, that you
 19 understood from his remark at the time that,
 20 look, this involves really almost all of us?
 21 DR. DENIC:
 22 A. That's correct.
 23 COFFEY, Q.C.:
 24 Q. Okay. Doctor, looking at this, this is
 25 February 23rd, Exhibit P-0025, February 23rd,

<p style="text-align: right;">Page 241</p> <p>1 2006, a report to the Board of Trustees, MAC, 2 and there's a note that Dr. Cook here has 3 submitted his resignation as clinical chief, 4 they thank him for his work, and then Dr. 5 Williams advised that Dr. Nash Denic has 6 agreed to serve as interim clinical chief for 7 a six month period. So you had signed on to 8 that role at least by February 23rd. How is 9 it that you came to be interim clinical chief? 10 DR. DENIC: 11 A. Dr. Cook approached me and he told me that his 12 term is coming to the end, he is looking for 13 somebody to replace him, and I told him to let 14 me think about it. I have a young family, you 15 know, that's a lot to be dedicated to, it is 16 very hard work that the clinical chiefs are 17 put in, especially seeing him in that period 18 of time when he took himself of the service 19 just to deal with this matter. So I told him 20 to go and ask the other pathologists as well 21 and to see if anybody else would take on this 22 position. So eventually he came back to me 23 and, obviously, this wasn't a desirable 24 position as such, and his term was coming to 25 the end, and I think he was also exhausted as</p>	<p style="text-align: right;">Page 243</p> <p>1 A. To a certain extent. I knew that tumour panel 2 was established, that he was working through 3 the tumour panel, and he was--he even asked me 4 and brought me to the tumour panel just to 5 basically see how it works, rather than 6 (unintelligible) well because Dr. Cook, I, and 7 Dr. Williams, we had understanding that Dr. 8 Cook started all of this. While he's not the 9 clinical chief any more, he should continue in 10 completing this task because for me going 11 through his notebooks, spreadsheets, it could 12 be very difficult and wouldn't be beneficial 13 to anybody. So I did go to the tumour board 14 to see what they were doing and how they were 15 panelling the patients, and I went a few 16 times, and not to any greater extent, nobody 17 at that time processed any data. We were 18 working as hard as possible, usually evenings 19 after the regular work job that they had, just 20 to put all the patients through in order to 21 present them with the results or their 22 attending physicians so these patients could 23 be treated. 24 COFFEY, Q.C.: 25 Q. The tumour panel --</p>
<p style="text-align: right;">Page 242</p> <p>1 well after all of this, and I decided to step 2 in and take on the position. 3 COFFEY, Q.C.: 4 Q. Doctor, you had not been, based upon what 5 you've told us up to this point, involved in 6 ER/PR matter except to the extent that you've 7 already told us about? I mean, that's--is 8 there anything else we haven't covered? 9 DR. DENIC: 10 A. That is basically it. 11 COFFEY, Q.C.: 12 Q. Is there anything else you can think of that 13 we haven't covered? 14 DR. DENIC: 15 A. Not really. 16 COFFEY, Q.C.: 17 Q. Okay. So you're going to become clinical 18 chief. Did you discuss with Dr. Cook where 19 they were with it at the time? I mean, you're 20 taking over his role and he has been in charge 21 of the overall--I shouldn't say "in charge", I 22 protract that. He had been significantly 23 involved in the response to it. So did you 24 get briefed on it? 25 DR. DENIC:</p>	<p style="text-align: right;">Page 244</p> <p>1 DR. DENIC: 2 A. Tumour panel. 3 COFFEY, Q.C.: 4 Q. They're doing their work as best they can at 5 the time. 6 DR. DENIC: 7 A. That's right. 8 COFFEY, Q.C.: 9 Q. And your understanding was as quickly as they 10 could? 11 DR. DENIC: 12 A. As quickly as they could, and as I said, they 13 were meeting late at night. 14 COFFEY, Q.C.: 15 Q. So in terms of handling from the pathologist 16 end, kind of the representative of the 17 pathologists and the group that's handling 18 this within Eastern Health, Dr. Cook is going 19 to remain as that? 20 DR. DENIC: 21 A. That's right. 22 COFFEY, Q.C.: 23 Q. That's bearing in mind that you're going to be 24 the clinical chief, though? 25 DR. DENIC:</p>

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<p>1 A. That's right, and Dr. Carter was there too.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Okay.</p> <p>4 THE COMMISSIONER:</p> <p>5 Q. Sorry, I just want to make sure I understand.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Sure.</p> <p>8 THE COMMISSIONER:</p> <p>9 Q. Dr. Cook was to carry on effectively dealing</p> <p>10 with the issue as a whole or -</p> <p>11 DR. DENIC:</p> <p>12 A. The group that he had started.</p> <p>13 THE COMMISSIONER:</p> <p>14 Q. Or related to the tumour panel?</p> <p>15 DR. DENIC:</p> <p>16 A. No, the whole group, because that we are</p> <p>17 eventually coming to the panel and again he</p> <p>18 had to -</p> <p>19 THE COMMISSIONER:</p> <p>20 Q. All right. So while you were becoming</p> <p>21 clinical chief the issue of ER/PR was going to</p> <p>22 remain with Dr. Cook?</p> <p>23 DR. DENIC:</p> <p>24 A. Pretty much.</p>	<p>1 Q. So you got a spreadsheet, and we'll come to</p> <p>2 that. And in terms of where they were with--</p> <p>3 and there are certain memos that the</p> <p>4 Commissioner has seen, kind of internal memos</p> <p>5 about, you know, we've got so many back, 800</p> <p>6 and some odd have been tested, we have so many</p> <p>7 back, we've informed, panelled so many and so</p> <p>8 on and so forth, those sorts of documents at</p> <p>9 that time?</p> <p>10 DR. DENIC:</p> <p>11 A. Not really because for me those document</p> <p>12 wouldn't mean much just coming into the middle</p> <p>13 of it if not at the end of it.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Thank you, Commissioner.</p> <p>16 THE COMMISSIONER:</p> <p>17 Q. All right, we'll take the afternoon break.</p> <p>18 (RECESS)</p> <p>19 THE COMMISSIONER:</p> <p>20 Q. Please be seated. Mr. Coffey?</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Thank you, Commissioner. Exhibit P-1749?</p> <p>23 Doctor, I'll be taking you to this in a</p> <p>24 moment, but this, I take it, it's dated March</p> <p>25 6th, 2006. And you would have just started</p>
<p>Page 246</p> <p>1 THE COMMISSIONER:</p> <p>2 Q. Yeah, okay. Mr. Coffey, wherever you can find</p> <p>3 a spot, we'll take the afternoon break.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Yes. What, if any documents, were you shown</p> <p>6 at the time or given at the time relating to</p> <p>7 the ER/PR issue? Were you given at that point</p> <p>8 Dr. Banerjee's report back, the October 7th</p> <p>9 report and Ms. Wegrynowski's report in</p> <p>10 November or, in fact, a status, like, based</p> <p>11 upon something you could read, a status</p> <p>12 account -</p> <p>13 DR. DENIC:</p> <p>14 A. Sometime in March, I believe, could be the</p> <p>15 April, March or April I received a spreadsheet</p> <p>16 from -</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Okay, so -</p> <p>19 DR. DENIC:</p> <p>20 A. - Mr. Gulliver, but not their documents.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Not the original reports?</p> <p>23 DR. DENIC:</p> <p>24 A. No.</p> <p>25 COFFEY, Q.C.:</p>	<p>Page 248</p> <p>1 this, I know you were interim clinical chief,</p> <p>2 but I'll be calling you clinical chief in that</p> <p>3 context here. And that's why at this point in</p> <p>4 time you would be copies or you would be sent,</p> <p>5 you would be one of those sent the e-mail</p> <p>6 because it would somewhat relate to your</p> <p>7 duties?</p> <p>8 DR. DENIC:</p> <p>9 A. That's correct.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Okay. Doctor, you've told the Commissioner</p> <p>12 that from your perspective, up to this point,</p> <p>13 up to that point in time you would report, as</p> <p>14 a pathologist, a percentage of ER and PR,</p> <p>15 whatever you saw?</p> <p>16 DR. DENIC:</p> <p>17 A. That's correct.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Made your own eyeball and you called it the</p> <p>20 way you saw it?</p> <p>21 DR. DENIC:</p> <p>22 A. That's correct.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And the oncologist, you felt, would, of the</p> <p>25 number you gave them, make what they felt</p>

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1 appropriate?

2 DR. DENIC:

3 A. That's correct.

4 COFFEY, Q.C.:

5 Q. Doctor, and you would have understood, I take

6 it, that there might be clinical ramifications

7 in you making a correct call between calling

8 something 20 and calling something 80? You

9 understood, look, you know, I got to be at

10 least fairly careful about this in the sense

11 of if it's closer to 20, call it 20 rather

12 than call it 80 if, in fact, it was 80?

13 DR. DENIC:

14 A. We are pathologists, we always trying to be

15 objective, so whatever we see, we report.

16 COFFEY, Q.C.:

17 Q. Would you have understood there might be

18 clinical ramifications between, for a

19 particular patient, between an ER of 20 and an

20 ER of 80 at times, depending upon the context

21 that there might be? Did you know that there

22 might be, at that time? You're just getting

23 yourself involved in this now as clinical

24 chief, did you appreciate that?

25 DR. DENIC:

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1 A. You mean now from the point of 2006?

2 COFFEY, Q.C.:

3 Q. Yes, in '06, when you're getting yourself

4 involved in this in the sense of you're being

5 asked to and -

6 DR. DENIC:

7 A. We knew that, and I, as well, that clinical

8 consideration for the positivity rate is above

9 ten percent of -

10 COFFEY, Q.C.:

11 Q. Cutoff, so -

12 DR. DENIC:

13 A. Cutoff. But I wouldn't completely use cutoff.

14 If you say cutoff, the people just say this is

15 ten and this is not. Because at the time I

16 believe it was well known that there was a

17 group of low expressers, as well, and it's

18 recognized it was a working meeting in

19 Switzerland, I believe, so--and where

20 subclassification of the positives came into

21 the place, so you have the ones which are

22 zero, which are negative, then you have a low

23 expresser, from one to ten, and everybody else

24 well expresser from ten. So -

25 COFFEY, Q.C.:

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1 Q. But even the fact there might be, say, 15 to

2 95, a 15 and a 95 wouldn't necessarily be

3 treated the same by an oncologist, you would

4 have understood that for some patients it

5 would matter whether it was 95 or 15? Would

6 you have understood that?

7 DR. DENIC:

8 A. But that wouldn't be my call -

9 COFFEY, Q.C.:

10 Q. No, I appreciate it's not your call.

11 DR. DENIC:

12 A. - (inaudible) would be that it's positive. I

13 wouldn't go into the treatment because the

14 treatment wasn't something from the very

15 beginning, obviously from St. Clare's Hospital

16 that why we were reporting, so we report

17 whatever it is, what we see on the slide and

18 if it's 15, so be it.

19 COFFEY, Q.C.:

20 Q. Oh, yes.

21 DR. DENIC:

22 A. So oncologists have to take that as 15.

23 COFFEY, Q.C.:

24 Q. But did you understand that there might be,

25 whatever the clinical ramifications might be,

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1 that there might be clinical ramifications,

2 depending upon whether the call was 15 or 95,

3 did you understand that at that time, when you

4 first got involved in this? Did you

5 appreciate that? I appreciate if you're

6 calling it, seeing it as 15, you'd call it 15,

7 if you saw it as 95, you'd call it as 95. But

8 did you, at that time were you aware that

9 there might be for the particular patient?

10 DR. DENIC:

11 A. I mean, it could be any ramification for the

12 patient who is positive and still is not going

13 to receive the therapy. I mean, I knew about

14 those kind of instances. But any great

15 ramification unless--I really don't know what

16 are you heading at because -

17 COFFEY, Q.C.:

18 Q. It will become apparent in a moment. So at

19 the time you called it like it was, as you saw

20 it, and that really then it was in the

21 oncologists' world whatever they were to make

22 of it?

23 DR. DENIC:

24 A. That's right.

25 COFFEY, Q.C.:

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<p>1 Q. Their approach?</p> <p>2 DR. DENIC:</p> <p>3 A. That's right.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Okay. Now, Doctor, in relation to this, as</p> <p>6 you said, in fact, you just told me now that</p> <p>7 cutoff, it's in the documents a number of</p> <p>8 places, you're a bit uncomfortable with the</p> <p>9 word itself, as a pathologist?</p> <p>10 DR. DENIC:</p> <p>11 A. You know, just because somebody is ten, I</p> <p>12 would say don't--just because number ten and</p> <p>13 cutoff is there so you just say, oh, you're</p> <p>14 not going to receive the therapy or something</p> <p>15 like that. That's why I don't like the word</p> <p>16 "cutoff".</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Doctor, were you aware of what the criteria</p> <p>19 were that had been used to determine who was</p> <p>20 going to be retested?</p> <p>21 DR. DENIC:</p> <p>22 A. The criteria, it was my understanding that</p> <p>23 criteria was to use until 2000 the patients</p> <p>24 that were tested until the end of 2000, 30</p> <p>25 percent and less and from 2001 to 2005, ten</p>	<p>1 sit here, as you sit here now, have you had</p> <p>2 any--do you have any concerns about it now?</p> <p>3 And here's where I'm going with it, Doctor, is</p> <p>4 this, is that we've heard evidence that</p> <p>5 certainly in 2001 some oncologists here in St.</p> <p>6 John's were still using 30 as kind of the rule</p> <p>7 of thumb determination of whether somebody was</p> <p>8 positive or not. And if, for example, in 2001</p> <p>9 someone was called a 20, say one of your</p> <p>10 patients you said was 20 percent and you</p> <p>11 reported it that way, that patient might have</p> <p>12 been, may very well have been treated by an</p> <p>13 oncologist as if the patient was negative but</p> <p>14 the patient wouldn't have been retested and</p> <p>15 whether the 20 is accurate or not, the patient</p> <p>16 has not been retested but was treated as,</p> <p>17 clinically as negative. So what I've just</p> <p>18 referred to now, are you aware of that</p> <p>19 possible scenario?</p> <p>20 DR. DENIC:</p> <p>21 A. I am.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Okay. When did you first become aware of</p> <p>24 that?</p> <p>25 DR. DENIC:</p>
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<p>1 percent and less.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. And when did you become aware of that?</p> <p>4 DR. DENIC:</p> <p>5 A. I mean, I had that knowledge through the</p> <p>6 tumour board, which was in February. I could</p> <p>7 have known that before or Dr. Cook might have</p> <p>8 briefed me about it and what was the cutoff,</p> <p>9 but I wasn't a part of the group that made any</p> <p>10 kind of decision.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Doctor, when you began to actually act as</p> <p>13 clinical chief in March, 2003 and then</p> <p>14 continued on, and we'll see your name then</p> <p>15 throughout certain documents, did you ever</p> <p>16 have occasion to question or to have any</p> <p>17 doubts about or concerns about the way that</p> <p>18 the 30 and ten had been utilized as cutoffs,</p> <p>19 and they were used as cutoffs in those periods</p> <p>20 of time in choosing the patients to be</p> <p>21 retested?</p> <p>22 DR. DENIC:</p> <p>23 A. No.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Have you up until now, up until today as we</p>	<p>1 A. I came aware of that approach and the concerns</p> <p>2 recently, it was this year. I would say</p> <p>3 sometime April, May.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And what, if anything, was thought about it,</p> <p>6 was it discussed, if so, by whom, and what was</p> <p>7 done about it?</p> <p>8 DR. DENIC:</p> <p>9 A. It was discussed at one of the meetings, I</p> <p>10 think involved various individuals from Ms.</p> <p>11 Pilgrim, Heather Predham, Dr. Laing, myself,</p> <p>12 Terry Gulliver, could have been Oscar Howell,</p> <p>13 so I think it was even Mr. Barrett, who is the</p> <p>14 epidemiologist, as well, that we discussed</p> <p>15 that.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And were any decisions made about it?</p> <p>18 DR. DENIC:</p> <p>19 A. I am not aware that any firm decision was made</p> <p>20 at the time, but it was, it was brought at the</p> <p>21 time to my attention that Dr. Laing also</p> <p>22 consulted one of the oncologists should we</p> <p>23 look into this group and I think the advice</p> <p>24 from that oncologist, I think, Maureen</p> <p>25 Trudeau, was that it would be worthwhile to</p>

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

15 COFFEY, Q.C.:

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

20 DR. DENIC:

21 A. That's right.

22 COFFEY, Q.C.:

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

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1 the sense of there were a number of,
2 certainly, I won't say many, but certainly a
3 number of people who went from zero to 40, 50,
4 70, 80 ER?

5 DR. DENIC:

6 A. That's correct.

7 COFFEY, Q.C.:

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

11 DR. DENIC:

12 A. That's correct.

13 COFFEY, Q.C.:

14 Q. Doctor, for example, for a patient in 2002,
15 2001 or 2002 patient who tested at 20, okay, I
16 take it that even leaving aside whether or not
17 the oncologist treated the person as positive
18 or negative, leaving that aside for the
19 moment, based upon 30, is it entirely possible
20 that if that patient's block was retested now,
21 that they might go from 20 to 80 or 20 to 90,
22 if other blocks went from zero to 80, is it
23 entirely possible that it would go from 20 to
24 80?

25 DR. DENIC:

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

10 COFFEY, Q.C.:

11 Q. Yes.

12 DR. DENIC:

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

24 COFFEY, Q.C.:

25 Q. Yes.

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1 DR. DENIC:

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

8 COFFEY, Q.C.:

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

15 DR. DENIC:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. The overall result. The fact that that was so
19 in under reporting ER, then for the years
20 2002, 2001, 2002, 2003 that if the current
21 results you were aware of hold true on the
22 others, the positives?

23 DR. DENIC:

24 A. That's correct.

25 COFFEY, Q.C.:

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1 Q. The positives, as a group, would probably, on
 2 retest, be higher, wouldn't it?
 3 DR. DENIC:
 4 A. Some of them they could, some of them they
 5 wouldn't change at all.
 6 COFFEY, Q.C.:
 7 Q. And how much higher and for which patients,
 8 you wouldn't know until you did it?
 9 DR. DENIC:
 10 A. That's correct. I mean, we retested some of
 11 the positive patients recently, not much
 12 difference that we found in these patients.
 13 They were positive, they stayed positive.
 14 Some of them were almost neck to neck with our
 15 results that we reported, some of them have a
 16 small variation. So -
 17 COFFEY, Q.C.:
 18 Q. Were there any with a large variation, do you
 19 know?
 20 DR. DENIC:
 21 A. Depends what you define as a large variation.
 22 COFFEY, Q.C.:
 23 Q. I know, I know.
 24 DR. DENIC:
 25 A. The way I'm -

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

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1 tissue, primary breast tumour tissue, they
 2 were the only ones that were retested for
 3 ER/PR and outside St. John's, for example,
 4 some ER/PRs that were non-primaries were
 5 retested. Are you aware of that?
 6 DR. DENIC:
 7 A. Might have been that they'd been picked up
 8 during the search. And I'm only aware of
 9 probably one case or -
 10 COFFEY, Q.C.:
 11 Q. Okay. I'll come at it this way, then. In St.
 12 John's it's your understanding that the only
 13 people retested were primary breast?
 14 DR. DENIC:
 15 A. That's correct.
 16 COFFEY, Q.C.:
 17 Q. Are you aware of what happened outside in the
 18 other health authorities in terms of which
 19 ER/PRs they had retested?
 20 DR. DENIC:
 21 A. No, but I assume that they should send -
 22 COFFEY, Q.C.:
 23 Q. Only primary breast?
 24 DR. DENIC:
 25 A. Primary breast. I think based on the memo

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1 that I seen from Dr. Cook or something like
 2 that, they should send out -
 3 COFFEY, Q.C.:
 4 Q. Doctor, in relation then to non-primary
 5 breast, okay, when you got involved as the
 6 clinical chief at the point you got involved,
 7 you understood that it was primary breast
 8 tumours that were being retested?
 9 DR. DENIC:
 10 A. That's correct.
 11 COFFEY, Q.C.:
 12 Q. Did you understand, were you given to
 13 understand the rationale as to why the other
 14 ER/PR tissue samples were not being retested,
 15 the non-primary breast tissue?
 16 DR. DENIC:
 17 A. You mean metastatic tissue in the lymph nodes,
 18 for example?
 19 COFFEY, Q.C.:
 20 Q. Yes. Or whatever. By the other ER/PR, and
 21 there were a number of other ER/PR tests
 22 ordered, why they were not retested?
 23 DR. DENIC:
 24 A. Why they are not retested, you want to test
 25 the primary lesion, I mean, that's the bottom

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<p>1 line, if it's present and you want to test it. 2 So I think that's the right way to do, test 3 the primary lesions. What can happen if you 4 test metastatic lesion, that the estrogen 5 expression in the metastatic lesion could be 6 different than the primary. 7 COFFEY, Q.C.: 8 Q. Okay. 9 DR. DENIC: 10 A. So therefore, and the reasons are well 11 described in the literature, that the 12 metastatic tumour is negative, the primary is 13 positive and other way around but in a lesser 14 degree. So, of course, you would go after the 15 primary source, which would be the primary 16 breast cancer rather than to go to the 17 metastasis. In case that for whatever reason 18 you don't have slides, blocks for the primary, 19 then you would opt to do metastasis and just 20 to see what you're going to get. 21 COFFEY, Q.C.: 22 Q. Doctor, are you aware of whether any 23 consideration was given at least by Eastern 24 Health to retesting ER/PR--I'm sorry, 25 retesting tumour tissue for ER/PR that was not</p>	<p>1 A. Oh, non-primary breast. 2 COFFEY, Q.C.: 3 Q. In other words, all the ER/PRs, all the other 4 ER/PRs, okay, there are a whole bunch of 5 blocks sitting over there in the General 6 Hospital and probably at St. Clare's that are 7 ER/PR tests were done, they have not been 8 retested because they're not primary breast 9 tissue tumours, right? 10 DR. DENIC: 11 A. (Inaudible). 12 COFFEY, Q.C.: 13 Q. If they were to be retested, the negatives, 14 for example, I'll use negatives here now, and 15 they were to convert, some of them, one or 16 more of them were to convert, is there a 17 possibility that the clinical care of a 18 patient could be affected by the result, by 19 the changed result? 20 DR. DENIC: 21 A. But depends on the primary tumour. Now, if 22 the patient had the primary tumour tested, if 23 that's the case, primary tumour and she has 24 metastasis tested, we usually don't test 25 metastasis unless, as I said, for the reason</p>
<p>1 primary breast? 2 DR. DENIC: 3 A. I only know of one case. 4 COFFEY, Q.C.: 5 Q. Okay. So I take it then no consideration is 6 being given to - 7 DR. DENIC: 8 A. Not to my knowledge, just for the reason I 9 stated. 10 COFFEY, Q.C.: 11 Q. Is there a possibility that if such retests 12 were to occur and there were changed results, 13 conversions, is there a possibility that any 14 one, any one patient might be assisted by 15 that? 16 DR. DENIC: 17 A. Could you repeat that? 18 COFFEY, Q.C.: 19 Q. If all of those that have not been retested, 20 all the non - 21 DR. DENIC: 22 A. Which one? 23 COFFEY, Q.C.: 24 Q. All the non-primary breasts. 25 DR. DENIC:</p>	<p>1 that there's no primary tumour. So you would 2 treat the patient based on that expression. 3 COFFEY, Q.C.: 4 Q. Example, primary is negative, retested 5 negative, but there is a possibility that the 6 metastasis is positive, isn't there? 7 DR. DENIC: 8 A. That's correct, it is, it is a possibility 9 because rare occasions that can happen. 10 COFFEY, Q.C.: 11 Q. If that, the block representing the metastasis 12 was to be retested and it was now found to be 13 positive. 14 DR. DENIC: 15 A. Okay. 16 COFFEY, Q.C.: 17 Q. Because it hasn't been retested as of yet, 18 could that affect the patient's care? Is it 19 your understanding that it might? 20 DR. DENIC: 21 A. It can. However, that has to be a part of the 22 clinical guidelines, you know, how they treat 23 the patient. Because I don't think it is our 24 practice, and I don't think so--probably Dr. 25 Laing can reflect to that, when do you retest</p>

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

10 COFFEY, Q.C.:

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

15 DR. DENIC:

16 A. Oh, yes.

17 COFFEY, Q.C.:

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

20 DR. DENIC:

21 A. There's no need for those ones.

22 COFFEY, Q.C.:

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

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1 reported as a percentage?

2 DR. DENIC:

3 A. No. It wouldn't be percentage -

4 COFFEY, Q.C.:

5 Q. It's not -

6 DR. DENIC:

7 A. - it's positive, negative.

8 COFFEY, Q.C.:

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

11 DR. DENIC:

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

14 COFFEY, Q.C.:

15 Q. Okay.

16 DR. DENIC:

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

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1 COFFEY, Q.C.:

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

6 DR. DENIC:

7 A. That's correct.

8 COFFEY, Q.C.:

9 Q. For non-breast cases?

10 DR. DENIC:

11 A. That's correct.

12 COFFEY, Q.C.:

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

17 DR. DENIC:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Give her some examples.

21 DR. DENIC:

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

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

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<p>1 clinician and say, she has that lesion, you 2 know, but cytokeratin 7 is negative, but 3 cytokeratin 20 is positive, that rules in 4 bowel, but rules out breast.</p> <p>5 So if somebody has breast cancer, as 6 such, most common would be to think that this 7 is coming from the breast, if you don't know 8 anything about this patient. So you still 9 would be ordering cytokeratin 7. I would 10 order the cytokeratin 20 to rule out the other 11 possibility, which is bowel cancer, which is 12 very common in Newfoundland, but I would order 13 S100, which is still positive in the breast. 14 I would order gross cystic disease fluid 15 protein, which is another immunostain which is 16 positive in the breast, and I could have 17 ordered ER and PR.</p> <p>18 So when I receive the batteries of the 19 stains and I go through all of this and I 20 said, okay, cytokeratin 20 negative, move the 21 bowel cancer away. So cytokeratin 7 positive, 22 that means still breast, could be lung 23 primary, could be pancreas or other biliary 24 tract cancers. So it did narrow down, but not 25 completely. Then I said, okay, what about</p>	<p>1 determine where the lesion is coming from, but 2 furthermore, why I said these days are over- 3 utilization of the stains, and we even send a 4 memo around and "don't use ER/PR because we 5 are wasting the stains for that reason," but 6 the single reason that ER/PR negative stain 7 doesn't rule out breast. So if you have the 8 lesion on the skin and could be still 9 metastatic lesion from the breast, it could be 10 negative. So you didn't rule it out, breast, 11 because ER/PR can be positive in lung cancers 12 and the cancer come from the genitourinary 13 tract like endometrium, you know, so you 14 didn't go anything with ER/PR. So in that 15 context, you don't retest those patients, 16 because this is not done for the prognostic 17 purposes. That's what the pathologist uses, 18 utilizing the stain trying to narrow down 19 where the tumour is coming from.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. So Doctor, for the prognostic purposes, ER/PR 22 is used for primary breast and metastatic 23 breast cancer, that's two instances?</p> <p>24 DR. DENIC:</p> <p>25 A. That's correct.</p>
<p>Page 274</p> <p>1 S100? S100 is positive, it's not specific, is 2 positive in some tumours of the--malignant 3 tumours of the skin, for example, like 4 melanomas, but it's also positive in the 5 breast. So now I have cytokeratin 7 positive. 6 I have S100 positive. So I am closer to think 7 that this lesion is the breast lesion. And 8 third stain that I'm ordering is gross cystic 9 disease fluid protein. It's large number of 10 breast, they express this antigen or gross 11 cystic disease. So if you find this, now I 12 have three of them telling me that this is 13 breast.</p> <p>14 And on top of this, if I order PR, ER/PR, 15 that could be negative because people are 16 negative with ER/PR of course. Still doesn't 17 rule it out, breast, because I have the three 18 of them telling me it's breast. But if it's 19 positive, I nailed it down that this is--so I 20 have four or five stains utilizing to pinpoint 21 the lesion, because it's a different treatment 22 of metastatic than a primary lesion of the 23 lung, for example.</p> <p>24 So ER/PR in that context would be just 25 adjunct to batteries of the stains trying to</p>	<p>Page 276</p> <p>1 COFFEY, Q.C.:</p> <p>2 Q. Prognostically. Are they the only -</p> <p>3 DR. DENIC:</p> <p>4 A. Metastatic breast cancer.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Yes. Are they the only two prognostic 7 situations in which ER/PR is ordered? Is there 8 any other? I'm not suggesting there is.</p> <p>9 DR. DENIC:</p> <p>10 A. Not that I know of.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Okay. In terms then, Doctor, of ER/PR's 13 utilization otherwise, for all other purposes, 14 okay, the results are either accurate or 15 they're not. If they're false negatives, if 16 the results that have been done between 1997- 17 2005, in all those other situations were false 18 negatives, if there were any false negatives 19 there, could there have been an effect on how 20 the tumour was classified and how it was dealt 21 with?</p> <p>22 DR. DENIC:</p> <p>23 A. I would say absolutely not, because this is 24 not a way that we subclassify the metastatic 25 tumour.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. Okay, so I ask you then, Doctor, then why was</p> <p>3 anyone bothering to do it at all?</p> <p>4 DR. DENIC:</p> <p>5 A. Why was anybody doing it all?</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Yes.</p> <p>8 DR. DENIC:</p> <p>9 A. Mr. Coffey, that's why I said today we think</p> <p>10 that's over utilization of the stains and as</p> <p>11 such, why we should be using those ones</p> <p>12 because I use myself too at certain point.</p> <p>13 Again, as I say, you're working--you're trying</p> <p>14 to narrow down the stuff. If it's positive,</p> <p>15 it's great. But not alone positive, not the</p> <p>16 stand-alone positive. It's not utilized in</p> <p>17 any kind of treatment. It was utilized -</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. No, I'm not asking about treatment now.</p> <p>20 DR. DENIC:</p> <p>21 A. No, but what I'm saying, it's not--it was just</p> <p>22 utilized as a panel of the stains to narrow</p> <p>23 down where the tumour is coming from.</p> <p>24 THE COMMISSIONER:</p> <p>25 Q. Sorry, did I understand you to say that if</p>	<p>1 Q. No, ER/PR is not used there?</p> <p>2 DR. DENIC:</p> <p>3 A. No, definitely not. Definitely not.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And so for, in the context then of breast</p> <p>6 cancer, whether primary or metastatic, you</p> <p>7 understand that all the primaries, at least</p> <p>8 the ones you are aware of exist, and</p> <p>9 classified as negative, based upon the</p> <p>10 criteria that was used back in 2005, have been</p> <p>11 retested?</p> <p>12 DR. DENIC:</p> <p>13 A. That was my understanding. I know one case,</p> <p>14 the lymph node was tested.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And for metastatic breast cancer, suspected</p> <p>17 metastatic breast cancer, generally in St.</p> <p>18 John's, they were not retested? ER/PRs were</p> <p>19 not retested for them?</p> <p>20 DR. DENIC:</p> <p>21 A. No, unless inadvertently something fell into</p> <p>22 it.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. You've indicated that for the ones in the</p> <p>25 second category there that there could be</p>
<p>Page 278</p> <p>1 such a case came through your lab today, you</p> <p>2 would not order an ER/PR test?</p> <p>3 DR. DENIC:</p> <p>4 A. That's correct.</p> <p>5 THE COMMISSIONER:</p> <p>6 Q. Okay, and what's more, there is a directive in</p> <p>7 effect to that effect? Seemed to be saying</p> <p>8 that that was communicated to everybody else</p> <p>9 as well?</p> <p>10 DR. DENIC:</p> <p>11 A. Yeah, that's right. That's right, I think we</p> <p>12 communicated, so even to outside the hospitals</p> <p>13 as well and just said "don't order it" because</p> <p>14 it doesn't have any value because positive or</p> <p>15 negative doesn't mean it's breast, because</p> <p>16 there is other tissue express estrogen and</p> <p>17 progesterone, as I said, even the lung tumours</p> <p>18 can have estrogen and progesterone receptor</p> <p>19 positive.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. In terms of gynecological concern, cancers,</p> <p>22 concerns?</p> <p>23 DR. DENIC:</p> <p>24 A. No.</p> <p>25 COFFEY, Q.C.:</p>	<p>Page 280</p> <p>1 situations where it could have, for individual</p> <p>2 patients, treatment ramifications if the</p> <p>3 original report was a false negative and</p> <p>4 hasn't been retested for metastatic breast</p> <p>5 cancer?</p> <p>6 DR. DENIC:</p> <p>7 A. For metastatic in the lymph node.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Yes.</p> <p>10 DR. DENIC:</p> <p>11 A. May have, but I--that depends on the case. I</p> <p>12 mean, and this is not that I'm comfortable</p> <p>13 talking about. The oncologist should address</p> <p>14 that.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And for all other ER/PR tests, for the reasons</p> <p>17 you've explained, you cannot think of any</p> <p>18 reason why a false negative ER result would be</p> <p>19 of any concern at all clinically?</p> <p>20 DR. DENIC:</p> <p>21 A. That's--I mean, I can guarantee that it's not</p> <p>22 a concern because it's never utilized as a</p> <p>23 single test.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. No, see, Doctor, see, this is what I'm--you</p>

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<p>1 say single test, all right. Then we can get 2 into discussions about well, was it ever 3 utilized as a part of two tests or is one of 4 three or one of four or one of five, and 5 arguably, I suppose, if it's one of five, it 6 has less significance than if it has one of 7 two. So what I'm asking you is--I'm not just 8 talking about the four panel or the five 9 panel. I'm asking you, period, okay - 10 DR. DENIC: 11 A. And the answer is no. 12 COFFEY, Q.C.: 13 Q. No, okay. So no matter whether it's used - 14 DR. DENIC: 15 A. The answer is no, even if it's two panel. 16 COFFEY, Q.C.: 17 Q. Okay. Okay, now, we're looking at 1749 and in 18 terms of that, just trying to get some sense 19 for the Commissioner of kind of what, at the 20 time, when you first got involved your 21 understanding was overall. Ms. Wegrynowski 22 is, this indicates, it's an e-mail from Denise 23 Dunne, March 6th, 2006 to a number of 24 individuals, including yourself. "Further to 25 my e-mail below, with respect to Trish</p>	<p>1 lab. 2 COFFEY, Q.C.: 3 Q. I'm sorry, what was that? 4 DR. DENIC: 5 A. That she was pleased that there is the support 6 given by the management - 7 COFFEY, Q.C.: 8 Q. Management, okay. 9 DR. DENIC: 10 A. - towards moving to the quality in the 11 immunohistochemistry lab. She also said that 12 she wasn't sure that all SOPs were written. I 13 think the fridges were not in place at the 14 time. I'm not certain about thermometers in 15 the fridges. So she had some concern. It was 16 a positive and negative vibes that I got from 17 her on that exit interview. 18 COFFEY, Q.C.: 19 Q. Doctor, at that time, I'm going to suggest to 20 you that, in fact--I'm going to ask you, how 21 many SOPs had been written? 22 DR. DENIC: 23 A. I don't know at that time because I just took 24 my position and I wasn't checking on that. 25 COFFEY, Q.C.:</p>
<p>Page 282</p> <p>1 Wegrynowski, I wonder if you would follow up 2 with her directly. She would like to have 3 some information to update her on our progress 4 prior to her arrival. I advised her that we 5 have a spreadsheet of issues that we're 6 working on in an updated format. Terry, once 7 you talk to her, that may be sufficient to 8 help her prepare for her visit." 9 Doctor, did you deal with Ms. Wegrynowski 10 when she came to St. John's in the spring of 11 '06? 12 DR. DENIC: 13 A. I met her and being a part of the team that 14 conducted the exit interview. 15 COFFEY, Q.C.: 16 Q. And what do you recall about the exit 17 interview? 18 DR. DENIC: 19 A. I think that interview was held at Mr. 20 Gulliver's office. So Mr. Gulliver was there, 21 Mr. Dyer, Dr. Fontaine, myself and Dr. Cook. 22 She started with she was pleased in a way that 23 technologists received the training, that 24 there is support of management towards moving 25 towards the quality in immunohistochemistry</p>	<p>Page 284</p> <p>1 Q. Did you make any inquiries? 2 DR. DENIC: 3 A. I don't remember I made at the time any 4 inquiries. 5 COFFEY, Q.C.: 6 Q. When you did make--well, when did you make 7 inquiries about that? 8 DR. DENIC: 9 A. Later on, I think in May. We had a meeting 10 with Dr. Williams where we were discussing 11 about the action items with Dr. Elms and Dr. 12 Makarla, because at that time Dr. Fontaine was 13 out of the picture. He resigned from that 14 duty. 15 COFFEY, Q.C.: 16 Q. And I take it this was a meeting because this 17 is a meeting to deal with the 18 immunohistochemistry issue overall? 19 DR. DENIC: 20 A. I think the action plan to be made how to deal 21 with the recommendations. 22 COFFEY, Q.C.: 23 Q. Okay, and that's when SOPs were certainly, I 24 take it, came up at that meeting? 25 DR. DENIC:</p>

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<p>1 A. That's right.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. And what did you learn then about the status</p> <p>4 of the SOPs?</p> <p>5 DR. DENIC:</p> <p>6 A. I don't think that they were written, and if</p> <p>7 anything was written about it.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Now Doctor, in relation to that, if we could,</p> <p>10 if we could look, please, at Exhibit P-1751?</p> <p>11 Doctor, this is an e-mail from yourself, March</p> <p>12 24th 2006, to Denise Dunne re: IHC quality</p> <p>13 review. You write "Hi, Dr. Williams. Can you</p> <p>14 give her our spreadsheets so she will know in</p> <p>15 advance what has been accomplished?" Signed</p> <p>16 Nash. And because Dr. Williams, on the 24th,</p> <p>17 earlier that day had written to you saying</p> <p>18 "Nash, Terry, Barry, do we have anything to</p> <p>19 send to Trish? Thanks, Bob." And she had,</p> <p>20 herself, we look down through the page here,</p> <p>21 she had sent an e-mail on March 23rd to Dr.</p> <p>22 Williams saying "if there are any protocols or</p> <p>23 paperwork that you would like me to review</p> <p>24 prior to my arrival, they can be faxed to" her</p> <p>25 number, and so she was looking for any</p>	<p>1 Wegrynowski, updated April 25/06, compiled</p> <p>2 December 16th '05, you see in the top right-</p> <p>3 hand corner there. And that's been updated on</p> <p>4 April 25th. Doctor, look down through this,</p> <p>5 it's--on the second page of the exhibit, there</p> <p>6 are 30 recommendations, and while we're on the</p> <p>7 topic, Doctor, I'm going to go on to the next</p> <p>8 page of the exhibit, which is the document</p> <p>9 entitled the same thing, except it's updated</p> <p>10 June 30th '06 and we go to page three and then</p> <p>11 page four of this exhibit. The number of</p> <p>12 recommendations has grown from April 25th,</p> <p>13 2006 from 30 to 52 on June 30th '06. So</p> <p>14 Doctor, I guess, there's 22 more</p> <p>15 recommendations.</p> <p>16 Doctor, when you took over and then met</p> <p>17 with Ms. Wegrynowski on her exit interview,</p> <p>18 what understanding did you have going into</p> <p>19 this, as to where the lab was with her</p> <p>20 recommendations from the fall?</p> <p>21 DR. DENIC:</p> <p>22 A. That's correct, I mean, it was to find out</p> <p>23 where the lab was.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Okay, so by the end of April, you still,</p>
<p>1 protocols or paperwork St. John's would like</p> <p>2 her to review. Bob Williams was asking</p> <p>3 yourself and Mr. Gulliver and Mr. Dyer whether</p> <p>4 you have anything to give her and you were</p> <p>5 telling Ms. Dunne to give her the spreadsheet.</p> <p>6 DR. DENIC:</p> <p>7 A. That's correct.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. So certainly, there were no protocols to give</p> <p>10 her at that point. Otherwise, presumably you</p> <p>11 would have told her to?</p> <p>12 DR. DENIC:</p> <p>13 A. I think the spreadsheet, this was all</p> <p>14 happening before I even came into the picture.</p> <p>15 There were some of the items that were ticked</p> <p>16 had been done, so while obviously there was no</p> <p>17 paperwork to present, there were some of the</p> <p>18 items that were addressed at that time, so</p> <p>19 that's why I was saying at least submit what</p> <p>20 had been dealt with.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Doctor, if we could look, please, at Exhibit</p> <p>23 P-0277? This is a spreadsheet</p> <p>24 recommendations, immunohistochemistry service,</p> <p>25 spreadsheet, Dr. D. Banerjee, Trish</p>	<p>1 yourself, had not had the opportunity to</p> <p>2 become apprised of where they are with all</p> <p>3 this?</p> <p>4 DR. DENIC:</p> <p>5 A. No, I think you have to understand, it's very</p> <p>6 early in my position and cannot expect this</p> <p>7 kind of past to be accomplished even in a</p> <p>8 month, if month.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Doctor, your impression, based upon the exit</p> <p>11 interview of Ms. Wegrynowski was that she had</p> <p>12 some positive things to say and some -</p> <p>13 DR. DENIC:</p> <p>14 A. Less positive.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. - less positive, negative or helpful</p> <p>17 criticism?</p> <p>18 DR. DENIC:</p> <p>19 A. That's correct.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Doctor, going out of that exit interview and</p> <p>22 coming away from it, from your perspective,</p> <p>23 whose responsibility was it or what</p> <p>24 responsibility did you have to implement or</p> <p>25 get involved in implementing that?</p>

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1 DR. DENIC:
 2 A. I had a responsibility, it is a mutual
 3 responsibilities really. Mr. Dyer and Mr.
 4 Gulliver were supposed to deal with the
 5 technical stuff, which is quite
 6 understandable, and I was supposed to address
 7 the issues of subspecialization and a few
 8 things more. While you can see in the
 9 spreadsheet, which I never objected, it says
 10 that "Dr. Denic, do evaluation of appropriate
 11 use of negative controls," which really wasn't
 12 -
 13 COFFEY, Q.C.:
 14 Q. Okay, you're looking at page five?
 15 DR. DENIC:
 16 A. Page five, and sausage block, which really
 17 it's more technical stuff, but I never
 18 objected, as I said, I'm going to just assign
 19 this to Dr. Elms and Dr. Makarla at that time.
 20 So you can see that these are the technical
 21 stuff that I was charged. I think Mr.
 22 Gulliver put my name on it, probably in a good
 23 faith that probably I'm going to be pushing
 24 this to Dr. Elms and Dr. Makarla, and so, but
 25 the main item that I had to deal with is to

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1 subspecialize obviously people, because vast
 2 majority of these recommendations are
 3 technical.
 4 COFFEY, Q.C.:
 5 Q. Doctor, what was your understanding as to what
 6 it was Ms. Wegrynowski was supposed to review
 7 in the spring of 2006?
 8 DR. DENIC:
 9 A. She was supposed to review
 10 immunohistochemistry lab, pathology lab as
 11 such related to the immunohistochemistry, but
 12 she also, along that course, she did made some
 13 recommendations too to the other parts of the
 14 lab and going to the Meditech, which wasn't
 15 really the part of immunohistochemistry. In
 16 one way, of course, you log and everything
 17 immunohistochemistry, but I think she made the
 18 suggestion of standardizing of reporting
 19 diagnosis versus interpretation which is
 20 really nothing related to
 21 immunohistochemistry.
 22 COFFEY, Q.C.:
 23 Q. So that was from your understanding of what
 24 her role was. Did you ask her to come or was
 25 that Dr. Williams that asked?

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

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

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<p>1 lines.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Did you have any understanding about why Dr.</p> <p>4 Banerjee thought that would be advisable?</p> <p>5 DR. DENIC:</p> <p>6 A. The idea to standardize fixation would be</p> <p>7 since we are central lab and we are receiving</p> <p>8 the tissue from the peripheral labs.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. For all IHC, in fact.</p> <p>11 DR. DENIC:</p> <p>12 A. For all IHC, that we should have the same</p> <p>13 processes in place, such as fixation, which he</p> <p>14 found in one of his recommendations as a</p> <p>15 culprit for--possible culprit for the failure</p> <p>16 of the test, and I think that was the reason.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. So in terms of implementing then, Dr.</p> <p>19 Banerjee's recommendations, who was</p> <p>20 responsible for that?</p> <p>21 DR. DENIC:</p> <p>22 A. It would be myself.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. In particular, addressing the issue of</p> <p>25 fixation, standardized fixation protocol or</p>	<p>1 find enclosed a template for reporting of the</p> <p>2 ER/PR and HER2/neu. Sincerely, Nash Denic."</p> <p>3 And you have attached there a Word document.</p> <p>4 DR. DENIC:</p> <p>5 A. That's correct.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Which, I take it, is the template. So Doctor,</p> <p>8 why the template for reporting of ER/PR and</p> <p>9 HER2/neu at that point in time?</p> <p>10 DR. DENIC:</p> <p>11 A. I wasn't quite certain about what did they</p> <p>12 have at the periphery and how they would log</p> <p>13 their cases in. This was just for information</p> <p>14 to be used.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And it was a suggestion, I take it?</p> <p>17 DR. DENIC:</p> <p>18 A. That's right.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And what had happened to cause you to have to</p> <p>21 send out the e-mail about sending in the</p> <p>22 actual original report from Mount Sinai</p> <p>23 Hospital along with the pathology report? I</p> <p>24 take it there had been a couple of cases at</p> <p>25 least where there were transcription errors?</p>
<p>Page 294</p> <p>1 approach, you understood that that would be</p> <p>2 your responsibility?</p> <p>3 DR. DENIC:</p> <p>4 A. That's correct.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Doctor, if we could look, please, at Exhibit</p> <p>7 P-2639? And Doctor, in the meantime, as it</p> <p>8 were, in your first month as clinical chief,</p> <p>9 this is an e-mail from yourself on March 27th,</p> <p>10 2006 to--well, that's probably all the</p> <p>11 pathologists in St. John's at the time?</p> <p>12 DR. DENIC:</p> <p>13 A. That's correct.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Subject is ER/PR and HER2/neu reports, and to</p> <p>16 be fair, it's to pathologists, for example,</p> <p>17 outside St. John's as well. I notice Maurice</p> <p>18 Dalton's name is there. It says "please be</p> <p>19 advised that due to some problems arising from</p> <p>20 inaccurate transcription or interpretation of</p> <p>21 the reports for ER/PR and HER2/neu received</p> <p>22 from Mount Sinai Hospital from Toronto, the</p> <p>23 Cancer Clinic is requesting the original</p> <p>24 report from Mount Sinai Hospital be sent along</p> <p>25 with your pathology reports. Also, please</p>	<p>Page 296</p> <p>1 DR. DENIC:</p> <p>2 A. That's correct. Not that I would have known</p> <p>3 that. I received a call from Dr. Joy McCarthy</p> <p>4 and she told me that they noticed there had</p> <p>5 been a couple of cases, a few, that they</p> <p>6 picked up transcription errors, and if I can</p> <p>7 address this with the pathologists across the</p> <p>8 province. Not only in the role as the</p> <p>9 clinical chief, but I signed it also as the</p> <p>10 president of NAP, you know, because I acted as</p> <p>11 the president of NAP as well.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. So Doctor, were there any other problems</p> <p>14 subsequently that you were aware of anyway,</p> <p>15 were brought to your attention about kind of</p> <p>16 the transcription error relating to the ER/PR</p> <p>17 ?</p> <p>18 DR. DENIC:</p> <p>19 A. No, nobody brought to me from the Cancer</p> <p>20 Centre.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Okay. Exhibit P-2068? Doctor, this is</p> <p>23 entitled Discipline of Laboratory Medicine,</p> <p>24 Minutes of meeting, March 28th, 2006. Would</p> <p>25 this be a program meeting?</p>

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1 DR. DENIC:
 2 A. That's right.
 3 COFFEY, Q.C.:
 4 Q. That's what you refer to as a program meeting?
 5 DR. DENIC:
 6 A. That's right. They changed its name.
 7 COFFEY, Q.C.:
 8 Q. Yes, but so where we see Discipline of
 9 Laboratory Medicine, minutes of meeting -
 10 DR. DENIC:
 11 A. That's right.
 12 COFFEY, Q.C.:
 13 Q. - in fact -
 14 DR. DENIC:
 15 A. These are now joint program and discipline
 16 meetings.
 17 COFFEY, Q.C.:
 18 Q. And here, you called it to order. I take it
 19 you were chairing it because you were clinical
 20 chief?
 21 DR. DENIC:
 22 A. That's correct.
 23 COFFEY, Q.C.:
 24 Q. And then there's, under new business, quality
 25 assurance, you thank Dr. Cook for his work,

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1 and then "implementation of the new quality
 2 assurance program was discussed at length.
 3 Dr. Beverley Carter will act as manager of the
 4 new quality management program for the
 5 pathology department. There will be a
 6 technical member and a clerical member of the
 7 team. Dr. Carter will act independently and
 8 answer to quality management team. This is
 9 supported by Dr. Williams, VP Medical. Dr.
 10 Morris-Larkin expressed concern about being
 11 audited." I take it Dr. Larkin worked at the
 12 General Hospital?
 13 DR. DENIC:
 14 A. That's correct.
 15 COFFEY, Q.C.:
 16 Q. The next page, the minutes go on, "Dr. Denic
 17 stated that random slides would be audited."
 18 So I take it you were responding here to Dr.
 19 Larkin's expression of concern?
 20 DR. DENIC:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. "Dr. Carter says that the random cases will be
 24 picked by the technologist who is working with
 25 the quality management program. Dr. Morris-

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

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

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<p>1 March of 2006.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. So Doctor, just so we're clear, this quality</p> <p>4 management team was internal to the pathology</p> <p>5 department?</p> <p>6 DR. DENIC:</p> <p>7 A. It's part of the pathology department.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Part of it, and internal to it?</p> <p>10 DR. DENIC:</p> <p>11 A. That's correct.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Now the quality assurance program, which is</p> <p>14 the way it's described, just reading what's</p> <p>15 there, where is--this here, where--this</p> <p>16 quality assurance program, how, if at all, did</p> <p>17 that relate to the quality management program</p> <p>18 for the pathology department or is it the same</p> <p>19 thing?</p> <p>20 DR. DENIC:</p> <p>21 A. It's the same thing, you know, just--quality</p> <p>22 assurance is really a part of the quality</p> <p>23 management, you know. Quality control or</p> <p>24 quality assurance, quality management is</p> <p>25 overseeing the entire system. So, I mean,</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. And taking over then as clinical chief, and</p> <p>3 being approached in the way you were, this was</p> <p>4 an issue you were going to push?</p> <p>5 DR. DENIC:</p> <p>6 A. That's right.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Doctor, there's a reference to the shortage of</p> <p>9 staff pathologists and potential for</p> <p>10 recruiting them, and--which you told the</p> <p>11 Commissioner about earlier in terms of</p> <p>12 recruiting some of the residents, about them</p> <p>13 joining after graduation in June is referred</p> <p>14 to there, and then, though, there's a</p> <p>15 reference at the bottom of the page, you</p> <p>16 encouraged the idea of pathologists</p> <p>17 subspecializing?</p> <p>18 DR. DENIC:</p> <p>19 A. That's correct.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And the next page, "Dr. Matheson expressed</p> <p>22 that option that subspecializing is not always</p> <p>23 good. If a person subspecializing leaves, the</p> <p>24 department could have a fair amount of</p> <p>25 trouble", and you felt that this problem could</p>
<p>1 it's just a wording.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Okay, and here on page two, Doctor, Dr. Cook</p> <p>4 is noted as having said, "There was no QA</p> <p>5 committee before November, 2004", and we've</p> <p>6 seen materials relating to--in fact, that</p> <p>7 there was one set up then. I take it that you</p> <p>8 were implementing one--as you were</p> <p>9 implementing one in March of 2006, had the QA</p> <p>10 committee that dated back to November, 2004,</p> <p>11 for pathology, had that been inactive?</p> <p>12 DR. DENIC:</p> <p>13 A. That was inactive.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Inactive. So when had it gone inactive, how</p> <p>16 long had it been inactive?</p> <p>17 DR. DENIC:</p> <p>18 A. I wasn't a part of that committee, so it was a</p> <p>19 short-lived committee.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Okay.</p> <p>22 DR. DENIC:</p> <p>23 A. So I--I don't believe it lasted more than a</p> <p>24 year or maybe even less. I'm not quite</p> <p>25 certain about it.</p>	<p>1 be solved by overlapping subspecialties</p> <p>2 studied, okay, that was your response.</p> <p>3 DR. DENIC:</p> <p>4 A. That's correct.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. How then has that evolved since, and I</p> <p>7 appreciate there had been shortages of staff?</p> <p>8 DR. DENIC:</p> <p>9 A. It did evolve, of course, and we were going</p> <p>10 through the certain hurdles, and, obviously,</p> <p>11 even now you realize one of the comments</p> <p>12 that's made by the professor of the pathology</p> <p>13 at that time, he was still retired, but coming</p> <p>14 at a meeting, and neuropathologist, Dr.</p> <p>15 Matheson, the man with the great experience.</p> <p>16 Being in a high turnover like we had is--</p> <p>17 sustaining subspecialties, today you have two</p> <p>18 people reporting certain tissue, and suddenly</p> <p>19 overnight, they disappear. That's what</p> <p>20 happened with the breast group. We started</p> <p>21 with four, and then one by one they left. One</p> <p>22 of them left because the pathologist found no</p> <p>23 interest in breast pathology per se. The</p> <p>24 second pathologist went to BC and currently</p> <p>25 practising in BC. Who left behind was Dr.</p>

<p style="text-align: right;">Page 305</p> <p>1 Cook and Dr. Beverley Carter, and at the end 2 of the day I came back to ground zero in May. 3 Nobody left from them, and all of these people 4 were reporting just breast cases. So you're 5 almost cutting the arms from the rest of the 6 people, just giving a certain tissue type to 7 the certain group of people that not 8 necessarily going to be there in a year time, 9 and then you go back to your own staff and 10 say, okay, guys, now you're going to take it 11 back and now you're going to be reporting the 12 breast tissue, and they obviously going to 13 tell you, no, and because--not going to tell 14 you no because they don't want to do it, 15 because it's not safe any more. Because if 16 you're not reporting certain stuff, then 17 you're losing the grip on a certain tumour and 18 tissue type and reporting, and using that eye 19 that otherwise you would have for that tissue. 20 So that's what it's all about. So since then, 21 I sent another memo explaining the value of 22 the subspecialty training, and subspecialty 23 reporting to the pathologists, and after that 24 I also asked pathologists to send me a list of 25 their interests, tumour site interests, so</p>	<p style="text-align: right;">Page 307</p> <p>1 Clare's, and I have a great interest and they 2 are using me as internal consultant for the 3 lung. So we are moving along, and I think we 4 addressed most vulnerable issues in pathology. 5 COFFEY, Q.C.: 6 Q. So, Doctor, is any of this written down 7 anywhere in terms of like a schematic chart 8 or, you know, in terms of -- 9 DR. DENIC: 10 A. I think you must hear of the breast group -- 11 COFFEY, Q.C.: 12 Q. Yes, the breast group, yes. 13 DR. DENIC: 14 A. And--oh, schematic chart for how we divide the 15 interest. 16 COFFEY, Q.C.: 17 Q. Yes. 18 DR. DENIC: 19 A. I think I submitted to my lawyers and that you 20 can get. It was like a spreadsheet. 21 COFFEY, Q.C.: 22 Q. What I'm getting at, Doctor, is this -- 23 DR. DENIC: 24 A. Is a spreadsheet. 25 COFFEY, Q.C.:</p>
<p style="text-align: right;">Page 306</p> <p>1 that I can probably break them down into 2 certain groups, and that's what happened. But 3 only few groups been lifted off the ground 4 really, which is the first breast group, and 5 they had the first official meeting in 6 November of 2006, defining their terms of 7 reference and the way of the practice. The 8 second group that was--that's practising as 9 such is the prostate group, the group for the 10 prostate. They are reporting on needle core 11 biopsies of prostate. Then we have the liver 12 group in the meantime, although now this group 13 is cut in half because Dr. Beverley Carter was 14 part of the group. So now I have pretty much 15 Dr. Lynn Morris-Larkin as a group of one, and 16 we have a lymphoma group which is active, 17 which is a group that looks into the 18 malignancies of--not only malignancy, but 19 there's benign diseases as well of the lymph 20 nodes. While we don't still have what we call 21 ENT group for the ear, nose and throat 22 subspecialty, it's pretty much specialized 23 service at St. Clare's Hospital. It's only a 24 few of us are doing ENT service. Lung group, 25 we are still at St. Clare's, specialize at St.</p>	<p style="text-align: right;">Page 308</p> <p>1 Q. It has been organized to the extent that it 2 has been reduced to writing? From your 3 perspective, as the Chief of Laboratory 4 Service, from your perspective in approaching 5 this, you've actually written all this down? 6 DR. DENIC: 7 A. That's right, a spreadsheet that tells you 8 which people belongs in it. In the meantime, 9 obviously, it hasn't been updated because we 10 have so many people leaving now, but that 11 spreadsheet is available and I was thinking 12 would have been a part of the exhibits. 13 COFFEY, Q.C.: 14 Q. Yes, and -- 15 COMMISSIONER: 16 Q. Mr. Coffey, it's nearing the end of the day. 17 COFFEY, Q.C.: 18 Q. Thank you. Just before finishing up, 19 Commissioner, if we could look at this page 20 here, page three, "The pathology assistants", 21 you're noted as having said some people were 22 interviewed for the pathology assistants? 23 DR. DENIC: 24 A. Yes. 25 COFFEY, Q.C.:</p>

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- 1 Q. And one with experience is starting on Monday.
2 So this--at this point in time, March of 2006,
3 is the beginning of pathology assistants in
4 St. John's?
5 DR. DENIC:
6 A. That's correct.
7 COFFEY, Q.C.:
8 Q. And four are going to be trained. Perhaps
9 then what I'll do is when we come back
10 tomorrow, I'll take up with you where you are
11 with the pathology assistants.
12 DR. DENIC:
13 A. Okay.
14 THE COMMISSIONER:
15 Q. Okay, we'll meet at 9:30 in the morning.
16 COFFEY, Q.C.:
17 Q. Thank you, Commissioner.

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

<p>-\$-</p> <p>\$100,000 [1] 169:14 \$2,000 [1] 170:21 \$21,000 [1] 172:14 \$5,000 [2] 171:4 172:11</p> <p>-&-</p> <p>& [4] 60:7 88:5,7 224:8</p> <p>-'-</p> <p>'02 [1] 125:24 '03 [1] 79:24 '04 [2] 122:8 125:25 '05 [4] 143:15 144:5 222:1 287:2 '06 [5] 156:14 250:3 282:11 287:10,13 '07 [1] 156:18 '08 [1] 188:4 '90s [2] 31:7 36:1 '96 [1] 107:12 '97 [2] 40:8 260:12 '99 [3] 60:18 116:21 129:25</p> <p>---</p> <p>-that [2] 38:13 44:15 -well [1] 262:19 -you [1] 6:4</p> <p>-.-</p> <p>.5 [1] 139:11</p> <p>-0-</p> <p>0113 [1] 84:6</p> <p>-1-</p> <p>1 [1] 78:9 1.5 [1] 59:16 10 [2] 55:19 237:12 100 [3] 46:11 226:7,8 10th [1] 79:20 11 [2] 1:4 232:4 11th [2] 310:5,12 12 [3] 76:23,24 77:3 1372 [1] 146:25 15 [12] 51:17,19 109:22 115:13 251:1,2,5,18,22 252:2,6,6 16 [1] 147:1 16th [3] 34:6,13 287:2 17 [10] 176:18 179:1,12 180:5,6,7,22 181:3,13 181:15 172 [1] 146:25 1749 [1] 281:17 17th [1] 214:4</p>	<p>18 [3] 97:4 155:1 171:10 19 [2] 181:3,15 1913 [1] 119:13 1982 [1] 6:18 1983 [1] 6:24 1984 [2] 7:3,4 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