

COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 31, 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

- Darlene Russell. 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

1 COMMISSIONER:
2 Q. Mr. Coffey.
3 DR. BEVERLEY CARTER, EXAMINATION BY BERNARD COFFEY, Q.C.
4 (CONTINUED)
5 COFFEY, Q.C.:
6 Q. Thank you, Commissioner. Now, good morning,
7 Dr. Carter.
8 DR. CARTER:
9 A. Good morning, Mr. Coffey.
10 COFFEY, Q.C.:
11 Q. Doctor, when we concluded the last day we had
12 just, I had shown you, I had the Registrar
13 show you briefly the slide deck that you used
14 in November of 2006, the PowerPoint
15 presentation.
16 DR. CARTER:
17 A. Oh, yes, okay.
18 COFFEY, Q.C.:
19 Q. I've heard people refer to them as slide decks
20 too. Doctor, after that I gather that there
21 was an initiative then finally to reinstitute
22 ER and PR testing here in St. John's?
23 DR. CARTER:
24 A. I think it was ongoing.
25 COFFEY, Q.C.:

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1 Q. Ongoing and then a final push?
2 DR. CARTER:
3 A. Yes, but it certainly was ramped up at that
4 time.
5 COFFEY, Q.C.:
6 Q. Ramped up for that. And the presentation
7 itself was done, at least partially, with a
8 view to making people within the organization
9 and across Newfoundland for that matter, the
10 physicians you were speaking to by this
11 teleconference, aware of the current state of
12 affairs in the plans?
13 DR. CARTER:
14 A. Yes.
15 COFFEY, Q.C.:
16 Q. In Eastern Health. Doctor, at the time during
17 that teleconference, because you would have
18 sat through the whole, not only done your own
19 presentation, you would have sat through the
20 whole lot of it?
21 DR. CARTER:
22 A. Yes.
23 COFFEY, Q.C.:
24 Q. This teleconference, was it two way, you could
25 hear them, they could hear you if -

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1 DR. CARTER:
 2 A. Yes, because there were technical difficulties
 3 and we were notified of same by people out in
 4 the periphery and there was also a question
 5 and answer period afterward.
 6 COFFEY, Q.C.:
 7 Q. And that's what I wanted to ask you about. Do
 8 you recall getting many, if any, questions
 9 concerning your own presentation? Did you
 10 have to field many questions?
 11 DR. CARTER:
 12 A. No.
 13 COFFEY, Q.C.:
 14 Q. Okay. Doctor, do you recall during the
 15 presentation and the question and answer
 16 period afterward whether there were any
 17 questions that you recall concerning the
 18 reason this had happened, if there was
 19 anybody, the doctors outside St. John's, for
 20 example, asking, well, you know, how did this
 21 come about, what caused this?
 22 DR. CARTER:
 23 A. I don't remember, you know, a specific person
 24 asking that, but I know that a lot of people
 25 from the periphery were interested in the

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1 answer to that question, I mean, I was
 2 interested in the answer to that question. I
 3 don't--you know, I can't recall a specific
 4 conversation, but I'm sure that it probably
 5 did.
 6 COFFEY, Q.C.:
 7 Q. And do you recall what, if anything--well,
 8 who, during the teleconference, would have
 9 been the person who would answer that sort of
 10 a question? Would it be Dr. Denic, Dr. Howell
 11 or Dr. Denic at the time?
 12 DR. CARTER:
 13 A. I think it would have been Dr. Denic and Dr.
 14 Cook.
 15 COFFEY, Q.C.:
 16 Q. Dr. Cook, okay.
 17 DR. CARTER:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. As the former clinical chief and the current
 21 clinical chief?
 22 DR. CARTER:
 23 A. Yes, so they would have had an overall view of
 24 the issue.
 25 COFFEY, Q.C.:

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1 Q. And do you recall what, if anything, they told
 2 people about that? You, yourself, I take it,
 3 by that point, already had your own views and
 4 understanding as to, you know, various factors
 5 that -
 6 DR. CARTER:
 7 A. Possible causes.
 8 COFFEY, Q.C.:
 9 Q. - contributed?
 10 DR. CARTER:
 11 A. I don't remember that there was anything
 12 outside of the issues that we've talked about
 13 here, you know, fixation, technique, that sort
 14 of thing.
 15 COFFEY, Q.C.:
 16 Q. Antigen retrieval processes -
 17 DR. CARTER:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. - and so on we've discussed. Do you recall if
 21 the issue of internal controls came up during
 22 that?
 23 DR. CARTER:
 24 A. It came up during my presentation.
 25 COFFEY, Q.C.:

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1 Q. Yes, you do -
 2 DR. CARTER:
 3 A. But I'm not--I don't think it came up after.
 4 COFFEY, Q.C.:
 5 Q. In terms of -
 6 DR. CARTER:
 7 A. It may have.
 8 COFFEY, Q.C.:
 9 Q. What I'm getting at is this, because Dr. Cook
 10 has told the Commissioner that certainly in
 11 the summer of 2005 he realized that internal
 12 controls was one aspect of this matter.
 13 DR. CARTER:
 14 A. Yes, yes.
 15 COFFEY, Q.C.:
 16 Q. And you've told the Commissioner the same
 17 thing. And I'm just, you know, for the
 18 Commissioner's benefit in terms of what went
 19 on, kind of get some sense of what went on,
 20 other than the actual slide show, you know,
 21 and presentation at the time, what kind of
 22 questioning occurred in relation to the reason
 23 or reasons for the problem and what the
 24 responses were. So the internal controls, you
 25 don't recall anybody in particular explaining

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1 kind of explicitly in the way, for example,
 2 you have here in terms of the necessity for it
 3 -
 4 DR. CARTER:
 5 A. I don't remember that that -
 6 COFFEY, Q.C.:
 7 Q. - and the fact that you hadn't seen, for
 8 example, that you had seen a number of cases
 9 converted that had absent internal controls,
 10 they hadn't stained?
 11 DR. CARTER:
 12 A. I don't remember it specifically at that
 13 question and answer period, but we had also
 14 had a meeting at some point at the
 15 Newfoundland Association of Pathologists and
 16 we had a fairly frequent contact with
 17 pathologists from the periphery on the
 18 telephone about cases that they would send in
 19 to me, so I know that had come up as an issue
 20 and that we would talk about, you know,
 21 absence of internal controls or negative
 22 internal controls.
 23 COFFEY, Q.C.:
 24 Q. Okay. Doctor, if I could, again, to continue
 25 on then after November, 2006, Registrar,

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1 Exhibit P-1684, please? Doctor, sorry, this
 2 is the, these are the minutes of Division of
 3 Anatomic Pathology meeting of Wednesday,
 4 January 10th, 2007. Now here, Doctor, I want
 5 to note here you were absent?
 6 DR. CARTER:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. Thank you. But you, I take it, in the normal
 10 course, would have seen these minutes
 11 afterward?
 12 DR. CARTER:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Okay. And, Doctor, here on page 3, and there
 16 are a couple of things I wanted to ask you
 17 about, one is paragraph 6, "Pathology update"
 18 and it notes Dr. Denic is going to meet with
 19 Dr. Howell regarding sending pathologists for
 20 training. And then "Pathology update sessions
 21 will be arranged for presentation of any
 22 information received at the training. These
 23 will take place about an hour on Friday
 24 mornings before RHADIP. Dr. Bev Carter will
 25 work out the details with Dr. A. Pirzada.

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1 This was agreeable to all pathologists."
 2 Doctor, who is dr. Pirzada, first of all?
 3 DR. CARTER:
 4 A. She is the program director for the residency
 5 training program for Memorial University;
 6 she's also a pathologist at the Health Science
 7 Centre, General Hospital, sorry, site.
 8 COFFEY, Q.C.:
 9 Q. And while I have you here, what is RHADIP?
 10 DR. CARTER:
 11 A. It's spelled, the acronym is incorrect, it's
 12 Residents Academic Half Day in Pathology, so
 13 it's RAHDIP, we call it RAHDIP for short.
 14 COFFEY, Q.C.:
 15 Q. RAHDIP, okay, thank you. And Dr. Pirzada
 16 would have been the one who coordinated or was
 17 responsible -
 18 DR. CARTER:
 19 A. She would be in charge of the residency
 20 program, So there I was trying to insert a
 21 teaching session in a regular basis into the
 22 academic half day, so that would have to be
 23 with her approval. She would have to just
 24 review what the theme of the educational event
 25 was going to be about and then say whether or

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1 not it was suitable for residents teaching in
 2 that academic half day.
 3 COFFEY, Q.C.:
 4 Q. Now here, Doctor, and this is the beginning of
 5 2007, this portion of the minutes seems to
 6 suggest that, as they phrase it here,
 7 "Pathology update sessions will be arranged
 8 for presentation of any information received
 9 at training." That would be pathologists who
 10 would go away for education or training?
 11 DR. CARTER:
 12 A. It was more than pathologists. This was a lab
 13 wide.
 14 COFFEY, Q.C.:
 15 Q. The lab.
 16 DR. CARTER:
 17 A. For anatomic pathology or surgical pathology,
 18 but it was for pathologists, pathology
 19 assistants, technologists, management,
 20 residents.
 21 COFFEY, Q.C.:
 22 Q. Before this--I take it then that this is to
 23 implement a systematic approach to this?
 24 DR. CARTER:
 25 A. Yes. We were going--it was going to be a

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1 group education session.
 2 COFFEY, Q.C.:
 3 Q. Prior to this had there--well, you would have
 4 been in St. John's. Had you known of any such
 5 process being in existence in terms of, you
 6 know, that if Dr. Cook or Dr. Denic or Dr.
 7 Elms or whomever had gone away to a seminar in
 8 2005 or 2004, as an example, was there any
 9 process in place -
 10 DR. CARTER:
 11 A. Not that I know of. I don't think that there
 12 was.
 13 COFFEY, Q.C.:
 14 Q. So this was a new initiative?
 15 DR. CARTER:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. To ensure that the benefit of whatever
 19 somebody learned by attending something
 20 outside Eastern Health itself could be passed
 21 on?
 22 DR. CARTER:
 23 A. Yes, or everybody took a turn so you may have
 24 not necessarily been away at training, so just
 25 if it was your turn, if you hadn't been away

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1 at a conference, you could provide education
 2 around an area you were interested in. I
 3 provided one on frozen section but I hadn't
 4 attended a frozen section conference, but I -
 5 COFFEY, Q.C.:
 6 Q. Okay. But this was to ensure that anything
 7 picked up by someone else where hopefully
 8 would be passed on locally, shared?
 9 DR. CARTER:
 10 A. It would be a sharing of new information.
 11 COFFEY, Q.C.:
 12 Q. And as you've indicated, as then time went on
 13 then even if you weren't away, if you were at
 14 -
 15 DR. CARTER:
 16 A. It was your turn, it was your turn, so you had
 17 to come up with something that was of interest
 18 to the general group.
 19 COFFEY, Q.C.:
 20 Q. And, Doctor, has that continued?
 21 DR. CARTER:
 22 A. I think it started in April of that year was
 23 the first ones that we had and it went for the
 24 academic year, which we usually call September
 25 to June; and it was in place this year until

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1 June, it probably ended the beginning of June.
 2 I assume it will go ahead next year.
 3 COFFEY, Q.C.:
 4 Q. And paragraph 7 refers to quality management
 5 program. And I take it that this particular
 6 set of minutes begins by saying "Quality
 7 management is in the process of creating a
 8 book of policy and procedures for pathology."
 9 And we spoke about that the last day you were
 10 here. That was an ongoing process. Doctor,
 11 at the bottom of the page there's a paragraph
 12 that reads, "A review was done of cases
 13 discussed at rounds and on 31 of these there
 14 was no note that they were seen at rounds.
 15 This should be documented on reports along
 16 with any phone calls made to clinicians re
 17 reports." So was this something that you were
 18 trying to--I think you were the chair of this
 19 group?
 20 DR. CARTER:
 21 A. Yes, I mean, and the preceding paragraphs
 22 before would be what we had hoped, Ms. Parnell
 23 and I, to come out of the quality management
 24 program is that you would begin to look at
 25 these markers of quality and then make

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1 suggestions to the group as to how they could
 2 facilitate a process of monitoring and make
 3 sure that these things that we had identified
 4 as quality issues would be adhered to.
 5 COFFEY, Q.C.:
 6 Q. Doctor, if we look, please, at Exhibit P-2114?
 7 Doctor, this is a letter of February 8th, 2007
 8 from Dr. Denic, it's copied to a number of
 9 other physicians. Doctor, of course it's
 10 addressed to yourself and it reads, it's "Re
 11 ER/PR and HER2/neu reporting." "I want to
 12 inform you that after the period of 18 months
 13 during which the immunohistochemical stains
 14 for ER/PR and HER2/neu were stopped in our lab
 15 and after thorough review of our
 16 immunohistochemistry service we are
 17 reinstating immunohistochemicals testing for
 18 ER/PR and HER2/neu. I was given assurance by
 19 the director of immunohistochemistry
 20 department, Dr. Ford Elms, that
 21 immunohistochemistry services met all the
 22 requirements to continue with forementioned
 23 tests. The reporting of ER/PR and HER2/neu
 24 should come into effect immediately according
 25 to the approved standardized protocols. It is

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1 my expectation and the expectation of the
 2 senior management of Eastern Health that your
 3 group should take over the reporting of
 4 status--of the status of breast receptors and
 5 HER2/neu province wide. Due to past problems
 6 in interpreting the stains, it is obvious that
 7 outside consultants in pathology have limited
 8 expertise. Having said that I will first
 9 offer our services to other departments and
 10 medical directors across the province and
 11 recommend them to have this service provided
 12 by your group. Since I have no authority over
 13 their decisions, in case they decide to retain
 14 interpretation of breast receptors in their
 15 centres, an in-service would have to be
 16 provided by your group. If they accept the
 17 offer, we will request that our tissue
 18 fixation and processing policies must be
 19 followed in order to increase the
 20 reproducibility of the results." Just, Dr.
 21 Denic continues, "I will also expect that your
 22 group should monitor and take an active role
 23 in QA of these tests with certain numbers of
 24 cases as provided by this group to be sent to
 25 an outside institution such as Mount Sinai for

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1 validation. Log books and correlations should
 2 be kept and readily available for review. You
 3 should give your feedback and maintain good
 4 relationship with the director of the
 5 immunohistochemistry department." And,
 6 Doctor, here the group in question, you are
 7 described as the leader breast pathology,
 8 subspeciality task group?
 9 DR. CARTER:
 10 A. Um-hm.
 11 COFFEY, Q.C.:
 12 Q. And as the leader, well, first of all, what
 13 was that group responsible for?
 14 DR. CARTER:
 15 A. It had come out of the discussions on
 16 subspecialization within Eastern Health. So
 17 our group was made of pathologists who were
 18 interested in breast pathology and our mandate
 19 would be to handle cases that would be
 20 identified by any group of pathologists as
 21 having a degree of difficulty that may require
 22 some subspecialist interpretation and we would
 23 also make policy around how breast specimens
 24 should be handled, how they should be
 25 interpreted, how they should be reported and

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1 we would also have then a broader overview of
 2 the breast service that was occurring in
 3 Eastern Health, so theoretically we would have
 4 been able to identify any problems that would
 5 come up and then address those.
 6 COFFEY, Q.C.:
 7 Q. Doctor, in the first paragraph, this, in
 8 effect, I take it, is Dr. Denic's official
 9 advice to yourself and your group that -
 10 DR. CARTER:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. - we're going to reinstitute ER/PR and
 14 HER2/neu. And we understand that ER and PR
 15 was reinstated?
 16 DR. CARTER:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. Do you recall when, in fact, that happened?
 20 DR. CARTER:
 21 A. I think it was in March of 2007, but I don't
 22 have the exact date.
 23 COFFEY, Q.C.:
 24 Q. Yes. I take it one could just check the
 25 pathology records?

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1 DR. CARTER:
 2 A. Yes. And you'll see that they're signed out.
 3 COFFEY, Q.C.:
 4 Q. Locally?
 5 DR. CARTER:
 6 A. Yes. You can see using the Ventana system on
 7 them as opposed to "Please see Mount Sinai
 8 report".
 9 COFFEY, Q.C.:
 10 Q. And HER2/neu, I take it, did not begin here in
 11 St. John's again at that time in 2007?
 12 DR. CARTER:
 13 A. No, it didn't.
 14 COFFEY, Q.C.:
 15 Q. The reporting. Can you tell the Commissioner
 16 then why that was because this certainly as of
 17 February 8th, apparently, this envisages that
 18 ER/PR and HER2/neu would -
 19 DR. CARTER:
 20 A. I mean, Dr. Elms would be able to give you a
 21 lot more detail.
 22 COFFEY, Q.C.:
 23 Q. Sure.
 24 DR. CARTER:
 25 A. But when they were validating the HER2/neu

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1 antibodies, there's a positive and a negative
 2 HER2/neu.
 3 COFFEY, Q.C.:
 4 Q. Yes.
 5 DR. CARTER:
 6 A. Which again, like I talked about with ER/PR,
 7 is fairly easily recognizable, you know, you
 8 just look at it on the slide and it's done.
 9 But there's a category that's indefinite or
 10 sometimes referred to as a 2 plus.
 11 COFFEY, Q.C.:
 12 Q. Yes.
 13 DR. CARTER:
 14 A. Which is your problem area like the weak
 15 expressers in estrogen receptor and when they
 16 are trying to validate the 2 pluses, so their
 17 antibodies against the 2 pluses and to get
 18 some sort of reasonable correlation between
 19 the two, Dr. Elms wasn't happy with the
 20 correlation that he was getting. I mean, I
 21 looked over the numbers or the validation very
 22 briefly, you know, and agreed but would defer
 23 to him that he wanted tight validation of this
 24 and I know it was the 2 pluses that were -
 25 COFFEY, Q.C.:

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1 Q. The problem?
 2 DR. CARTER:
 3 A. - the problem. And that's not just a problem
 4 for here either. I mean, it's tough to get 2
 5 pluses to be able to perform a validation and
 6 it's tough to get your system so tight that
 7 that's a reliable -
 8 COFFEY, Q.C.:
 9 Q. And so it was--and this is what I wanted to
 10 ask you about is because you were the leader
 11 of this subspecialty task group and, in
 12 effect, I take it, by this letter, whatever
 13 testing was reinstated, you'd be responsible
 14 ultimately for -
 15 DR. CARTER:
 16 A. For the reading and reporting of, so they
 17 would pass things by our group. I know that's
 18 not very good language, but they would pass
 19 things by our group because we would end up
 20 being ultimately responsible.
 21 COFFEY, Q.C.:
 22 Q. And just so the Commissioner understands, but
 23 by this, by early 2007, the relationship had
 24 evolved such that Dr. Elms, from his
 25 perspective, could say yes or no to whether or

Page 23

1 not ER/PR slides were going to be provided to
 2 you or HER2/neu slides were going to be
 3 provided to you at all?
 4 DR. CARTER:
 5 A. Yes, and I think Dr. Cook and Dr. Naghibi and
 6 I. Dr. Afrouzian, I think had--was not on the
 7 group at this time, even though she's cc'd on
 8 it. We also felt that we were quite
 9 comfortable to say no, we're not accepting
 10 those either. I mean, it was quite a nice
 11 open relationship.
 12 COFFEY, Q.C.:
 13 Q. And you would--you'd hardly accept it, I take
 14 it, if the Director of Immunohistochemistry
 15 was saying "I don't think it's appropriate for
 16 you to do those."
 17 DR. CARTER:
 18 A. And I'm not going to go over that, but if he
 19 said "I think it's appropriate" and I didn't,
 20 then I would say "no, I don't think so."
 21 COFFEY, Q.C.:
 22 Q. Okay.
 23 DR. CARTER:
 24 A. That never happened, but -
 25 COFFEY, Q.C.:

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1 Q. And so in terms of how this evolved then, from
 2 the beginning of February, it was anticipated
 3 at that point that ER/PR and HER2/neu would
 4 all be reinstated? ER and PR did proceed?
 5 DR. CARTER:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Dr. Elms and your own group concurred in that,
 9 and Dr. Elms expressed then reservations about
 10 the HER2/neu. He wasn't satisfied and
 11 therefore it wasn't reinstated at that
 12 point. Doctor, looking at this, it refers to,
 13 in the second paragraph, first sentence, the
 14 expectation that your group should take over
 15 the reporting of the status of breast
 16 receptors and HER2/neu province wide, and then
 17 in the second sentence, Dr. Denic says "it is
 18 obvious--due to past problems interpreting the
 19 stains, it is obvious that outside consultants
 20 in pathology have limited expertise." Now you
 21 understood who--did you understand, have any
 22 understanding as to who these outside
 23 consultants in pathology were, in this
 24 context?
 25 DR. CARTER:

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1 A. I would assume that he was talking about the
 2 pathologists who worked in centres other than
 3 Eastern Health, actually other than St.
 4 John's, sorry, because I think by that time,
 5 Eastern Health included more.
 6 COFFEY, Q.C.:
 7 Q. And what did you understand, having received
 8 this letter and read it, was expected then of
 9 your group? Were you going to report all the-
 10 -if others utilized St. John's?
 11 DR. CARTER:
 12 A. Yeah, so that was the first step. They had to
 13 decided whether or not they wanted to continue
 14 with their interim staining agreement, so I
 15 think -
 16 COFFEY, Q.C.:
 17 Q. With Mount Sinai.
 18 DR. CARTER:
 19 A. - many of them had done Mount Sinai, but I
 20 think one hospital, at least, was using a
 21 different consult service, so they would have
 22 to make that decision and if they did make
 23 that decision, then myself, Dr. Cook and Dr.
 24 Naghibi would read and report.
 25 COFFEY, Q.C.:

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1 Q. For the province?
 2 DR. CARTER:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. Anybody who wanted to utilize the IHC ER/PR
 6 service in St. John's would, by doing so, the
 7 understanding would be that it would be
 8 reported, the slides would be reported by one
 9 of this group?
 10 DR. CARTER:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. Doctor, there's a reference then to, at the
 14 bottom of this page, to "our tissue fixation
 15 and processing policies must be followed."
 16 DR. CARTER:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. You can see that there. Doctor, did you ever
 20 have any interaction with or visit with
 21 centres outside St. John's to talk to them
 22 about their fixation policies and tissue
 23 processing?
 24 DR. CARTER:
 25 A. Yes. Again, I'm not sure of the dates. In

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1 one instance, it had arisen from the breast
 2 disease site group, from that group. It's
 3 difficult because you're Eastern Health, so
 4 you only have certain jurisdiction, but you're
 5 cancer program for the province. So we had
 6 talked about that and talked about having all
 7 pathology groups in the province act in a
 8 similar fashion and at that time, I'm not sure
 9 if the Department of Medical Oncology or if it
 10 was the Cancer program, but it was certainly
 11 through Dr. Kara Laing. They provided funding
 12 for me to go to Gander and I went to Gander
 13 and in the evening, I did a CME presentation
 14 for all disciplines on standardized reporting.
 15 It's not just for pathologists, because that's
 16 what's coming down the pike now. Surgeons
 17 must use standardized reporting, nurses,
 18 pharmacists. So I did a lecture that night
 19 and then the next morning, I met with the
 20 pathologists from that region. They were from
 21 Gander and Grand Falls, maybe somebody from
 22 Clarendville, but I'm not real sure about that.
 23 And we went through the fixation protocols,
 24 grossing protocols, reporting protocols, and
 25 after that or maybe just before, I'm not sure

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1 which one, we actually put together all of the
 2 policies and procedures that we had and Dr.
 3 Denic e-mailed that to all the pathologists in
 4 the province, with the suggestion that they
 5 please, please, you know, use it, but we had
 6 no jurisdiction to make them do that.
 7 COFFEY, Q.C.:
 8 Q. Doctor, bearing in mind your kind of overall
 9 experience in this whole matter, is that--does
 10 that present any obstacles or challenges, the
 11 fact that there is no one authority here
 12 within the province that has kind of
 13 jurisdiction, as you put it, to ensure that
 14 certain protocols and procedures and, you
 15 know, certain practices are followed?
 16 DR. CARTER:
 17 A. I mean, there will be some limitations to it
 18 that if you have an outlier, if they're within
 19 Eastern Health, it's sort of "well, this is
 20 our policy." So you know, you can either make
 21 an intelligent argument about why we should
 22 change it, or you can follow it, or you know,
 23 maybe we can help you find a job somewhere
 24 else," that sort of conversation. I think
 25 outside, you don't have any jurisdiction. You

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1 can't force people, you know, to follow policy
 2 and procedures. I mean, that being said, this
 3 was not a difficult sell. Anyone that I
 4 talked to outside of St. John's was eager for
 5 the information, for any teaching knowledge.
 6 I don't think anyone really protested against
 7 it.
 8 COFFEY, Q.C.:
 9 Q. Doctor, the reference that Doctor--and I
 10 anticipate probably I'll take this up a little
 11 bit more with Dr. Denic when he comes to
 12 testify, but in his reference to "due to past
 13 problems interpreting the stains, it is
 14 obvious that outside consultants in pathology
 15 have limited expertise," based upon what you
 16 knew at the beginning of 2007, would that
 17 comment be limited to the pathologists outside
 18 St. John's or would it, in fact, based upon
 19 what you've seen in your own review, it might
 20 apply as well to at least some pathologists
 21 within the City at that time?
 22 DR. CARTER:
 23 A. Yeah, I mean, I would disagree with that
 24 sentence. I don't think that anybody had made
 25 any clear distinction that the pathologists

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1 were located in a particular place. Nobody
 2 had really made the distinction that there was
 3 a problem in interpreting stains. I mean, we
 4 saw those trends, but I talked to you about
 5 evidence based, the decisions and things, and
 6 I'm not sure that there's any evidence that
 7 the pathologists in St. Anthony or Corner
 8 Brook would have limited--any more limited
 9 expertise than the average pathologist in St.
 10 John's.
 11 COFFEY, Q.C.:
 12 Q. Exhibit P-2336. Doctor, this is an e-mail
 13 from Ms. Silver to Dr. Laing, March 5, 2007,
 14 and it says "I was talking to Dr. Bev Carter
 15 on Thursday to clarify some ER/PR info. In
 16 the past, with the Mount Sinai rereads, we
 17 were told by Dr. Dan Fontaine that anything
 18 positive was a positive and then that is how
 19 we entered them. Dr. Carter says that I
 20 should clarify with you as to the oncologists
 21 decision, as they are only saying 'testing
 22 shows nuclear staining in tumour cells.' To
 23 me, that would be a positive, but I wanted to
 24 be sure. If you could let me know so I can
 25 inform all registry staff." Do you recall

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1 what this was about?
 2 DR. CARTER:
 3 A. Callista Silver is with the Cancer Registry.
 4 COFFEY, Q.C.:
 5 Q. Yes, I understand.
 6 DR. CARTER:
 7 A. Again, I mean, not this specific conversation,
 8 but I have spoken to the women, the Registry
 9 staff that I've spoken to. So I have spoken
 10 to them on a couple of occasions about they
 11 would read me reports and ask me to interpret,
 12 you know, parts of it.
 13 COFFEY, Q.C.:
 14 Q. So read you reports written by pathologists?
 15 DR. CARTER:
 16 A. Written by other pathologists in breast, just
 17 in breast, so they may phone me and say "I've
 18 got a report from -
 19 COFFEY, Q.C.:
 20 Q. Dr. X.
 21 DR. CARTER:
 22 A. - Yeah, you know, "Dr. Neal in Corner Brook
 23 and it says 'infiltrating ductal with lobular
 24 features.' Is that an infiltrating ductal or
 25 is that an infiltrating lobular?" things like

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1 that, and I would just answer the questions
 2 and they wanted to know when they should put
 3 the patients in as estrogen receptor positive
 4 and when they should put them in as estrogen
 5 receptor negative. I think then I would have
 6 been talking about a ten percent cut off
 7 point. So I'm not sure if the quotation should
 8 be testing shows nuclear staining in ten
 9 percent of tumour cells, but she had called.
 10 She had been talking to Dan Fontaine, I don't
 11 know in what context, and he felt that
 12 anything that was marked as positive, so if it
 13 said it's positive in two percent of cells,
 14 then you would put it in as a positive and I
 15 think that's something that you decide with
 16 the oncologists and my experience here, and in
 17 many other places, ten percent was being used
 18 as a cut off for clinical decision making.
 19 COFFEY, Q.C.:
 20 Q. In terms of that, and I take it this was being
 21 input in relation to the Cancer Registry
 22 itself, how they input the data for their own
 23 purposes, in their own registry?
 24 DR. CARTER:
 25 A. Yes, I think. I would have been just

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1 clarifying for her how to make the registry
 2 more user friendly for her.
 3 COFFEY, Q.C.:
 4 Q. Now Doctor, I appreciate you just concluded
 5 your engagement here in St. John's, but you
 6 know, up until certainly the time you
 7 resigned, what's the current situation in
 8 terms of pathology reporting and how
 9 standardized or not it is right now?
 10 DR. CARTER:
 11 A. Do you mean since I left on June 20th or as I
 12 was working up?
 13 COFFEY, Q.C.:
 14 Q. Working up to it.
 15 DR. CARTER:
 16 A. Okay. For the most part, across the province,
 17 people were using the College of American
 18 Pathologists standardized reporting formats
 19 for all oncology specimens. June the 21st
 20 actually we had a meeting of the Newfoundland
 21 Association of Pathologists and I was
 22 president at that time and we agreed province
 23 wide that this would be the accepted format
 24 and for the estrogen receptor and progesterone
 25 receptor testing, it was only coming out of

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1 our lab, you know, the testing that was done
 2 at Eastern Health, and we were using a
 3 standardized type report for that as well.
 4 COFFEY, Q.C.:
 5 Q. Doctor, I'll ask you about this. You would,
 6 of course, have used Meditec here quite a
 7 number of times.
 8 DR. CARTER:
 9 A. Yes, every day.
 10 COFFEY, Q.C.:
 11 Q. During your time here. If you wanted to enter
 12 an addendum, okay, how did that work in terms
 13 of would it always show up in the same place,
 14 you know, in relation to the report? After
 15 the initial report was entered and signed off
 16 and you wanted to go back and enter an
 17 addendum, like addendum number one, and then
 18 come back and enter addendum number two, where
 19 would the addendum show up?
 20 DR. CARTER:
 21 A. I think it would be above the sign out, but
 22 I'm not sure. I mean, mostly we would dictate
 23 them and sign them out, but I wouldn't really
 24 look at the format of the report, but I think
 25 the most addendum comes out on top of the--but

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1 I'm not sure about that at all.
 2 COFFEY, Q.C.:
 3 Q. So in terms of that, this is what I wanted to
 4 ask you about, from your perspective, your
 5 involvement is you use a dictaphone, dictate
 6 whatever it is you want to say and then you
 7 wait and what happens? How do you know the
 8 report has actually been typed?
 9 DR. CARTER:
 10 A. With the old system, when we were actually
 11 using dictaphones with the tapes, then the
 12 secretary would bring it all back to you for
 13 your editing or corrections and your sign out.
 14 Then you would do an electronic sign out on
 15 the computer.
 16 COFFEY, Q.C.:
 17 Q. What would she bring back to you?
 18 DR. CARTER:
 19 A. Depended on who the pathologist was, I think.
 20 Some pathologists wanted to see every piece of
 21 paper, you know, that was ever in the whole
 22 dictating, editing, correcting. Some
 23 pathologists wanted to see all that. I think
 24 most of us would just want the most recent.
 25 COFFEY, Q.C.:

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1 Q. Version of it?
 2 DR. CARTER:
 3 A. Yes. So if I changed -
 4 COFFEY, Q.C.:
 5 Q. The initial would come back on a piece of
 6 paper, I take it?
 7 DR. CARTER:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Typed out. Would it be the whole of the
 11 pathology report or just what you recently
 12 typed or you just recently edited or most
 13 recently?
 14 DR. CARTER:
 15 A. I think it would just be the addendum, but you
 16 know, you may get part of the pathology
 17 report, but I don't think they would give you
 18 the whole thing.
 19 COFFEY, Q.C.:
 20 Q. And then when you said, you know, you're
 21 finally satisfied that--say it's an addendum
 22 and you're finally satisfied that's okay, what
 23 would you then do?
 24 DR. CARTER:
 25 A. Then, I mean, we would do an elect--what's

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1 called an electronic sign out, so you actually
 2 go into the report.
 3 COFFEY, Q.C.:
 4 Q. You have to actually log on whatever you do?
 5 DR. CARTER:
 6 A. And use a password and then add my electronic
 7 signature to it, with the password. I mean,
 8 that would then, you know, assume that I had
 9 actually read the report, because your
 10 password is your own.
 11 COFFEY, Q.C.:
 12 Q. Doctor, if, for example, a case you got
 13 involved, for example, in being asked to
 14 report a particular thing for a patient that
 15 had been dealt with a year before by yourself
 16 or another pathologist for that matter, okay,
 17 in reviewing the pathology report, if you had
 18 to go back and look at it and then decide what
 19 it was you were going to do and/or how you
 20 were going to report something further, a new
 21 test, had you ever encountered any difficulty
 22 in ascertaining exactly what had happened to
 23 the patient during the proceeding two, three
 24 or four years from a pathology perspective,
 25 just because of the layout of the report?

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1 DR. CARTER:
 2 A. Sometimes the report would be locked in
 3 addendum status. I don't know if that's what
 4 you mean. So it wouldn't be visible to
 5 clinicians, but we can get around that because
 6 we have a different menu. Sometimes the
 7 reports could look quite confusing because the
 8 latest addendum comes on top of the diagnosis
 9 and that, I think, eventually moves down as
 10 you add addendums onto it, but I think you may
 11 be initially a bit confused, but once you sat
 12 and looked at the report, you could do a
 13 little bit of a trace.
 14 COFFEY, Q.C.:
 15 Q. But you'd actually, at times, some reports,
 16 because of the way they were laid out, you'd
 17 actually have to kind of look through the
 18 report and follow the different -
 19 DR. CARTER:
 20 A. Yes, you're looking up there and it's '05 and
 21 down there it's '07 and in there it's '05 and
 22 that sort of thing.
 23 COFFEY, Q.C.:
 24 Q. Did you ever question why that is? Did it
 25 ever occur to you to question -

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1 DR. CARTER:
 2 A. No.
 3 COFFEY, Q.C.:
 4 Q. Okay. Exhibit P-1695? Doctor, this is a
 5 series of letters. The first of them is a
 6 letter of March 22nd, 2007, it's at page 3 of
 7 the exhibit, it's from yourself to Dr. Denic
 8 as clinical chief. And here, I take it,
 9 you're looking for a recommendation letter, a
 10 reference letter concerning your application
 11 for a position elsewhere?
 12 DR. CARTER:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. And you do say here that you love being back
 16 home in Newfoundland, happy to work with your
 17 many pathology and clinical colleagues,
 18 however, "I do have many difficulties with the
 19 current management structure for the
 20 laboratories." And you go on to refer to the
 21 fact that you're not happy with the
 22 remuneration, especially Dr. Bradbury's recent
 23 unilateral decision to cancel all consultative
 24 fees for pathologists in Newfoundland and
 25 Labrador. Now, Doctor, then you conclude by

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1 saying "employment opportunities are rare in
 2 this popular area"--which is elsewhere--"and
 3 with the recent pessimistic reports from our
 4 government, I thought that this employment
 5 possibility should not be allowed to pass
 6 unnoticed." Doctor, now first of all, the
 7 recent pessimistic reports from the
 8 government, do you recall in this context, in
 9 March of '07, what that was? What the status
 10 was of the remuneration issue at that point?
 11 DR. CARTER:
 12 A. I'm not sure exactly what was going on with
 13 remuneration at that point. I know that there
 14 had been the decision to remove consultative
 15 fees from all of the pathologists in the
 16 province. Those had been refused to me on my
 17 arrival in the province, so it didn't really
 18 affect me.
 19 COFFEY, Q.C.:
 20 Q. It didn't affect you in the sense because when
 21 you arrived here -
 22 DR. CARTER:
 23 A. I was told by Dr. Bradbury that I wasn't
 24 allowed to consult for my services across the
 25 province.

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1 COFFEY, Q.C.:

2 Q. That was back in 2003, 2004?

3 DR. CARTER:

4 A. 2004 when I became permanent staff. So, I

5 mean, it is just a reflection, I think, of the

6 ongoing negotiations with the government.

7 COFFEY, Q.C.:

8 Q. And you referred to difficulties with the

9 current management structure for the

10 laboratories, what is that in reference to at

11 that point in time?

12 DR. CARTER:

13 A. I think it was the ongoing, trying to change

14 things in the Quality Management Program, but

15 I think it was a reflection of the lack of

16 medical head, if you will, or medical director

17 for the laboratory, so decisions were still

18 being made that I thought were best placed in

19 the hands of a medical person.

20 COFFEY, Q.C.:

21 Q. Doctor, in relation to the issue of kind of

22 standardized reporting or particular--yes,

23 standardized reporting, Doctor, I believe I

24 asked you about this last day, but I just want

25 to be sure I'm clear on it. In terms of your

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1 own practice, now in particular, for example

2 in relation to ER and PR, did you have any one

3 style of reporting ER/PR?

4 DR. CARTER:

5 A. No. Since we restarted the testing, I mean,

6 we had agreed on, you know, using this very

7 detailed outline, but before that, sometimes I

8 would use it, sometimes I wouldn't.

9 COFFEY, Q.C.:

10 Q. And sometimes, for example, you might report

11 ER/PR negative, sometimes report them

12 positive, sometimes report them positive with

13 external and internal controls -

14 DR. CARTER:

15 A. Give a percentage.

16 COFFEY, Q.C.:

17 Q. Seen those.

18 DR. CARTER:

19 A. So there would be variability in my own

20 reports and the same when I was at McMaster,

21 we would -

22 COFFEY, Q.C.:

23 Q. And, Doctor, in relation to that, do you ever

24 recall getting any query at all from the

25 oncologist or attending physicians in

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1 Newfoundland to query what you meant by

2 negative or positive?

3 DR. CARTER:

4 A. I don't remember it as a specific incidence. I

5 think that the oncologists are relying on the

6 fact that we're keeping up with the literature

7 and that we're keeping up with what they, as a

8 large group of medical oncologists, not just a

9 local group, would, you know, think of as

10 positive and negative.

11 COFFEY, Q.C.:

12 Q. If we could look, please, at Exhibit P-1840?

13 Well actually, before we go to that, I

14 apologize, Exhibit P-2426, something I wanted

15 to clarify. Doctor, these are--page 32,

16 please. Doctor, these are the minutes of the

17 QCQA meeting, January 11th, 2005.

18 DR. CARTER:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. And you are in fact the chair, of course, of

22 this group and on the second page, under

23 paragraph 7, it says, "No further progress has

24 been made on the designing of the QAQC program

25 for technical staff." Do you see that?

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1 DR. CARTER:

2 A. Yes, sorry.

3 COFFEY, Q.C.:

4 Q. And this would have been, of course, just

5 before the spring of 2005 when, you know,

6 these events unfolded as they have. Was it

7 then generally recognized within the

8 laboratory program that there was no QA or QC

9 for the technical staff, the technologists?

10 DR. CARTER:

11 A. There was no formalized QAQC program that I

12 was aware of.

13 COFFEY, Q.C.:

14 Q. And even an informal one?

15 DR. CARTER:

16 A. I'm sure informally people are doing QA

17 practises because it's just the nature of

18 doing your work, so I'm sure if one of the

19 technologist was cutting a section, for

20 example, and found that there was a lot of

21 folds or wrinkles in it, they would think that

22 the paraffin was too cold and they would check

23 the water temperature, but I don't think that

24 there was any formalized quality programs

25 there.

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1 COFFEY, Q.C.:

2 Q. And the fact that there were no such formal

3 programs, was that generally known, do you

4 think, a laboratory program?

5 DR. CARTER:

6 A. I would think so. But I was much more

7 interested in this than other people, so I may

8 be over-estimating.

9 COFFEY, Q.C.:

10 Q. I'm sorry, Exhibit P-1840. Now, Doctor, this

11 is a letter of April 14th, 2008 and it's

12 addressed to myself as the Commission co-

13 counsel. It's from Dr. Mullen, I'll just show

14 you, I apologize.

15 DR. CARTER:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. Have you seen this letter before?

19 DR. CARTER:

20 A. This is one of the evidence pieces?

21 COFFEY, Q.C.:

22 Q. Yes.

23 DR. CARTER:

24 A. Yes.

25 COFFEY, Q.C.:

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1 Q. Doctor, here Dr. Mullen examined a number of

2 slides, he's come in and testified about that,

3 but he, at the bottom of the first page, says

4 "To summarize my observations, the

5 overwhelming majority of cases had one or more

6 of the following problems." And he refers to

7 poor fixation or processing resulting in

8 incomplete tissue sections, loss of the

9 internal structure of the nucleus and staining

10 restricted to the periphery of the slide. And

11 he talks then about exploding sections and

12 hollow nuclei, and then he continues "because

13 of poor fixation the nuclear substance has

14 lost, markedly decreases the chance of

15 staining for ER/PR." The third issue

16 "staining restricted to the periphery of the

17 slide refers to staining of the periphery of

18 the section with absence of staining

19 centrally. It is difficult to interpret the

20 results of these cases as the peripheral

21 staining results may not reflect the results

22 of the entire tumour." Paragraph 2, "absence

23 of the internal controls. Many of the cases

24 had no normal duct epithelium to use as an

25 internal control on the initial H&E section.

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1 Additionally many cases where the original H&E

2 section had normal duct epithelium, it was not

3 present on the ER/PR slides as a result of the

4 exploding section issue. Negative internal

5 controls"--paragraph three--"In many cases the

6 internal control either did not stain or

7 stained very weakly. Also with the exception

8 of a small minority of cases, the ER internal

9 control was significantly weaker than the PR

10 internal control." And then he refers to

11 stain deposit obscuring morphology. "In many

12 cases excess stain was present either on the

13 surface or beneath the section, both artifacts

14 preclude assessment of the ER/PR staining in

15 the areas affected." And then external

16 controls, "The external controls were

17 inconsistent both between slides and within

18 slides. In many cases the positive cells were

19 barely stained. In occasional cases from

20 2005, the control stained both the nucleus and

21 the cytoplasm, reflecting inadequate or

22 incorrect validation." And then the

23 discrepancy between internal and external

24 controls, in only one or two of the 539 cases

25 he reviewed, was the staining in the internal

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1 control as strong as the corresponding

2 external control. Well, Doctor, I appreciate

3 the sampling of cases that you looked at was

4 narrower in time or confined to a narrower

5 point in time and it was smaller.

6 DR. CARTER:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. But in terms of what you saw in June and July

10 of 2005, compared to the comments of Dr.--I'm

11 just going to look through this now and

12 indicate to the Commissioner what, in your own

13 analysis, you would have already arrived it?

14 DR. CARTER:

15 A. One, two and three I would be fine with his

16 conclusions and I think I had seen those

17 already. Number four, "Stain deposit

18 obscuring morphology" I actually hadn't seen a

19 whole lot of that, but that may have been, as

20 you have just explained, the sampling.

21 COFFEY, Q.C.:

22 Q. He looked at it on a much wider grouping.

23 DR. CARTER:

24 A. Yes.

25 COFFEY, Q.C.:

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1 Q. Over time.
 2 DR. CARTER:
 3 A. And I think many of mine were restricted to
 4 just two or three institutions, so there may
 5 be an institution because fixation and
 6 processing can affect this sort of gross -
 7 COFFEY, Q.C.:
 8 Q. That particular aspect of it.
 9 DR. CARTER:
 10 A. - stain deposit. The external controls, I
 11 hadn't looked at a whole lot of external
 12 controls, so five and six I would just have no
 13 knowledge of, but I would tend to agree that
 14 that was probably a possibility.
 15 COFFEY, Q.C.:
 16 Q. Now, Doctor, is there anything further that, I
 17 appreciate Mr. Browne may ask you generally if
 18 you want to say something, but is there
 19 anything in terms of the mandate of the
 20 Commission and you would be aware of generally
 21 what it is -
 22 DR. CARTER:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. - that we haven't covered that you think the

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1 Commissioner should be made aware of?
 2 DR. CARTER:
 3 A. No.
 4 COFFEY, Q.C.:
 5 Q. Thank you.
 6 THE COMMISSIONER:
 7 Q. Thank you. Mr. Pritchard?
 8 MR. PRITCHARD:
 9 COFFEY, Q.C.:
 10 Q. Thank you, Commissioner, I don't have any
 11 questions for this witness and thank you for
 12 your evidence, Doctor.
 13 THE COMMISSIONER:
 14 Q. Mr. Simmons?
 15 MR. SIMMONS:
 16 Q. Thank you, Commissioner.
 17 DR. BEVERLEY CARTER, EXAMINATION BY MR. DANIEL SIMMONS
 18 MR. SIMMONS:
 19 Q. Good morning, Dr. Carter.
 20 DR. CARTER:
 21 A. Good morning, Mr. Simmons.
 22 MR. SIMMONS:
 23 Q. Dan Simmons, as you know. Just two or three
 24 brief things I wanted to follow up on you
 25 about, you told us about the meeting on the

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1 17th of May, 2005.
 2 DR. CARTER:
 3 A. Yes.
 4 MR. SIMMONS:
 5 Q. And if I can recall correctly, at that point
 6 it was decided to go back and retest cases
 7 from 2002.
 8 DR. CARTER:
 9 A. Yes.
 10 MR. SIMMONS:
 11 Q. And you were asked a number of questions about
 12 how that decision came to be made. And do I
 13 understand that at that point you didn't know
 14 anything about the fact that Dr. Ejeckam had
 15 suspended some testing back in 2003 and had
 16 done some work on the antibodies back then.
 17 Do I understand that that's something you
 18 learned later?
 19 DR. CARTER:
 20 A. I learned it that summer, spring, summer, so I
 21 wouldn't state with certainty that I didn't
 22 know it at that time. I may have.
 23 MR. SIMMONS:
 24 Q. Okay, and was there any discussion at that
 25 meeting on May 17th, that first meeting that

Page 52

1 you attended, of what Dr. Ejeckam had done
 2 back in '03? Did that come up as a topic or
 3 did it appear to be something that the people
 4 at that meeting were aware of?
 5 DR. CARTER:
 6 A. Not that I recall. I recall the meeting being
 7 about let's make a plan.
 8 MR. SIMMONS:
 9 Q. Okay, so--and you've told us that your
 10 recollection is that the decision to
 11 concentrate on 2002 for the initial retesting
 12 that was going to be done was because that was
 13 where the index case had come from and the
 14 other cases that, a few cases that had come up
 15 had come from 2002, do I have that correct?
 16 DR. CARTER:
 17 A. Yes, so we were going to start at that point.
 18 MR. SIMMONS:
 19 Q. So do I understand then that there was no
 20 connection made by anybody between anything
 21 Dr. Ejeckam had done and the decision to look
 22 at 2002 initially for retesting?
 23 DR. CARTER:
 24 A. Not that I remember. I think we were looking
 25 at it as sample and then to see, you know,

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1 what information we could get from that sample
 2 and to move out from there.
 3 MR. SIMMONS:
 4 Q. Okay, Mr. Coffey asked you a few minutes ago
 5 about your own reporting of ER/PR testing and
 6 you told us that until the standardization
 7 happened within Eastern Health, you had used
 8 different formats and you hadn't consistently
 9 reported the percentage of the stain?
 10 DR. CARTER:
 11 A. That's correct.
 12 MR. SIMMONS:
 13 Q. And you said the same when you were at
 14 McMaster in Hamilton or that was your practise
 15 when you were at McMaster in Hamilton.
 16 DR. CARTER:
 17 A. Generally.
 18 MR. SIMMONS:
 19 Q. And I'm just curious, when you did your work
 20 with Dr. Page who you've identified as being
 21 one of North America's experts in the area,
 22 was there any particular reporting practice
 23 that was in use at his facility or by him, for
 24 example, did they universally report
 25 percentages or not?

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1 DR. CARTER:
 2 A. I worked on a consultative service, so we were
 3 getting consults from all across the United
 4 States, all across the world, so I wouldn't be
 5 able to comment on what the histopathology lab
 6 did in Vanderbilt University Medical Centre.
 7 But we would just say positive and negative
 8 when we were reporting.
 9 MR. SIMMONS:
 10 Q. You told us about the slides that had been
 11 sent to Montreal for quality assurance
 12 purposes and that had come back and initially
 13 were un-interpretable, and why was that? What
 14 was the problem with those slides?
 15 DR. CARTER:
 16 A. The first set, because as Mr. Coffey reminded
 17 me, there were two sets, but the first set
 18 that we had sent off we had asked for them to
 19 be stained and just sent back and then the
 20 interpretation was going to be done by myself
 21 and/or Dr. Cook. And when we received the
 22 slides and began to look at them, they were
 23 testing on a Ventana. I think it was the same
 24 Ventana or a very similar Ventana, so that's
 25 why we had picked that to do a sort of

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1 parallel study and when we looked at the
 2 slides, only a portion of each slide had been
 3 stained. Without getting too technical, it
 4 looked like the cover slipper had dropped
 5 before the antigen antibody reaction had been
 6 able to take place. So, when we actually
 7 looked at the tissue slide, one portion of it
 8 was staining with the estrogen receptor and
 9 progesterone receptor and the other half of it
 10 would be naked. And there was a clear mark in
 11 the centre or to one side of the centre of the
 12 slide. So, it looked like some mechanical
 13 event had happened.
 14 MR. SIMMONS:
 15 Q. Okay. So, there was a second set of slides
 16 then stained at Montreal was therein sent back
 17 again for your review.
 18 DR. CARTER:
 19 A. Yes, but I think the--I'm not sure if they
 20 used a different technology or if they, went
 21 back, did some troubleshooting, and did the
 22 Ventana.
 23 MR. SIMMONS:
 24 Q. Did you see the second set of slides when they
 25 came in?

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1 DR. CARTER:
 2 A. Yes, I think that was the memo actually that
 3 Mr. Coffey put up.
 4 MR. SIMMONS:
 5 Q. And they were stained satisfactorily the
 6 second time.
 7 DR. CARTER:
 8 A. Yes.
 9 MR. SIMMONS:
 10 Q. Okay. And only one other question, you've
 11 told us about the meeting on the 1st of
 12 August, 2005 which was the meeting that Mr.
 13 Tilley was present at and there's a number of
 14 people there. We've gone through some of the
 15 detail. By that point, you had reviewed a
 16 number of the slides from 2002 and some from
 17 some other years as part of the work that you
 18 had been doing up to that point.
 19 DR. CARTER:
 20 A. Yes.
 21 MR. SIMMONS:
 22 Q. Yes, because there's two batches that you'd
 23 see. At that meeting, did you give any kind
 24 of summary or explanation of what you had
 25 found up to that point from your review of

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1 those slides?

2 DR. CARTER:

3 A. I didn't give an official, here's my report,

4 that I remember, but I know in all of the

5 arguing back and forth, I mean, a lot of these

6 issues would have been raised.

7 MR. SIMMONS:

8 Q. Okay. Was the issues you identified regarding

9 internal controls, were they brought out at

10 that meeting?

11 DR. CARTER:

12 A. Again, I'm not sure if they would have been

13 brought out at that meeting, but they would

14 have probably have been known to people.

15 MR. SIMMONS:

16 Q. Well, they would have been known to you and to

17 Dr. Cook.

18 DR. CARTER:

19 A. At least, but I think other people as well,

20 but I'm not sure.

21 MR. SIMMONS:

22 Q. Okay. Thank you very much.

23 THE COMMISSIONER:

24 Q. Mr. Pritchett?

25 MR. PRITCHETT:

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1 Q. I have no questions, Commissioner. Thank you,

2 Dr. Carter.

3 THE COMMISSIONER:

4 Q. Ms. Newbury?

5 DR. BEVERLEY CARTER, EXAMINATION BY JENNIFER NEWBURY

6 MS. NEWBURY:

7 Q. Good morning, Dr. Carter.

8 DR. CARTER:

9 A. Good morning.

10 MS. NEWBURY:

11 Q. My name is Jennifer Newbury and I represent

12 the Canadian Cancer Society, Newfoundland and

13 Labrador Division. I have a few questions for

14 you this morning. And I wanted to start with,

15 I guess, the role and interaction between a

16 pathologist and oncologist in raising

17 potential concerns about an ER/PR test result

18 and there's been some evidence I think by Dr.

19 Cook and Dr. Parai that prior to 2005 no one

20 had raised concerns about ER/PR tests results.

21 And that's, generally speaking, there were no

22 concerns raised. And I guess I'm curious what

23 your views are on the ability of an oncologist

24 to raise potential concerns with results from

25 an ER/PR test and what means would an

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1 oncologist have of detecting any possible

2 discrepancies in those results?

3 DR. CARTER:

4 A. I think that they would have a very limited

5 role in identifying things like that. I think

6 there are some motherhood statements, you

7 know, that can be made, you know, infiltrating

8 lobulars are positive, adenoid cystics are

9 negative. So, I mean, there's those kinds of

10 very basic things, but I think that largely

11 they rely on what we say.

12 MS. NEWBURY:

13 Q. And generally speaking in pathology, and I'm

14 wondering if there are situations in other

15 instances where you might have a test result

16 regarding a patient and based on that

17 pathology report, an oncologist might start

18 treatment and then because the treatment may

19 not go as expected they might say, well, let's

20 perhaps have another look at that test result.

21 Are there situation in pathology and oncology

22 where you might get some immediate response

23 based on decisions made or clinical picture of

24 the patient?

25 DR. CARTER:

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1 A. Well, just say for example colon cancer, if I

2 had signed out a colon cancer as being T2,

3 pathology stage 2, which means that it's still

4 confined to the bowel and the surgeon has done

5 the surgery and the surgeon knows that he or

6 she had difficulty removing it from the

7 sidewall of the abdominal cavity, yes, they're

8 going to phone you right away and say, what

9 are you talking about? This is not a T2, I

10 mean, I couldn't get that off the sidewall,

11 it's a T4. So, there are issues like that. I

12 can think of very rare instances where you

13 would be in treatment and come back and have a

14 look at the pathology because there may be

15 some odd type of tumour. I'm just thinking of

16 a case of an esophageal cancer that we had

17 that was, you know, quite resistant to

18 therapy. And in a therapy that is generally

19 successful. As you know, with oncology

20 treatment, that's a bit of a broad statement.

21 So, I mean, they wanted that looked--you know,

22 could this be some kind of odd chemotherapy

23 resistant, some type of carcinoma, but that

24 would be a very rare event.

25 MS. NEWBURY:

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1 Q. Okay. So, then in terms of how ER/PR test
 2 results fits into the scheme of pathology,
 3 it's not that unusual that an oncologist may
 4 not be able to look at the clinical features
 5 or response to treatment to maybe raise some
 6 concerns about the accuracy of the ER/PR test
 7 results.
 8 DR. CARTER:
 9 A. I don't think, in response to treatment, but
 10 again the oncologist would be able to explain
 11 this to you better, but I don't think that
 12 response to treatment and Tamoxifen are that
 13 tightly. We know that some negative people
 14 respond; some positive people don't respond.
 15 So, I don't think that that correlation could
 16 be expected. And again, I think outside of
 17 some very basic statements, in my opinion, it
 18 would be unreasonable to expect that an
 19 oncologist should know pathology as well as
 20 their own speciality.
 21 MS. NEWBURY:
 22 Q. And ER/PR is not that different from other
 23 types of test results in that regard? I guess
 24 I want to find out whether ER/PR test results
 25 are unique, you know, are there other types of

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1 test results that might be more readily
 2 identified as being perhaps inaccurate?
 3 DR. CARTER:
 4 A. Well, there's CD117 expression in a
 5 gastrointestinal stromal tumour which I know
 6 oncologists are interested in and it's not and
 7 area of my expertise. I don't know if they
 8 would feel more comfortable questioning a test
 9 if you said that CD117 was negative.
 10 MS. NEWBURY:
 11 Q. So, basically in terms of relying on an
 12 oncologist to say, listen, I don't know if
 13 that ER/PR test result might warrant a repeat
 14 because it doesn't fit with my picture, you
 15 don't really expect that to happen as
 16 pathologists because the, like I said, the
 17 Tamoxifen and response to that is not as
 18 tightly connected to the actual result.
 19 DR. CARTER:
 20 A. And I think as a pathologist, I wouldn't look
 21 to an oncologist to act as a quality assurance
 22 measure for my work. I would look more in a
 23 multi-disciplinary team meeting when you are
 24 coming up against individual problems that
 25 perhaps from that, something in the fallout

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1 form all that, something may change in labs,
 2 but no, I don't think that oncologists act as
 3 QA for my work.
 4 MS. NEWBURY:
 5 Q. Okay. And I want to ask you a couple of
 6 questions about your review of the 90 or so
 7 cases in the summer of 2005, just some general
 8 questions there. And I take it from your
 9 evidence that what you had reviewed at that
 10 time would have been primarily ER negative
 11 cases on their initial testing as well as some
 12 other cases that had surrogate markers.
 13 DR. CARTER:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. And just would have been a few of those
 17 surrogate marker cases. And those surrogate
 18 marker cases would have been chosen because
 19 you had expected that the result would have
 20 been a higher percentage of ER positivity?
 21 DR. CARTER:
 22 A. Yes, my view when I started this process is
 23 that I was answering the question, what went
 24 wrong in the lab. I wasn't answering the
 25 question, you know, how many patients are

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1 affected and how can we resolve that quickly.
 2 I was investigating what had gone wrong in the
 3 lab. So, I looked for negative cases because
 4 that seemed to be where our problem was from,
 5 but the plan was to expand it to look at any
 6 cases as issues arose as we were going
 7 through. And also I would look at cases where
 8 the results I saw in the chart were different
 9 from what I had expected.
 10 MS. NEWBURY:
 11 Q. Okay. And I wonder if we can bring up Exhibit
 12 P-0069 please. And this is your letter to Dr.
 13 Cook dated July 14th, 2005. And this was your
 14 proposal for the review. And paragraph two,
 15 you indicated that "as quickly as possible, I
 16 would like to know the estrogen receptor
 17 status of every patient tested in our
 18 laboratory between 1997 and 2004. From that
 19 information I would also like an estimate of
 20 the total of positive cases given out per
 21 year. I would need all of the reports pulled
 22 from the computer for review. Patient
 23 demographics including name, age and MCP
 24 should be collated along with their surgical
 25 number, their histologic type of carcinoma and

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1 the histologic grade. All of the slides from
 2 the cases including the estrogen receptor
 3 slides need to be pulled and organized. All
 4 slides then need to be reviewed by me, both
 5 estrogen receptor negative and estrogen
 6 receptor positive patient. Estrogen receptor
 7 negative patients should be given priority".
 8 So, I take it at that time your review
 9 contemplated not just looking at ER negative,
 10 but also looking at ER positive test results.
 11 DR. CARTER:
 12 A. You may move out into that area, I don't know
 13 if I discussed it in this process or in my
 14 interviews, but in the lab many of these
 15 things are stored in far away places and in
 16 obscure locations. So, if you're asking for
 17 something, you ask for the maximum because if
 18 Judy Quinlan is going to go and find a block
 19 for you, she may bring the whole thing. So, I
 20 mean, that's why we're putting it there, but
 21 also as we were going through the process, we
 22 may find that, you know, it's on a certain
 23 day. So, then you'll want to look at all the
 24 tests of that day.
 25 MS. NEWBURY:

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1 Q. Okay. So, at this point in time, your plan
 2 was perhaps a little bit fluid. You may have
 3 changed it based on what you started to find -
 4 DR. CARTER:
 5 A. It would have changed.
 6 MS. NEWBURY:
 7 Q. - as the process started.
 8 DR. CARTER:
 9 A. Yes.
 10 MS. NEWBURY:
 11 Q. But you were certainly contemplating looking
 12 at ER positive test results at that point in
 13 time.
 14 DR. CARTER:
 15 A. At that point in time.
 16 MS. NEWBURY:
 17 Q. And based on your observations and the review
 18 of the 90 or so slides, did you have any
 19 concerns about--I know they were primarily ER
 20 negative and there were some positive slides,
 21 I think, with the appropriate surrogate
 22 markers, but did you have any reason to be
 23 concerned about ER positive results based on
 24 what you saw? Could you extrapolate from that
 25 90 slide review?

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1 DR. CARTER:
 2 A. I hadn't at the time.
 3 MS. NEWBURY:
 4 Q. Okay. So, you hadn't focused on any possible
 5 concerns with ER positive test results at that
 6 point in time?
 7 DR. CARTER:
 8 A. Not at that point.
 9 MS. NEWBURY:
 10 Q. Okay. And at any point after did you have any
 11 concern about ER positive test results?
 12 DR. CARTER:
 13 A. We talked about it a little bit yesterday or
 14 the day before yesterday, sorry, that when we
 15 had sent some cases up for quality assurance
 16 to Mount Sinai in the summer of 2005 that that
 17 had been raised as a concern.
 18 MS. NEWBURY:
 19 Q. And that related to the possible overcalling
 20 on the Ventana machine due to the non-specific
 21 staining.
 22 DR. CARTER:
 23 A. Yes, but that was not investigate further.
 24 MS. NEWBURY:
 25 Q. Right. And anything for test results from

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1 prior to the implementation of Ventana?
 2 DR. CARTER:
 3 A. Not that I recall in specific, but I haven't
 4 really thought about it in preparation for
 5 this.
 6 MS. NEWBURY:
 7 Q. And perhaps if you want to think about it,
 8 that's fine, if you want to raise something
 9 later on, that's fine as well. But I guess
 10 the review that you did probably wouldn't
 11 focus on that anyway, you were trying to zero
 12 in on what you knew to be a possible problem
 13 which is ER negative slides.
 14 DR. CARTER:
 15 A. Yes.
 16 MS. NEWBURY:
 17 Q. Would you have been able to give assurances at
 18 that time that there are no problems with
 19 possible false positives either on the Ventana
 20 equipment or before that? Or is that
 21 something that would have warranted some
 22 further investigation?
 23 DR. CARTER:
 24 A. If somebody had asked me that question at the
 25 time, I would not have given assurances that

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1 this was not a possibility. I had no
 2 information about that.
 3 MS. NEWBURY:
 4 Q. Okay. And I note there, further down on that
 5 report on the bottom of the paragraph, you've
 6 indicated that ten percent of cases should be
 7 randomly selected for outside quality
 8 assurance consultation. And at that time,
 9 just you know, on that particular day when you
 10 were looking at the type of review that might
 11 be necessary, do you think that that would
 12 have included ER positive test results, not
 13 just after the Ventana was implemented but
 14 before that or had you not given any specific
 15 -
 16 DR. CARTER:
 17 A. No, at the time I was looking to apply quality
 18 measures to the retesting that I was having
 19 done, so when we randomized the cases, I mean,
 20 it was a directed randomization. We would
 21 include ones that had not converted, ones that
 22 had shown on repeat testing to be weakly
 23 positive and then routine positive cases.
 24 MS. NEWBURY:
 25 Q. Okay. So it would have covered the gamut of

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1 testing, and that was not subsequently
 2 followed as far as you're aware? Did you
 3 subsequently proceed with a full review as
 4 you've laid out there in paragraph 2?
 5 DR. CARTER:
 6 A. No, I stopped on August the 2nd.
 7 MS. NEWBURY:
 8 Q. And you're not aware that anyone else
 9 proceeded to do any random testing that might
 10 include ER positive cases subsequently?
 11 DR. CARTER:
 12 A. On the retrospectives?
 13 MS. NEWBURY:
 14 Q. Yes.
 15 DR. CARTER:
 16 A. No, they had sent them to Mount Sinai and
 17 Mount Sinai takes part in their own quality
 18 program, so I would assume that at Mount Sinai
 19 they did but not at Eastern Health's.
 20 MS. NEWBURY:
 21 Q. Okay.
 22 DR. CARTER:
 23 A. We didn't do the retesting.
 24 MS. NEWBURY:
 25 Q. Was there any retesting of ER positive test

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1 results from '97 to 2005, random or otherwise?
 2 DR. CARTER:
 3 A. Not directed by me. As part of the
 4 retrospective review there may have been.
 5 MS. NEWBURY:
 6 Q. Okay. And you'd mentioned that some of the
 7 slides that you selected from your 90, I guess
 8 90 or so case review early in the summer of
 9 2005 would have included some of the surrogate
 10 markers for, and I guess those are cases that
 11 you expected to be perhaps a higher percentage
 12 of positivity?
 13 DR. CARTER:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. Are there any comparable cases or surrogate
 17 markers where you might expect it to be ER
 18 negative as opposed to ER positive?
 19 DR. CARTER:
 20 A. Medullary carcinomas of the breast, atypical
 21 medullary carcinomas of the breast would fall
 22 into that category.
 23 MS. NEWBURY:
 24 Q. Um-hm.
 25 DR. CARTER:

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1 A. But again, you know, you have to have very
 2 strict histologic definitions of those, like,
 3 for example, mucinous carcinomas, pathologists
 4 will tend to add that adjective to anything
 5 that produces mucin or mucous, which is not a
 6 wrong thing to do; I mean, you're giving a
 7 descriptive, so if you're talking about very
 8 strict histologic criteria. Adenoid cystic is
 9 an extremely unusual breast cancer and that's
 10 defined as negative.
 11 MS. NEWBURY:
 12 Q. Um-hm.
 13 DR. CARTER:
 14 A. If you're looking at very high-grade tumours,
 15 you would expect them to be negative more
 16 often than a low-grade tumour, but still
 17 you're talking about 75 percent positivity.
 18 So it may be down to 60 percent in grade 3s
 19 but no strong correlation.
 20 MS. NEWBURY:
 21 Q. So there are a couple of possible surrogate
 22 markers there but I guess your reservations
 23 are they're rare types of cancers to begin
 24 with?
 25 DR. CARTER:

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1 A. Paget's disease, I mean, now that you're
 2 asking the question they're all popping into
 3 my head. Paget's disease of the breast, which
 4 is in an in situ kind of change, you'd expect
 5 a pattern from that, as well.
 6 MS. NEWBURY:
 7 Q. And you'd expect it to be ER negative as
 8 opposed to ER positive?
 9 DR. CARTER:
 10 A. Usually.
 11 MS. NEWBURY:
 12 Q. And is that a rare type of cancer, as well?
 13 DR. CARTER:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. Do you know if any analysis had been done to
 17 see if the results for these types of breast
 18 cancers had resulted in ER positive test
 19 results versus ER negative test results?
 20 DR. CARTER:
 21 A. I am not aware of any analysis that's been
 22 done.
 23 MS. NEWBURY:
 24 Q. You indicated to Mr. Coffey the other day that
 25 when you did the reviews of 90 or so cases,

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1 that you came across a couple of cases that
 2 had been repeated sometime earlier and at
 3 least one of those, in your recollection, had
 4 a significant change of result. And you
 5 indicated that you hadn't brought this to
 6 anyone's attention during your review in the
 7 summer of 2005 because you assumed that it
 8 would have been handled at the time. And I'm
 9 just wondering if you could explain what you
 10 meant by that, how would you have expected it
 11 to have been handled at the time?
 12 DR. CARTER:
 13 A. Well, if I'm working on any sort of case, I
 14 mean, you move outside a breast, I mean, if
 15 you're, you know, working on a liver case, you
 16 know, and you begin to work it up and send out
 17 a report to the clinician and say, you know, I
 18 think that this is hepatitis B.
 19 MS. NEWBURY:
 20 Q. Um-hm.
 21 DR. CARTER:
 22 A. You know, for example. Then if I get
 23 information three or four days after that that
 24 would directly contradict what I had already
 25 reported to the clinician, usually we would

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1 telephone the clinician and say, you know,
 2 listen, there's a change in the information
 3 and issue an addendum on it. But usually if
 4 you issue contradictory reports, you preempt
 5 the phone call that you're inevitably going to
 6 get. If you call it hepatitis B one day and
 7 hepatitis C the next day somebody is going to
 8 phone you and say, well, which one is it.
 9 MS. NEWBURY:
 10 Q. Right. So would your primary concern then in
 11 terms of handling a repeat test result with a
 12 significant change is to ensure that the
 13 clinician that's treating the patient is aware
 14 of the change and the reason for the change?
 15 DR. CARTER:
 16 A. Yes.
 17 MS. NEWBURY:
 18 Q. Are there any other procedures done for
 19 quality assurance purposes to perhaps look
 20 into why was there a change, is it a change
 21 that's unique to this particular patient,
 22 could there be any problems that might expand
 23 beyond this particular patient?
 24 DR. CARTER:
 25 A. Well, it would depend on the circumstance of

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1 why the change was made. If I looked at a
 2 case and, you know, diagnosed it to the best
 3 of my abilities and then got contradictory,
 4 you know, results, because of, you know, a lab
 5 test or whatever, I mean, you would report
 6 that to the lab manager and, you know, assume
 7 that from there they would see what it was.
 8 If I had said hepatitis B when I meant to say
 9 hepatitis C, I mean, I would probably notify
 10 the clinical chief that I had just, you know,
 11 made a really goofy error in my report. So it
 12 would depend on the circumstance of why the
 13 change had been made.
 14 MS. NEWBURY:
 15 Q. Okay, and would you want to satisfy yourself
 16 that the change, you know, can be explained
 17 and it's not indicative of any sort of a
 18 larger problem that might affect other test
 19 results?
 20 DR. CARTER:
 21 A. I mean, that would be the ideal, yes.
 22 MS. NEWBURY:
 23 Q. If I could have Exhibit P-2457, please? The
 24 exhibit that I'm bringing up now is the
 25 physician panel meeting number one minutes and

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1 there's a revised version later, but I think
 2 for the purposes of my question, this exhibit
 3 should suffice. Now this is dated October
 4 13th, 2005, and you are one of the attendees
 5 there at the meeting, and there is some
 6 discussion there about the mandate of the
 7 panel and I think the second paragraph there
 8 indicates that "it was agreed that the
 9 referring physician should be notified and
 10 that the primary cancer treating physician
 11 would be responsible for follow up of the
 12 recommendations from the panel." Now in terms
 13 of--and I think you alluded to this the other
 14 day, in terms of the physicians who would
 15 ultimately receive the letters from the panel,
 16 in all instances, the treating physician or
 17 the referring physician referenced here may no
 18 longer be actively involved with the patient.
 19 They may have--I think you indicated one had
 20 since died and others may have moved on, and
 21 in some cases, the patients were discharged
 22 from care of the oncologists or the Cancer
 23 Clinic and were you generally aware at this
 24 time what other physicians might be the
 25 recipient of the letter? Was there any

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1 discussion about that?
 2 DR. CARTER:
 3 A. We would send the letter to the family
 4 physician identified on the chart, the
 5 oncologist most recently involved in active
 6 treatment on the chart, but I'm not aware of
 7 other physicians. I'm not really sure what
 8 you mean.
 9 MS. NEWBURY:
 10 Q. I'm just trying to gauge, at this point in
 11 time, who you contemplated would be receiving
 12 the bulk of the letters. Would it be an
 13 actively involved oncologist or would many of
 14 the letters not ultimately be received by
 15 someone who's then currently treating the
 16 patient? And I guess one of the questions is
 17 how--this goes back to 1997.
 18 DR. CARTER:
 19 A. So many of those patients would have, in fact,
 20 been discharged from--not many. Some of those
 21 patients would have been discharged from the
 22 Cancer Centre.
 23 MS. NEWBURY:
 24 Q. Are you aware, as a pathologist, how long an
 25 oncologist or the Cancer Clinic tends to

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1 follow a patient after their initial
 2 diagnosis?
 3 DR. CARTER:
 4 A. That wouldn't be in the scope of my practice.
 5 MS. NEWBURY:
 6 Q. Okay, and that wasn't discussed at the time of
 7 this meeting, that you recall?
 8 DR. CARTER:
 9 A. No, only as an individual case, "this patient
 10 is no longer at the Cancer Centre. That
 11 patient is no longer."
 12 MS. NEWBURY:
 13 Q. If I could bring up Exhibit 2461, please, P-
 14 2461? And there are a group of letters here
 15 that you sent. I think this was the day that
 16 you were acting as chair of the panel, and I
 17 guess I'm trying to get a sense as to how many
 18 of the letters would have gone to oncologists,
 19 and because the names here are redacted, it's
 20 hard for me to draw any conclusions, but I
 21 don't know if you would have any recollection
 22 here of, you know, whether these letters--I
 23 think there's 14 letters there--would have
 24 gone typically to the oncologists or the
 25 family physician. You have no recollection of

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1 -
 2 DR. CARTER:
 3 A. I have no recollection of what physicians they
 4 would have gone.
 5 MS. NEWBURY:
 6 Q. Was an introductory letter sent to treating
 7 physicians explaining the purpose and
 8 composition of the physician panel review? Is
 9 this the only letter here that may have gone
 10 to a physician say outside of the St. John's
 11 area who -
 12 DR. CARTER:
 13 A. I have no information about how it was set up.
 14 MS. NEWBURY:
 15 Q. Okay, and looking back at Exhibit 2457, there
 16 are a variety of people at your first meeting
 17 and some of them, I think, continued on to
 18 attend subsequent meetings of the physician
 19 review panel.
 20 DR. CARTER:
 21 A. Yes.
 22 MS. NEWBURY:
 23 Q. And Dr. Kara Laing is an oncologist. Dr.
 24 McCarthy is an oncologist. Dr. Kwan and Felix
 25 are surgeons, I believe.

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1 DR. CARTER:
 2 A. Yes, they are.
 3 MS. NEWBURY:
 4 Q. So presumably these physicians would have
 5 dealt with--would have been the treating
 6 physicians for some of the patients or perhaps
 7 many of the patients whose cases were reviewed
 8 by the panel.
 9 DR. CARTER:
 10 A. Yes, so some patients--and again, treatment is
 11 not my area of expertise, but some patients,
 12 their treatment would be entirely the surgery
 13 then yes or no on Tamoxifen. So they would
 14 not have been referred to the Cancer Centre,
 15 but treatment is not my area.
 16 MS. NEWBURY:
 17 Q. Okay, sure. So in any event, some of the
 18 patient whose cases were being reviewed by the
 19 panel may, in fact, have had their own
 20 treating physician at a panel meeting when
 21 their case was reviewed?
 22 DR. CARTER:
 23 A. Yes.
 24 MS. NEWBURY:
 25 Q. Was there an effort made to have the patient

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1 present on the night that his or her patients
 2 case was being reviewed or was it just luck of
 3 the draw, how the cases came up?
 4 DR. CARTER:
 5 A. I think the surgeons would often bring a list
 6 of their own patients for submission to the
 7 panel. I think for the medical and radiation
 8 oncologists that came, it would be just the
 9 routine patients for that evening.
 10 MS. NEWBURY:
 11 Q. Okay. So there was no concerted effort,
 12 perhaps with the exception of the surgeons, to
 13 have the oncologist present? Say if Dr.
 14 McCarthy was unavailable at a later panel
 15 meeting, would she postpone review of any of
 16 her own patients to a meeting where she was
 17 present?
 18 DR. CARTER:
 19 A. I don't think so.
 20 MS. NEWBURY:
 21 Q. Okay.
 22 DR. CARTER:
 23 A. But they would be able to tell you more about
 24 that.
 25 MS. NEWBURY:

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1 Q. And were there treating oncologists and any
 2 other treating physicians who were not ever
 3 present at any panel meetings?
 4 DR. CARTER:
 5 A. Well, certainly, I guess, the surgeons, they
 6 would treat patients for breast cancer, but
 7 there was just two surgeons on the panel. The
 8 same with radiation oncology, I think.
 9 MS. NEWBURY:
 10 Q. So is it fair to say that there are a number
 11 of patients whose cases were reviewed and
 12 their treating physician would not have been
 13 at that particular panel meeting?
 14 DR. CARTER:
 15 A. Yes.
 16 MS. NEWBURY:
 17 Q. And aside from this, I guess the initial
 18 discussion here at this meeting, did you
 19 personally have any input into the composition
 20 of the panel or the mandate of the panel?
 21 DR. CARTER:
 22 A. The composition of the panel, I think was
 23 fluid. You know, medical oncologists and
 24 radiation oncologists and surgeons, I think,
 25 were welcome to attend. I know Dr. Cook and I

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1 used to substitute off of one another and the
 2 night that I was the acting chair, Doctors
 3 Laing and McCarthy were unavailable so two
 4 other medical oncologists attended that
 5 evening because we would need somebody to make
 6 treatment decisions. I think the composition
 7 did vary over time.
 8 MS. NEWBURY:
 9 Q. Okay, and in terms of who ought to be sitting
 10 on the panel, that's not something that you
 11 were involved in from the outset?
 12 DR. CARTER:
 13 A. No, I came in after the panel had been
 14 initially formed.
 15 MS. NEWBURY:
 16 Q. Yes, so the idea of the panel had been formed
 17 and then you were subsequently invited to sit
 18 on the panel?
 19 DR. CARTER:
 20 A. Yes.
 21 MS. NEWBURY:
 22 Q. Okay. Have you ever encountered a panel of
 23 this type before?
 24 DR. CARTER:
 25 A. With this mandate, no.

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1 MS. NEWBURY:
 2 Q. Okay.
 3 DR. CARTER:
 4 A. But I mean, there's lots of multidisciplinary
 5 tumour panels that we serve on.
 6 MS. NEWBURY:
 7 Q. The tumour boards, and you were describing
 8 that, and I'll ask you a couple of questions
 9 about that in a moment. Do you know if there
 10 was any discussion or effort by the panel
 11 members, either you know, perhaps particularly
 12 at this meeting here, to seek any guidance or
 13 discuss with anyone outside of Eastern Health
 14 who might have some familiarity with this sort
 15 of a panel and its, what might be a unique
 16 mandate?
 17 DR. CARTER:
 18 A. Not that I'm aware of, but that may have
 19 occurred in the preliminary stages. There was
 20 some discussion about, you know, how we were
 21 going to set up and how we were going to
 22 report, so there may have been.
 23 MS. NEWBURY:
 24 Q. Okay. There were a number of patients
 25 identified in the early stages of 2005, the

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1 summer of 2005, and a number of those had
 2 converted and had been advised of their
 3 results on the repeat testing. Do you know if
 4 any of those were part of any sort of a
 5 panelling process? Would you have been aware
 6 of that and are you aware?
 7 DR. CARTER:
 8 A. So are you talking about the 25 plus 33?
 9 MS. NEWBURY:
 10 Q. Yes.
 11 DR. CARTER:
 12 A. Did they go to panel? I don't know.
 13 MS. NEWBURY:
 14 Q. And you're not aware if there had been any
 15 concerns regarding those particular patients
 16 about how decisions were made about their
 17 treatment and this is the first stage of
 18 patients who converted? Did you ever hear any
 19 discussions about that?
 20 DR. CARTER:
 21 A. No. Those reports, I think, were released
 22 singly to the treating physician, so I would
 23 assume that the discussion was held with the
 24 patient about treatment possibilities.
 25 MS. NEWBURY:

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1 Q. So any discussion then, you feel, would have
 2 been between the patient and the treating
 3 physician at the time?
 4 DR. CARTER:
 5 A. I would assume, but I really don't know much
 6 about the process.
 7 MS. NEWBURY:
 8 Q. It didn't generate any sort of group
 9 discussion in your presence?
 10 DR. CARTER:
 11 A. No.
 12 MS. NEWBURY:
 13 Q. Are you aware of the patients that, whose
 14 cases were being reviewed by the panel, had
 15 been advised of their results prior to the
 16 panelling process, the fact that they had been
 17 received and generally what they were and the
 18 fact that their case would be reviewed by the
 19 panel? I'm just wondering, as a pathologist
 20 sitting on that committee, did you have any
 21 knowledge of those sorts of matters?
 22 DR. CARTER:
 23 A. That the patient would be told that they would
 24 be panelled?
 25 MS. NEWBURY:

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1 Q. Yes, and whether they had generally been aware
 2 that results were available for them but that
 3 a decision had been made to send their case--
 4 refer their case to a review panel?
 5 DR. CARTER:
 6 A. Again, I'm not sure that that happened.
 7 MS. NEWBURY:
 8 Q. Okay, and so sitting on the panel, that wasn't
 9 something that was discussed, about whether or
 10 not there should be notification or whether
 11 there had been notification or a decision made
 12 against notifying the patients about the
 13 process itself?
 14 DR. CARTER:
 15 A. No, I don't think so.
 16 MS. NEWBURY:
 17 Q. And were you aware of any consideration given
 18 to allow patients to opt into the panelling
 19 process or perhaps to opt out of the panelling
 20 process?
 21 DR. CARTER:
 22 A. No.
 23 MS. NEWBURY:
 24 Q. Who on the panel might have been aware of any
 25 discussions of those types of issues, you

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1 know, the procedure about notifying patients
 2 of the panel? Who did you see to be in charge
 3 of that?
 4 DR. CARTER:
 5 A. Dr. Laing would be the chair of the
 6 department. Ms. Predham from Quality
 7 Initiatives was supplying a lot of the
 8 information about what patients would be
 9 panelled at what time, and the panel, I think,
 10 had come from Dr. Williams' office, the Vice
 11 President Medical, so I would assume somewhere
 12 there, but I really--my role on this was to
 13 serve on an established panel as a pathologist
 14 and to review pathology reports.
 15 MS. NEWBURY:
 16 Q. And to give your input on that sort of narrow
 17 basis?
 18 DR. CARTER:
 19 A. Yes.
 20 MS. NEWBURY:
 21 Q. Okay, and you've mentioned the other day that
 22 you participated in--I think you said you
 23 personally participated in the surgical
 24 pathology rounds on Tuesday and I think you
 25 described it as tumour board rounds on

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1 Wednesdays?
 2 DR. CARTER:
 3 A. Yes.
 4 MS. NEWBURY:
 5 Q. Was it your practice to go to both of those
 6 types of rounds while you were at Eastern
 7 Health?
 8 DR. CARTER:
 9 A. Yes, and I take it from evidence that I've
 10 heard generally that the Tuesday surgical
 11 pathology rounds would take place in proximity
 12 of a multi-headed microscope?
 13 DR. CARTER:
 14 A. Yes, there would be all of the pathologists
 15 who were available on our site and residents.
 16 MS. NEWBURY:
 17 Q. Okay, and it would often involve looking at
 18 slides under the microscope, I take it?
 19 DR. CARTER:
 20 A. And almost all cases, that was the purpose of
 21 the round, microscopic review.
 22 MS. NEWBURY:
 23 Q. And the tumour board rounds would have a
 24 broader attendance, a number of different
 25 types of specialists would attend those?

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1 DR. CARTER:
 2 A. Yes, that was a multidisciplinary round.
 3 MS. NEWBURY:
 4 Q. Okay, and in terms of the surgical pathology
 5 rounds, would the sign out pathologist whose
 6 case was being reviewed on that particular
 7 Tuesday, would he or she always attend and
 8 present his or her own case?
 9 DR. CARTER:
 10 A. That's how the case would come to rounds, so
 11 it would have to be at the request of the
 12 original pathologist.
 13 MS. NEWBURY:
 14 Q. So as far as you know, it would never be the
 15 practice that a patient's case would be
 16 discussed when the actual sign out pathologist
 17 was present?
 18 DR. CARTER:
 19 A. Actually, yeah, that would happen rarely. So
 20 if the surgeon from head and neck phoned up
 21 and wanted, you know, a case that I had signed
 22 out, you know, just have a second look at it,
 23 and I was teaching or away, then yes, one of
 24 the pathologists would bring that to the
 25 board.

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1 MS. NEWBURY:
 2 Q. You would typically be aware of it?
 3 DR. CARTER:
 4 A. You would typically be aware of it, yes. You
 5 would bring them yourself, but -
 6 MS. NEWBURY:
 7 Q. Okay, and in terms of the tumour board rounds,
 8 would the treating physician typically attend
 9 the tumour board rounds at which that
 10 patient's case was being discussed?
 11 DR. CARTER:
 12 A. Usually that was how the patient arrived at
 13 the tumour board, because the treating
 14 physician would have a question about where
 15 they should go or what they should do, but
 16 often, at that point, the patients would have
 17 many treating physicians. They would be seen
 18 by a surgeon and a medical oncologist.
 19 MS. NEWBURY:
 20 Q. Would typically though, in that situation
 21 where you've got a patient who's got an
 22 oncologist and a surgeon and a medical
 23 oncologist, a radiation oncologist, and a
 24 surgeon, would you expect that at least one of
 25 those treating physicians would be present at

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1 a tumour board round?

2 DR. CARTER:

3 A. Yes.

4 MS. NEWBURY:

5 Q. And the Wednesday meetings, how long did those

6 typically last?

7 DR. CARTER:

8 A. Usually one hour.

9 MS. NEWBURY:

10 Q. Okay, and how many cases would you generally

11 discuss at that time?

12 DR. CARTER:

13 A. I would say most weeks we probably would have

14 somewhere around eight or nine cases.

15 Sometimes it would get quite extensive and

16 we'd have to, you know, book for a second

17 meeting or those sorts of things, but on an

18 average that would be.

19 MS. NEWBURY:

20 Q. In terms of the tumour, the physician review

21 panel, was there any concern about not having

22 a treating physician present for a particular

23 patient review?

24 DR. CARTER:

25 A. You're talking about the -

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1 MS. NEWBURY:

2 Q. The physician review panel for the ER/PR.

3 DR. CARTER:

4 A. So the tumour panel.

5 MS. NEWBURY:

6 Q. Yes.

7 DR. CARTER:

8 A. I don't recall it coming up as an issue.

9 MS. NEWBURY:

10 Q. After your involvement or at any time during

11 your involvement in the physician review

12 panel, the tumour panel for the ER/PR

13 situation, were you ever contacted by a

14 treating physician or a recipient of any of

15 the letters about your role in the panel, just

16 to, you know, have a further discussion or to

17 have some answers, questions answered?

18 DR. CARTER:

19 A. I don't think so.

20 MS. NEWBURY:

21 Q. And were you ever contacted by a treating

22 physician just in terms of the original

23 pathology results from Mount Sinai of a

24 patient whose test results had changed? Were

25 you ever contacted by someone, not necessarily

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1 in your capacity as a member of the physician

2 review panel, just to get further information

3 or to discuss the reports that were received?

4 DR. CARTER:

5 A. I think that I had discussions with

6 pathologists about it. Most of the

7 oncologists were on site and most of the

8 surgeons, you know, were on site, so I mean,

9 they would have known about these things as

10 they were going along.

11 MS. NEWBURY:

12 Q. I'm just wondering--I take it from your

13 evidence and evidence of other pathologists

14 that from time to time, you have an oncologist

15 that will call and I think some pathologists

16 expect them to call in mornings, or whatever,

17 at a designated time, to discuss a report, I

18 guess to help them come to decisions about

19 treatment. So that's--I take it that's not

20 uncommon generally speaking?

21 DR. CARTER:

22 A. No, that's not uncommon. I think I was trying

23 to explain that most of the oncologists that I

24 work with knew that we were having

25 conversions, so they wouldn't have called me

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1 and asked me about the conversion.

2 MS. NEWBURY:

3 Q. Okay.

4 DR. CARTER:

5 A. That's what I'm trying to explain.

6 MS. NEWBURY:

7 Q. Right, so just because they were generally

8 aware of what was going on, they would have no

9 need to call, but would there be a situation

10 where they might want to call to discuss, you

11 know, the significance of the conversion, to

12 have any other questions answered about the

13 pathology itself, not so much the situation,

14 but the results itself or is that something

15 that you wouldn't expect?

16 DR. CARTER:

17 A. I don't recall specifically having

18 conversations with them.

19 MS. NEWBURY:

20 Q. Do you know if treating physicians who were

21 not otherwise involved in the physician review

22 panel would have known who to contact if they

23 had any questions about the letters that they

24 received? If they wanted more information, I

25 guess they can contact the person there, but

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1 would they generally be aware of the types of
 2 people who were sitting on the panel?
 3 DR. CARTER:
 4 A. I mean, I really wouldn't know about the
 5 administration of the panel. I was there in a
 6 very minor, but necessary component, to review
 7 the pathology, but I really wouldn't have a
 8 whole lot of information about how it was set
 9 up and how things went.
 10 MS. NEWBURY:
 11 Q. And what was going on behind the scenes, that
 12 would be something for Dr. Laing or Dr.
 13 Williams or Ms. Predham perhaps?
 14 DR. CARTER:
 15 A. Yes, Dr. Williams, Ms. Predham, I would think.
 16 MS. NEWBURY:
 17 Q. Okay. You were shown a presentation that you
 18 gave November 2006, which you gave to all
 19 pathologists in the province, I believe, a
 20 session on the ER/PR testing from your -
 21 DR. CARTER:
 22 A. Pathologists, technologists, surgeons, anyone
 23 interested in the issue.
 24 MS. NEWBURY:
 25 Q. I'm just wondering, and I think you've

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1 indicated earlier that it was your
 2 understanding that physicians were generally
 3 aware that you had been involved in the start
 4 of a review back in the summer of 2005, that
 5 it wasn't a secret. They knew that you were
 6 involved in that. Did you receive any calls
 7 from any pathologist for perhaps some advice
 8 or tips or guidance on the whole issue?
 9 DR. CARTER:
 10 A. Yes, they would have telephoned me and asked
 11 my opinion on various cases. I would -
 12 MS. NEWBURY:
 13 Q. Specifically relating to the ER/PR testing and
 14 the concerns that you had?
 15 DR. CARTER:
 16 A. I'm sure that they would have asked me
 17 questions and we talked freely all the time.
 18 MS. NEWBURY:
 19 Q. So aside then from the presentation that you
 20 gave in November 2006, which was a formal
 21 presentation, you did receive individual calls
 22 from pathologists who were interested in the
 23 issue and perhaps what they might do or
 24 change?
 25 DR. CARTER:

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1 A. And I had given other CME events and we spoke
 2 about it at Newfoundland Association of
 3 Pathologists meetings and I had gone to
 4 Gander, distributed policies, so yes, there
 5 would have been a back and forth flow of
 6 information.
 7 MS. NEWBURY:
 8 Q. And at the physician review panel meetings,
 9 would you have had an opportunity to review
 10 patient files and, I guess, in particular, the
 11 pathology reports prior to the meeting or
 12 would you just see this information for the
 13 first time when you arrived at the panel
 14 meeting?
 15 DR. CARTER:
 16 A. For the most part, at the first--the first
 17 time I would see it would be at the panel
 18 meeting. Some of the patients would be my own
 19 patients, if you will, so I would have some
 20 familiarity with it.
 21 MS. NEWBURY:
 22 Q. Sure, okay, and I take it that the physician
 23 panel meetings weren't held at a location
 24 where slides could be reviewed if necessary?
 25 DR. CARTER:

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1 A. No. We would make note of that. Some of
 2 those cases did come up and we would make note
 3 of that and then go back to the lab the next
 4 day and start that process.
 5 MS. NEWBURY:
 6 Q. Okay. So there were some instances there
 7 where the physician panel meeting actually
 8 triggered a subsequent review of the slides?
 9 DR. CARTER:
 10 A. Yes.
 11 MS. NEWBURY:
 12 Q. Okay, and then you would deal directly, I
 13 guess, with the person at the meeting who
 14 suggested that, perhaps an oncologist, or how
 15 would you then handle that situation?
 16 DR. CARTER:
 17 A. We would go back and, you know, look at the
 18 case, look at the slides, look at the report.
 19 If it was an easily solvable issue, I mean,
 20 the most common thing was that we would send--
 21 or a block would be sent up to Mount Sinai and
 22 it would come back as no cancer and we would
 23 just look at the slides and it was yes, there
 24 is a huge cancer there, but the wrong block
 25 had been sent up. So in that case, we would

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1 just send forward the block and if there was
 2 any diagnostic difference of opinion, then I
 3 think we would talk with the oncologist of
 4 note on the chart, the original pathologist,
 5 if it was different from myself or Dr. Cook,
 6 and just carry through as we would with a
 7 consultation.
 8 MS. NEWBURY:
 9 Q. Dr. Carter, your CV makes reference to a
 10 project that you were involved in, your breast
 11 cancer pathology report, the role of your
 12 pathologists, and this suggests to me that you
 13 were of the view that a patient should be well
 14 informed about their diagnosis and their
 15 pathology situation?
 16 DR. CARTER:
 17 A. Yes.
 18 MS. NEWBURY:
 19 Q. And would you also think that they should be
 20 engaged and a partner in their treatment
 21 decisions?
 22 DR. CARTER:
 23 A. Yes.
 24 MS. NEWBURY:
 25 Q. Okay, and in light of this, and I know that

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1 your involvement in the, I guess, the
 2 administration aspects of the panel are fairly
 3 limited. You've indicated that you were there
 4 solely to provide input as a pathologist, as
 5 opposed to broader issues about informing
 6 patients there, but do you have any views or
 7 comments on the patient's role in decision
 8 making in view of the panel involvement?
 9 Would you have any expectations as to how that
 10 might have been handled?
 11 DR. CARTER:
 12 A. You mean, are you asking do I think that
 13 patients should have been on the review panel?
 14 MS. NEWBURY:
 15 Q. No, but just to be informed about the process,
 16 whether there might have been some input prior
 17 to a panel meeting or before the panel made a
 18 recommendation about a patient, to have some
 19 communication with the patient to find out
 20 what their concerns were, what their current
 21 status was and to perhaps make some effort to
 22 have a current treating physician have input
 23 into the panel's decision?
 24 DR. CARTER:
 25 A. That wouldn't be my area of expertise. I

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1 mean, I could give you my personal opinion.
 2 MS. NEWBURY:
 3 Q. Okay. I guess in terms of your role as a
 4 pathologist and the fact that you felt it a
 5 desirable project to have this report
 6 available to patients online and in
 7 oncologists' offices, to inform them about
 8 their pathology report. I mean, even that
 9 sort of information there, do you think the
 10 patient--there should be an engagement between
 11 the patient and the treating physicians?
 12 DR. CARTER:
 13 A. I mean, I agree that there's an engagement and
 14 that people need to have as much information
 15 about their diagnosis and their treatment as
 16 possible, and to be involved in their
 17 treatment decisions, but it wouldn't be my
 18 area to talk about at what point they would be
 19 involved.
 20 MS. NEWBURY:
 21 Q. Right, okay, and in terms of what actually
 22 happened as a result of the recommendations of
 23 the panel itself, you wouldn't have any
 24 knowledge as to how information was
 25 communicated and decisions ultimately made by

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1 the treating physician or the patient. That's
 2 not something that was ever brought back to
 3 the panel about how the program -
 4 DR. CARTER:
 5 A. I'm not sure I understood the question really.
 6 MS. NEWBURY:
 7 Q. I'm just wondering, in your role on the panel
 8 there, you've indicated it was fairly limited,
 9 but would you have had any feedback at all as
 10 to how patients were ultimately dealt with and
 11 how decisions were ultimately made by the
 12 patients, together with their treating
 13 physician about their treatment options?
 14 DR. CARTER:
 15 A. That information, no, would not have come back
 16 to me.
 17 MS. NEWBURY:
 18 Q. And you can't recall ever having received any
 19 feedback, you know, in terms of a panel
 20 discussion about how that was going along the
 21 way?
 22 DR. CARTER:
 23 A. No, I mean, it was a working meeting.
 24 MS. NEWBURY:
 25 Q. Okay. Thank you, Dr. Carter, those are all

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1 the questions I have for you.
 2 COMMISSIONER:
 3 Q. Thank you. Do you have any questions?
 4 MS. RUSSELL:
 5 COFFEY, Q.C.:
 6 Q. Yes.
 7 COMMISSIONER:
 8 Q. Okay then.
 9 DR. BEVERLEY CARTER, EXAMINATION BY MS. DARLENE RUSSELL
 10 MS. RUSSELL:
 11 Q. Hi, Dr. Carter. I'm Darlene Russell from the
 12 breast cancer testing group.
 13 DR. CARTER:
 14 A. Okay.
 15 MS. RUSSELL:
 16 Q. And I just want to follow up on a couple of
 17 points that Ms. Newbury made. I know that you
 18 didn't complete your initial investigations
 19 and those were halted in August of 2005, is
 20 that correct?
 21 DR. CARTER:
 22 A. Yes.
 23 MS. RUSSELL:
 24 Q. And that you're aware, obviously, that the
 25 negatives that were forwarded to Mount Sinai

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1 included some weak positives?
 2 DR. CARTER:
 3 A. Yes.
 4 MS. RUSSELL:
 5 Q. Yes. Do you know how many weak positives were
 6 included?
 7 DR. CARTER:
 8 A. When I looked over my papers in preparation
 9 for this, there were three as far as I know
 10 but that's not a vigorous, you know,
 11 examination of the data, but I think three.
 12 MS. RUSSELL:
 13 Q. Three weak positives or three that converted?
 14 DR. CARTER:
 15 A. There were three weak positives.
 16 MS. RUSSELL:
 17 Q. Okay. Because I think we know that at least
 18 four converted from positive to negative and
 19 these have been referred to as
 20 retroconverters.
 21 DR. CARTER:
 22 A. That wouldn't be the weak positives then.
 23 That's a separate kind of issue. You're
 24 asking about retroconverters?
 25 MS. RUSSELL:

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1 Q. Um-hm.
 2 DR. CARTER:
 3 A. I wouldn't have any direct knowledge of the
 4 retroconverters.
 5 MS. RUSSELL:
 6 Q. Okay.
 7 DR. CARTER:
 8 A. I know that that was raised as a possibility.
 9 MS. RUSSELL:
 10 Q. Okay, so retroconverters are those that
 11 convert from positive to negative?
 12 DR. CARTER:
 13 A. Yes, I think that would be -
 14 MS. RUSSELL:
 15 Q. You understand that?
 16 DR. CARTER:
 17 A. Yes.
 18 MS. RUSSELL:
 19 Q. That when the test results came back from
 20 Mount Sinai, there were some people who
 21 converted from positive to negative and these
 22 have been now termed as retroconverters?
 23 DR. CARTER:
 24 A. I'm not sure that that was in the first 25
 25 plus 33 -

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1 MS. RUSSELL:
 2 Q. No, no, no, I'm not indicating that at all. I
 3 mean when the results that went, or the tests
 4 that went to Mount Sinai, I'm just talking
 5 about the results that came back from Mount
 6 Sinai.
 7 DR. CARTER:
 8 A. In the large retrospective review?
 9 MS. RUSSELL:
 10 Q. Yes.
 11 DR. CARTER:
 12 A. I wouldn't have a lot of information about
 13 that.
 14 MS. RUSSELL:
 15 Q. Okay, so I'm just going to put it to you that
 16 I think we're aware that at least four came
 17 back as what we call retroconverters, they
 18 converted from positive to negative, okay.
 19 Are you aware of that term?
 20 DR. CARTER:
 21 A. Yes.
 22 MS. RUSSELL:
 23 Q. Okay. And I think that the reason why
 24 positives were included was because there were
 25 some weakly positives that were included due

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1 to cut off points, etcetera. You, would you
 2 agree with that?
 3 DR. CARTER:
 4 A. Again, I don't have a whole lot of knowledge
 5 about the retrospective review in the large
 6 part, but, yes, in general I would agree with
 7 that.
 8 MS. RUSSELL:
 9 Q. Okay, okay. So let's just say 40 weakly
 10 positives were sent. I'm just giving you a
 11 number, I'm just trying to put a hypothetical
 12 to you to see if you can answer a question.
 13 So if there were 40 weakly positives sent and
 14 four people came back as converted from
 15 positive to negative, would that cause you any
 16 concern?
 17 DR. CARTER:
 18 A. I mean, I would definitely look at the issue.
 19 MS. RUSSELL:
 20 Q. Okay. And what would you be looking for?
 21 DR. CARTER:
 22 A. Well, I mean, I would have to sit and think
 23 about it for awhile, but it would be similar
 24 to, you know, things that we're talking about
 25 here. You would have to look at the slides,

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1 look at the cases, look at the tests, look at
 2 the retests, see if there was some issue.
 3 MS. RUSSELL:
 4 Q. Okay, so you would look at it to see if there
 5 was an issue?
 6 DR. CARTER:
 7 A. And it may be answered in 30 seconds, but I
 8 haven't had knowledge of those.
 9 MS. RUSSELL:
 10 Q. Okay, so nobody has discussed that issue with
 11 you since any of this arose?
 12 DR. CARTER:
 13 A. Not in an official capacity, what is my
 14 opinion, what should be done, no.
 15 MS. RUSSELL:
 16 Q. Okay. What about in an unofficial capacity?
 17 DR. CARTER:
 18 A. Again, as I said, I've heard that this has
 19 happened, but I don't have a whole lot of
 20 information about it.
 21 MS. RUSSELL:
 22 Q. Okay, so if you were in charge at that point
 23 in time, would you have gone back and reviewed
 24 that issue?
 25 DR. CARTER:

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1 A. That's a really difficult question to ask if I
 2 was in charge at that time -
 3 MS. RUSSELL:
 4 Q. I know, it's difficult to get an answer -
 5 MR. BROWNE:
 6 Q. I think the witness has engaged counsel as far
 7 as she can with her knowledge base to try to
 8 answer that with the best information she has.
 9 She has qualified her answers by saying that
 10 she would require more information, depends
 11 looking at the slide, so I'm concerned about
 12 how far this witness can be pushed in that
 13 direction without, and to answer the question
 14 without having that evidence before her.
 15 COMMISSIONER:
 16 Q. Well, my concern is that the witness was
 17 answering a question and Ms. Russell
 18 intervened, so let's get the answer to the
 19 first question before we go on to the next
 20 one.
 21 MS. RUSSELL:
 22 Q. Okay.
 23 COMMISSIONER:
 24 Q. Do we remember which question you were
 25 answering now -

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1 DR. CARTER:
 2 A. If I could have the question repeated, please.
 3 MS. RUSSELL:
 4 Q. Okay, if I can remember the order. What would
 5 have caused you concern, what would the
 6 concern have been if you had seen four
 7 negatives, four conversions?
 8 DR. CARTER:
 9 A. So I have -
 10 COMMISSIONER:
 11 Q. Out of 40 you had said.
 12 MS. RUSSELL:
 13 Q. Out of 40, yes.
 14 DR. CARTER:
 15 A. So I have 40 weakly positive cases?
 16 MS. RUSSELL:
 17 Q. Yeah. Or let's just say there's most of the
 18 cases that were sent were negative. Out of
 19 these cases there were a number of positives
 20 that were included because the weakly
 21 positives were also included in the negatives.
 22 DR. CARTER:
 23 A. So I have 40 weakly positives?
 24 MS. RUSSELL:
 25 Q. You have 40 weakly positives.

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1 DR. CARTER:
 2 A. Yes.
 3 MS. RUSSELL:
 4 Q. And you have four that come back that convert.
 5 What -
 6 DR. CARTER:
 7 A. So I have four that come back that are now
 8 read as negative?
 9 MS. RUSSELL:
 10 Q. Yes.
 11 DR. CARTER:
 12 A. I guess I would want to know is what your
 13 definition of negative is, what your
 14 definition of positive is because if it's
 15 converted from 11 percent to 9 percent, then,
 16 you know, that's a different avenue that you
 17 would go down. I would like to look at the
 18 original slides again, as I've said, to see
 19 whether or not I would agree with the original
 20 pathologist, see if there are any aspects of
 21 the tissue that I could look at. I guess I
 22 would look at the retest slides to see if I,
 23 in fact, agreed with the retester.
 24 MS. RUSSELL:
 25 Q. Okay.

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1 DR. CARTER:
 2 A. To see if that was an issue. I would look at
 3 the original histology, I mean, and each of
 4 these steps maybe the answer would be there.
 5 I mean, it's a very difficult hypothetical to
 6 answer.
 7 MS. RUSSELL:
 8 Q. Okay.
 9 COMMISSIONER:
 10 Q. Dr. Carter, I take it from what you're saying
 11 is it's just not sufficient for one to say
 12 X percentage went from one classification to
 13 another, one has to then -
 14 DR. CARTER:
 15 A. Have a lot more information.
 16 COMMISSIONER:
 17 Q. - look below the surface to see what's the
 18 difference in the classifications and all
 19 kinds of other information which may or may
 20 not explain the differences?
 21 DR. CARTER:
 22 A. Yes.
 23 COMMISSIONER:
 24 Q. That's it?
 25 MS. RUSSELL:

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1 Q. Okay. I just have one final question, I just
 2 want to summarize. You would have at least
 3 investigated, you would have taken it a step
 4 further?
 5 DR. CARTER:
 6 A. I would have looked at it.
 7 MS. RUSSELL:
 8 Q. Okay. Thank you.
 9 COMMISSIONER:
 10 Q. Thank you, Ms. Taylor (sic.). Mr. Pike, do
 11 you have any questions?
 12 MR. PIKE:
 13 Q. No questions. Thank you.
 14 COMMISSIONER:
 15 Q. Mr. Browne, it's about the time for the break.
 16 I'm going to let you call this. Do you want
 17 me to press on or we'll have the break?
 18 MR. BROWNE:
 19 Q. We'll have the break because -
 20 COMMISSIONER:
 21 Q. All right then, we'll have the morning break.
 22 (RECESS)
 23 COMMISSIONER:
 24 Q. Please be seated. Mr. Browne.
 25 MR. BEVERLEY CARTER, EXAMINATION BY MR. PETER BROWNE

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1 MR. BROWNE:
 2 Q. Thank you, Commissioner. Good morning, Dr.
 3 Carter.
 4 DR. CARTER:
 5 A. Um-hm.
 6 MR. BROWNE:
 7 Q. Just a couple of areas I want to canvas with
 8 you. First of all, we've heard from several
 9 witnesses, including yourself, about different
 10 types of tumours and their propensity to be ER
 11 positive. And you mentioned, I think, the
 12 term this morning strict histological
 13 definition, we've heard about classic tumours
 14 and so on. The notion of one size fits all
 15 tumours, can you--is that a misconception, can
 16 tumours, for instance, have both infiltrating
 17 ductal features and lobular features or are
 18 all tumours say, for instances, lobulars
 19 strictly lobulars, can you explain that to the
 20 Commissioner?
 21 DR. CARTER:
 22 A. There'll be a wide variety of morphology or
 23 histopathology that you'll see on tumours
 24 because by their very nature, I mean, they can
 25 differentiate whatever way they want. If

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1 you're talking about estrogen receptor
 2 positivity as strict rules, you know, all or
 3 virtually all lobulars are estrogen receptor
 4 positive. That only applies to a very
 5 strictly defined lobular carcinoma which is
 6 defined as of low cellularity, always grades
 7 out as a two, single file, no duct formation,
 8 so we have to make sure that the histology is
 9 very strictly defined. People will call
 10 things lobular if they show five of the six
 11 criterion. Sometimes you'll see sign outs
 12 that say infiltrating ductal with prominent
 13 lobular features there, so you wouldn't be
 14 able to apply that virtually all to those
 15 sorts of tumours. The same thing with
 16 mucinous carcinomas, as I said earlier this
 17 morning, you know, people will use it as a
 18 descriptive term for what's going on in the
 19 tumour, but a mucinous carcinoma in terms of
 20 estrogen receptor positivity you're talking
 21 about a well encapsulated, grade one, mucin
 22 producing tumour that usually occurs in the
 23 post-menopausal age group. But you'll see on
 24 pathologists' reports a mucinous carcinoma
 25 grade two, well, then that's not a class

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1 mucinous carcinoma or you may see infiltrating
 2 ductal with mucinous features, so that's not a
 3 mucinous carcinoma strictly defined for
 4 purposes of estrogen receptor.
 5 COMMISSIONER:
 6 Q. So would there be a movement or is it just
 7 sort of those of use outside of pathology that
 8 might get hung up on this in the sense of is
 9 there encouraging of pathologists to use the
 10 terminology more strictly so that in conveying
 11 information that means something to the
 12 oncologist who gets it or is this just so well
 13 known in the medical world that these things
 14 are fuzzy that people don't worry about it?
 15 DR. CARTER:
 16 A. In terms of what pathologists want done and we
 17 know that when we're giving a report to a
 18 clinician, that the clinician is interested in
 19 things that are important to patient care in
 20 terms of prognosis and prediction of response
 21 to therapy. So a multi-varied analysis
 22 histologic subtype of tumour falls out really,
 23 I mean, it's not an important thing for
 24 prognostication or predictive value for
 25 response to therapy, so that wouldn't be large

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1 on our agenda, though it is large in the
 2 purpose of this Inquiry, but it wouldn't be
 3 large in our agenda. But for pathologists we
 4 would want strict criterion to be used largely
 5 so that in our research, you know, we would
 6 have a very clearly defined subgroup that we
 7 could study and make, you know,
 8 prognostications about it or do research on
 9 and advance the science. I mean, that would
 10 be our interest in strict histology. But in
 11 terms of patient care, it falls out on
 12 analysis as being of great significance.
 13 COMMISSIONER:
 14 Q. Okay, so within the world of pathologists I'm
 15 taking it that you would encourage people to
 16 be more precise in the use of language?
 17 DR. CARTER:
 18 A. Yes.
 19 COMMISSIONER:
 20 Q. Whereas the oncologist who receives the
 21 report, when they see the fuzzy edges, are
 22 just sort of saying, well, that doesn't help
 23 me in terms of what I have to decide -
 24 DR. CARTER:
 25 A. Yeah, I'm looking at size -

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1 COMMISSIONER:
 2 Q. - therefore I ignore this?
 3 DR. CARTER:
 4 A. - I'm looking at lymph node status.
 5 COMMISSIONER:
 6 Q. Yeah.
 7 DR. CARTER:
 8 A. You know, they're going down through the list.
 9 So for them histologic subtype is not of great
 10 value.
 11 COMMISSIONER:
 12 Q. Okay, thank you.
 13 MR. BROWNE:
 14 Q. As well, this morning, Dr. Carter, Ms. Newbury
 15 asked you a number of questions concerning
 16 your role and participation in the tumour
 17 panel. And just to deal with that, was it
 18 your understanding in terms of the function of
 19 the panel that its role was to usurp the
 20 endpoint? Now, what I mean by the endpoint
 21 that would mean the doctor/patient
 22 relationship. So a letter would--and we saw
 23 several letters that you signed with
 24 recommendations on those letters. Was it ever
 25 envisaged that that letter would usurp

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1 treatment decisions or discussions between the
 2 doctor and the patient?
 3 DR. CARTER:
 4 A. No. This was meant as a recommendation to
 5 facilitate that discussion.
 6 MR. BROWNE:
 7 Q. And as far as you know did those discussions
 8 generally occur, that the letter would go out
 9 would go to a physician and then a discussion
 10 between that physician and the patient would
 11 occur?
 12 DR. CARTER:
 13 A. I have no direct knowledge of that. I would
 14 assume that that's what happened.
 15 MR. BROWNE:
 16 Q. Lastly, Doctor, the notion of pathologists
 17 becoming involved in discussions with
 18 patients, and just to sort of follow along
 19 that line, ordinarily pathologists don't have
 20 a lot of patient contact, is that fair to say
 21 as a general statement?
 22 DR. CARTER:
 23 A. Not a lot. It's a very small part of our
 24 work.
 25 MR. BROWNE:

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1 Q. It does occur in some instances, for instance,
 2 in autopsy reviews a pathologist would meet
 3 with, I guess, the relatives of a family and
 4 discuss the findings, is that an example?
 5 DR. CARTER:
 6 A. Yes, and increasingly in oncology, but, you
 7 know, you're talking about going from 0.25
 8 percent of cases to one percent of cases. But
 9 it's also the mandate of the, or in the
 10 mission statement of the Canadian Association
 11 of Pathologists that pathologists make
 12 themselves available to the patient, you know,
 13 at the patient's request if they can provide
 14 information to them.
 15 MR. BROWNE:
 16 Q. With respect to oncology treatment, do you
 17 have any particular views on that beyond what
 18 the CAP statement, mission statement?
 19 DR. CARTER:
 20 A. I mean, I think that I should be available if
 21 patients request information about pathology
 22 and I've tried to facilitate that through the
 23 pamphlet that we now give out and that
 24 encourages patients to ask questions about
 25 their pathology reports.

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1 MR. BROWNE:
 2 Q. And that's the purple ribbon pamphlet you
 3 mentioned?
 4 DR. CARTER:
 5 A. Purple lupin.
 6 MR. BROWNE:
 7 Q. Lupin, sorry.
 8 DR. CARTER:
 9 A. It's a purple lupin project, it's a part of
 10 that.
 11 MR. BROWNE:
 12 Q. And that follows through on the, I guess, the
 13 seminar you gave a couple of years ago for the
 14 Atlantic Association on the role -
 15 DR. CARTER:
 16 A. That's an e-publication.
 17 MR. BROWNE:
 18 Q. Yes.
 19 DR. CARTER:
 20 A. So that's an article that's on their website
 21 for patient use.
 22 MR. BROWNE:
 23 Q. Lastly, Doctor, the Commissioner has offered
 24 witnesses the opportunity to make any comment,
 25 statements or recommendations. I understand

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1 you have a brief statement you wish to make?
 2 DR. CARTER:
 3 A. I just wanted to thank the Commissioner for
 4 allowing me to provide my testimony and I hope
 5 that it's helpful to you and I wish you well
 6 in your deliberations.
 7 COMMISSIONER:
 8 Q. Thank you.
 9 MR. BROWNE:
 10 Q. Thank you.
 11 COMMISSIONER:
 12 Q. Anything arising, Mr. Coffey?
 13 COFFEY, Q.C.:
 14 Q. I do have one question.
 15 DR. BEVERLEY CARTER, RE-EXAMINATION BY BERNARD COFFEY,
 16 Q.C.:
 17 COFFEY, Q.C.:
 18 Q. Doctor, at McMaster, in your period there, did
 19 you ever have occasion to be involved in
 20 patient, you know, contact, direct contact
 21 with patients concerning their pathology?
 22 DR. CARTER:
 23 A. Yes, I did.
 24 COFFEY, Q.C.:
 25 Q. On any kind of systematic basis?

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1 DR. CARTER:
 2 A. I did through the, it was called at that time,
 3 I think, the Hamilton Regional Cancer Centre,
 4 so there in one of the clinics bases I would
 5 visit, I would see patients who would visit,
 6 you know, during that clinic time if they
 7 wanted pathology questions answered.
 8 COFFEY, Q.C.:
 9 Q. And you've indicated if they wanted pathology
 10 questions answered, how did that work? And
 11 I'll ask you, is there anything comparable to
 12 that process here?
 13 DR. CARTER:
 14 A. I've offered that service to the oncologists
 15 as I talk to them on tumour boards and here
 16 I've just had patients come into my own office
 17 on a, you know, as requested, so there's no
 18 formal kind of arrangement. We did speak
 19 about that earlier in my career here but it's
 20 been mainly an informal type of arrangement,
 21 and we'll sometimes speak to patients on the
 22 telephone, as well. Other pathologists
 23 besides myself do it, obviously. So there's
 24 no formal arrangement here.
 25 COFFEY, Q.C.:

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1 Q. And in Hamilton, though, there was what?
 2 DR. CARTER:
 3 A. There was a clinic space, you know, made
 4 available for that, so if patients had
 5 questions, then I could have an office
 6 somewhere where I would sit down and do that
 7 as opposed to bringing them into my somewhat
 8 messy and probably not very attractive office
 9 for patients. But it was a little used
 10 service, I mean, this is not a big trend yet
 11 with patients. I think in the future it will
 12 move into that. Mostly it's in autopsy
 13 practice that we would talk to patients'
 14 families.
 15 COFFEY, Q.C.:
 16 Q. Okay. Thank you, Commissioner.
 17 COMMISSIONER:
 18 Q. Thank you.
 19 DR. BEVERLEY CARTER, EXAMINATION BY MADAM COMMISSIONER
 20 COMMISSIONER:
 21 Q. Dr. Carter, there were just a couple of points
 22 that have come up relatively frequently that
 23 I'd like your view on. And one is the
 24 business of whether or not there is a point at
 25 which one so infrequently does something like

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1 ER/PR that you should not be doing it at all.
 2 And I'm thinking of maybe if, I don't know
 3 what the number is but if you only see one
 4 case a month or one case a week, I don't know
 5 where the number is, but is there a number at
 6 which the lack of frequency of looking at
 7 ER/PR slides reaches a point where you really
 8 ought not to be doing them because in order to
 9 keep up the skill, you have to do it at a
 10 particular frequency?
 11 DR. CARTER:
 12 A. I don't think that there are any numbers out
 13 there. There are numbers for if your lab is
 14 not actually performing so many tests a year,
 15 then perhaps you shouldn't, and I think that
 16 number is quoted as 250, and that's from
 17 actually UK references, but I think it's been
 18 pretty widely accepted. There's no number in
 19 terms of what pathologists should see to
 20 maintain their competency. There had been a
 21 few opinion pieces. There is a
 22 cytopathologist in Calgary whose name escapes
 23 me right now, but she's written, Maher,
 24 (phonetic) I can't remember her last name,
 25 she's written several pieces about how many

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1 PAP smears you should see in order to maintain
 2 any sort of competency where you would miss
 3 subtleties, because the easy things are easy,
 4 I mean, it's the subtleties that you need
 5 expertise in. And again, in soft tissue and
 6 bone tumours, which are really quite rare,
 7 some pathologists have expressed their opinion
 8 about how many you should see a year. But,
 9 you know, that's not peer reviewed data,
 10 that's their opinion.
 11 COMMISSIONER:
 12 Q. Um-hm.
 13 DR. CARTER:
 14 A. So I don't think there is a strict number. I
 15 mean, I'm a believer in the generalization
 16 that subspecialization should be practised
 17 around these somewhat difficult areas.
 18 COMMISSIONER:
 19 Q. So I take it then your view is that in respect
 20 of IHC and in the aspect of IHC which I'm
 21 particularly interested in and ER/PR
 22 subspecialization is the way to go?
 23 DR. CARTER:
 24 A. Yes.
 25 COMMISSIONER:

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1 Q. If at all possible?

2 DR. CARTER:

3 A. Yes. That would be the other half of the

4 statement. I mean, it's a very difficult

5 thing to do. It's a common disease, a common

6 test in a system that has few pathologists, so

7 it may be difficult to achieve that, but if

8 you could have everything, that's what I would

9 have.

10 COMMISSIONER:

11 Q. Right. Now, can we go back for a moment to

12 the business of the organization of

13 laboratories? And my view of your evidence is

14 that you were dissatisfied with the

15 organization of the laboratory that you found

16 that Eastern Health, the structure?

17 DR. CARTER:

18 A. Yes.

19 COMMISSIONER:

20 Q. And can you tell me a little more about what

21 you would see as being the preferable type of

22 organization of a laboratory?

23 DR. CARTER:

24 A. The laboratory system, as I understood it, was

25 that the laboratory director, who would have

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1 been Mr. Gulliver, and the clinical chief,

2 which when I came would have been Don Cook,

3 now Dr. Denic, are at equivalent positions, so

4 there's no one directly responsible for the

5 lab who knows about what's going on in the

6 laboratory and a lot of the decisions that are

7 being made in the laboratory have direct

8 impact on patient care. So in my opinion that

9 should be a medical person who would act as

10 the, you know, the responsible director of the

11 laboratory.

12 COMMISSIONER:

13 Q. Okay. So essentially your problem with the

14 current structure is that a non-medical person

15 can make decisions regarding the laboratory

16 and its operation which, in your view, might

17 impact on patient care?

18 DR. CARTER:

19 A. Yes.

20 COMMISSIONER:

21 Q. And if the test is whether it impacts on

22 patient care, then in your view that's one

23 that should be made by somebody with medical

24 training and presumably if you're dealing with

25 the lab, a pathologist?

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1 DR. CARTER:

2 A. Yes.

3 COMMISSIONER:

4 Q. Of some sort. All right, thank you. Thank

5 you, very much for the last couple of days,

6 even if they were interrupted by another

7 witness. I do appreciate your contribution.

8 DR. CARTER:

9 A. Thank you.

10 COMMISSIONER:

11 Q. I'm sure you're all going to be just ever so

12 sad not to have to come back here this

13 afternoon, but look forward to seeing you

14 tomorrow morning at 9:30. And counsel may

15 have issued my small invitation to counsel as

16 Commission counsel may have issued the

17 invitation to meet with me for maybe 15, 20

18 minutes so we can sort out a few details about

19 the fall. If you didn't know about that, gee,

20 there's a surprise, but I'll only take 15, 20,

21 I promise. 9:30 in the morning. Thank you.

22 Adjourned at 11:51 a.m.

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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 31st day of July, A.D., 2008 before

6 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 31st day of July, A.D., 2008

13 Judy Moss

Inquiry on Hormone Receptor Testing

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