

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">June 23, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C./Mandy Woodland Commission Co-counsel</p> <p>Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury Doctors Kara Laing et al</p> <p>Daniel Simmons Eastern Regional Integrated Health Authority</p> <p>Ches Crosbie, Q.C. Members of the Breast Cancer Testing Class Action</p> <p>Mark Pike NL Medical Association</p> <p>Jennifer Newbury Canadian Cancer Society (NL Division)</p> <p>Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-1696 THROUGH P-1705, INCLUSIVE Pg. 5 EXHIBITS P-1720 THROUGH P-1722, INCLUSIVE Pg. 5 EXHIBITS P-1728 AND P-1729 Pg. 5 EXHIBITS P-1706 THROUGH P-1717 INCLUSIVE Pg. 198 EXHIBIT P-1726 Pg. 198 EXHIBIT P-1727 Pg. 279 EXHIBIT P-1767 Pg. 279</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. FRANCES O'MALLEY - SWORN</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 4 - 89 Examination by Daniel Simmons Pgs. 89 - 126 Examination by Peter Browne Pgs. 126 - 145 Examination by Jennifer Newbury Pgs. 145 - 158 Examination by Ches Crosbie, Q.C. Pgs. 158 - 182 Re-examination by Bernard Coffey, Q.C. Pgs. 182 - 189 Examination per Curiam Pgs. 189 - 195</p> <p>Discussion</p> <p>DR. KENNETH PRITZKER - AFFIRMED</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 196 - 256 Examination by Daniel Simmons Pgs. 256 - 277 Examination by Peter Browne Pgs. 277 - 297 Examination by Jennifer Newbury Pgs. 297 - 306 Examination by Ches Crosbie, Q.C. Pgs. 306 - 314 Re-examination by Bernard Coffey, Q.C. Pgs. 314 - 319</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 COMMISSIONER: 2 Q. Than you. Please be seated. Good morning. Mr. 3 Coffey. 4 COFFEY, Q.C.: 5 Q. Thank you, Commissioner. The next witness is 6 Frances O'Malley, Dr. O'Malley, Registrar, please. 7 COMMISSIONER: 8 Q. I think we have additional counsel. 9 COFFEY, Q.C.: 10 Q. Yes, I apologize. 11 MR. CLEMENTS: 12 Q. Yes, Simon Clements from Toronto, counsel for the 13 four witnesses you're going to hear from this week 14 from Mount Sinai Hospital. 15 COMMISSIONER: 16 Q. Welcome. 17 COFFEY, Q.C.: 18 Q. Thank you, Commissioner. 19 DR. FRANCES O'MALLEY (SWORN) EXAMINATION BY BERNARD COFFEY, 20 Q.C. 21 REGISTRAR: 22 Q. And would you please state and spell your complete 23 name for the Commission? 24 DR. O'MALLEY:</p>

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1 A. France O'Malley, F-r-a-n-c-e-s, O-'-M-a-l-l-e-y.
 2 REGISTRAR:
 3 Q. Thank you.
 4 COFFEY, Q.C.:
 5 Q. Commissioner, I have some additional exhibits,
 6 please? They are Exhibit P-1696, 1697, 1698, 1699,
 7 1700, 1701, 1702, 1703, 1704, 1705, 1720, 1721,
 8 1722, 1728 and 1729.
 9 COMMISSIONER:
 10 Q. Entered.
 11 EXHIBITS P-1696 THROUGH P-1705, INCLUSIVE, ENTERED INTO
 12 EVIDENCE.
 13 EXHIBITS P-1720 THROUGH P-1722, INCLUSIVE, ENTERED INTO
 14 EVIDENCE.
 15 EXHIBITS P-1728 AND P-1729 ENTERED INTO EVIDENCE.
 16 COFFEY, Q.C.:
 17 Q. Thank you, Commissioner. Exhibit, Registrar,
 18 please, 1729? Dr. O'Malley, this is a document
 19 entitled "Curriculum Vitae for Frances O'Malley" I
 20 take it that's your CV?
 21 DR. O'MALLEY:
 22 A. It is, yes.
 23 COFFEY, Q.C.:
 24 Q. Okay. Doctor, it goes on for, I'll just say quite a

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1 number of pages. I'm not going to take you through
 2 them all, but could you please given the
 3 Commissioner a brief outline of your educational
 4 background and your professional background?
 5 DR. O'MALLEY:
 6 A. Certainly. I graduated from medical school at
 7 Trinity College, Dublin in 1985 and started a
 8 residency in pathology in Dublin, Ireland, in 1986
 9 after an internship. I then immigrated to Canada in
 10 1988 where I entered the pathology residency program
 11 in, at the University of Western Ontario. I
 12 completed that residency in 1991 and then spent
 13 almost a year and a half doing a fellowship in
 14 breast pathology with Dr. David Page at Vanderbilt
 15 University in Nashville. I then came back on staff
 16 to Victoria Hospital in London and worked there as a
 17 staff pathologist with expertise in breast pathology
 18 until 1998, when I moved to Mount Sinai to my
 19 current position as a breast pathologist at Mount
 20 Sinai and professor of pathology at the University
 21 of Toronto.
 22 COFFEY, Q.C.:
 23 Q. Doctor, I understand that you've prepared a
 24 presentation related to estrogen and progesterone

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1 receptor testing of primary breast cancer, its
 2 clinical importance and technical validation. If
 3 we--it's Exhibit 1728, Commissioner, for the record.
 4 And I understand that it is a PowerPoint type
 5 presentation. So, Doctor, I'm going to ask that
 6 with that as an aid, that you go ahead and with an
 7 outline of that topic?
 8 DR. O'MALLEY:
 9 A. Certainly. So this presentation is really an
 10 overview of the clinical importance of estrogen and
 11 progesterone receptor testing in primary breast
 12 cancer. And I also want to focus on the technical
 13 validation of these tests. So by way of background,
 14 this slide just points out the difference, the
 15 essentially difference between an estrogen receptor
 16 positive breast cancer cell and an estrogen receptor
 17 negative breast cancer cell.
 18 So in an estrogen receptor positive breast
 19 cancer cell, the circulating estrogen in a woman's
 20 breast can enter the cell and it can bind to the
 21 estrogen receptor, as indicated by this green
 22 object. Through binding to the receptor, a series
 23 of cellular events are put into place, leading to
 24 proliferation or multiplication of the breast cancer

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1 cell. Now, importantly, Tamoxifen or other anti-
 2 estrogen agents can bind to this receptor, blocking
 3 binding of estrogen and in so doing it inhibits the
 4 proliferation of the cancer cell.
 5 Now, in contrast, in an estrogen receptor
 6 negative breast cancer cell, the receptor is
 7 negative, so estrogen, circulating estrogen does not
 8 have the same effect on these breast cancer cells,
 9 cell--specifically cell proliferation or
 10 multiplication of the breast cancer cells is not
 11 controlled by estrogen and it's not inhibited by
 12 anti-estrogen drugs such as Tamoxifen.
 13 Now, just to go into a little bit more detail
 14 what exactly happens at the cellular level when
 15 estrogen binds to the estrogen receptor. On binding
 16 to the receptor there's actually a confirmational
 17 change of this complex, so it's like a key, specific
 18 key, and this specific key fits into a very specific
 19 lock known as co-activators. These are a bunch of
 20 proteins then that help when they bind to the
 21 estrogen and estrogen receptor complex which sits in
 22 DNA, puts into event a series of events that leads
 23 to activation of genes that lead to multiplication
 24 of the tumor cells or cell proliferation.

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1 COFFEY, Q.C.:

2 Q. And just on that point, Doctor, I take it that cell

3 proliferation when you're talking about tumors is

4 not a good thing?

5 DR. O'MALLEY:

6 A. It is not a good thing.

7 COFFEY, Q.C.:

8 Q. That's a given?

9 DR. O'MALLEY:

10 A. That is absolutely correct.

11 COFFEY, Q.C.:

12 Q. Go ahead, I'm sorry.

13 DR. O'MALLEY:

14 A. Now, what Tamoxifen does is it binds to that same

15 receptor, the estrogen receptor, but when it binds,

16 it does not cause the same change in shape of the

17 complex, so it's like a different key, and that

18 different key cannot fit into this lock, so it

19 prevents--so while Tamoxifen binds the receptor, it

20 doesn't set into place the activation of genes that

21 lead to cell proliferation, okay.

22 Now, in terms of treating breast cancer,

23 obviously the most important thing is to excise,

24 surgically excise the breast tumor. However, we do

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1 know that sometimes breast cancer cells can escape

2 and get into the blood stream and can lodge in

3 different organs throughout the body, such as the

4 lung, the liver, the bone and the breast. What we

5 believe Tamoxifen and other anti-estrogen agents do

6 in the setting of estrogen receptor positive breast

7 cancer is that it links to the estrogen receptor in

8 these tumor cells and therefore prevents circulating

9 estrogen from stimulating these escaped cancer cells

10 which could lead to their growth down the road.

11 COFFEY, Q.C.:

12 Q. I take it that's wherever those cells might be in

13 the body?

14 DR. O'MALLEY:

15 A. Exactly, exactly. And we do indeed know that from

16 many clinical trials that the use of Tamoxifen in

17 this setting does indeed decrease the risk of cancer

18 recurrence.

19 Now, for any test that enters the clinical

20 arena, it must undergo very rigorous tests, very

21 rigorous guidelines as outlined by the American

22 Society of Clinical Oncology. And these stipulate

23 that a test, to be clinically useful, must be--must

24 undergo rigorous clinical validation, it must

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1 undergo rigorous technical validation and obviously

2 it must influence therapeutic decision making. We

3 know ER and PR certainly does influence therapeutic

4 decision making. I want to focus for the remainder

5 of this presentation on both the clinical and

6 technical validation of this test.

7 So I just want to start off by, start off with

8 a few definitions. So clinical validation means

9 that a test is able to identify subsets of patients

10 with significantly different risks of recurrence or

11 survival. So for ER that means that a patient who

12 has an ER positive breast cancer, it has, those

13 patients have a better disease free and overall

14 survival than patients whose tumors are ER

15 negative.

16 Now, clinical validation can be divided into

17 two parts, really. When we look at a test, we look

18 at whether it can act as a prognostic factor and/or

19 a predictive factor. So a prognostic factor is a

20 factor that provides information on the clinical

21 outcome in the absence of therapy, okay. So what it

22 basically does, it gives information on the

23 intrinsic biologic potential of that tumor, and

24 that's very different from a predictive factor,

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1 which is a factor that provides information on the

2 likelihood of response to therapy. So in a setting

3 of ER, ER positivity indicates that that patient is

4 very likely to respond to an anti-estrogen agent,

5 okay.

6 So I want to talk about the clinical validation

7 of ER in terms of both its prognostic and predictive

8 utility. But before doing that I just want to very

9 briefly review, from a historic perspective, the

10 what we previously used as the gold standard for ER

11 testing, and that was a biochemical test known as

12 the Ligand Binding Assay. And what it entailed was

13 it entailed taking a portion of tumor, once it had

14 been excised by the surgeon, taking about a half or

15 up to one gram of tissue from the specimen and

16 immediately freezing that portion of tumor in liquid

17 nitrogen and then that tumor was sent to a steroid

18 receptor lab.

19 I can speak to what happened in Ontario. In

20 Ontario in the '80s there were five steroid receptor

21 labs, so even though we have more than 80 hospitals,

22 all of the breast cancers, all of the specimens were

23 sent to one of these five steroid receptor labs.

24 These labs were funded by the provincial government

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1 and they were highly regulated in terms of their
 2 quality control and quality assurance procedures.
 3 The ER content in the tumors that were sent to
 4 these labs was assessed by what's known as a DCC
 5 method, dextron-coated charcoal. I'm not going to
 6 go into details on this because, as I say, this is
 7 the historic test. We do not use this test any
 8 more.
 9 The advantage, however, of this test beyond
 10 what I just mentioned, the strict QC and QA
 11 procedures that were in place was that it was a
 12 quantitative test, a specific number was generated
 13 when the test was performed, and a tumor with a
 14 quantitative value of 10fmol/mg was determined as a
 15 positive tumor, positive for estrogen receptor. The
 16 same cutoff was used for progesterone receptor.
 17 COFFEY, Q.C.:
 18 Q. Doctor, you just then--and I appreciate that some
 19 things are second nature to yourself, particularly
 20 abbreviations. You referred to QC and QA. Could
 21 you expand on that a little bit?
 22 DR. O'MALLEY:
 23 A. I certainly will. And, indeed, I'll be talking
 24 quite a bit about that later in the presentation.

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1 QA is quality assurance and QC, quality control.
 2 COFFEY, Q.C.:
 3 Q. Okay.
 4 DR. O'MALLEY:
 5 A. And as I mentioned, we'll get into that later in the
 6 presentation.
 7 Okay, so now back to clinical validation. Just
 8 to remind you, I broke this into two components
 9 prognostic and predictive factors within clinical
 10 validation. And as I mentioned, the biochemical
 11 method of assessing ER and PR was a historic method.
 12 We now uniformly use immunohistochemistry, and we
 13 have a lot of data on its clinical utility in breast
 14 cancer, in fact, we've over 25 years of data now on
 15 the use of immunohistochemistry for assessing ER and
 16 PR in breast cancer.
 17 I'm not going to go into details, technical
 18 details on the actual immunohistochemical procedure
 19 because I believe Trish Wegrynowski from Mount Sinai
 20 will be talking about this later in the week.
 21 But now, back to the clinical validation. We
 22 knew from many studies, in fact, we've about 25
 23 studies now in the literature with a cumulative
 24 patient database of over 5000 looking at the

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1 clinical validation of ER. And even though most of
 2 these patients have been treated, we do have a
 3 number of patients or number of studies that have
 4 looked at untreated patients. And just to remind
 5 you, we need to look a untreated patients to
 6 determine the prognostic utility of a test because
 7 that's looking at the intrinsic biology of that
 8 test. And from these studies we know that a patient
 9 with ER positive disease has about a 10 to 15
 10 recurrence or overall survival benefit over those
 11 patients who have ER negative tumors, and this is
 12 considered a WEAK Prognostic factor.
 13 COFFEY, Q.C.:
 14 Q. In terms of that, Doctor, I take it that's patients
 15 who are untreated?
 16 DR. O'MALLEY:
 17 A. Exactly, exactly.
 18 COFFEY, Q.C.:
 19 Q. Even for somebody who's untreated at all? No
 20 Tamoxifen?
 21 DR. O'MALLEY:
 22 A. That's exact it. Untreated patients, a patient with
 23 ER positive tumors will do slightly better. 10 to
 24 15 percent, as I say, recurrence or survival benefit

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1 of ER negative patients untreated, as well. But
 2 that's considered a WEAK Prognostic indicator. The
 3 main benefit of ER testing is it's in predictive
 4 utility, it is a strong predictive factor, ie, it
 5 very precisely, when it's performed accurately,
 6 identifies those patients who are going to benefit
 7 substantially from hormone therapy. We have data
 8 both in the advanced stage disease that is disease
 9 that has spread beyond the breast to other organs,
 10 as well as the adjuvant setting, that's early breast
 11 cancer. I'll show you the early breast cancer data
 12 in a moment. This slide summarized the advanced
 13 stage disease data where indeed there's a lot of
 14 data, approximately 25 studies with about 1500
 15 cumulative patient data. We know from these studies
 16 that about 70 percent of patients with ER positive
 17 disease will show a statistically significant
 18 clinical response to hormone therapy. On the other
 19 hand, 85 percent of ER negative patients will show
 20 absolutely no response to anti-hormone therapy.
 21 COFFEY, Q.C.:
 22 Q. Doctor, while that slide is up, clinical response in
 23 this context means what?
 24 DR. O'MALLEY:

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1 A. It means a decreased or actually increased disease
 2 free survival or decreased recurrences.
 3 COFFEY, Q.C.:
 4 Q. Okay, thank you.
 5 DR. O'MALLEY:
 6 A. Okay. Now this is the data in the adjuvant setting.
 7 We have less studies but very, very strong data.
 8 Again, ER is a very, very strong predictive factor
 9 in early breast cancer, showing a 25 to 30 percent
 10 recurrence or survival benefit over patients with ER
 11 negative disease. So these are patients who are
 12 treated. Okay.
 13 Now I just want to return to the ASCO
 14 guidelines. I've talked about clinical validation.
 15 I don't think there's any--there's really any
 16 controversy over the importance of ER and PR testing
 17 in the clinical setting. Why don't I focus on the
 18 technical validation of these tests?
 19 Now ASCO defined technical validation as a test
 20 that is sensitive, specific, reproducible and
 21 interpreted in a uniform manner from lab to lab, and
 22 I'll go over each of these points in detail.
 23 First of all, I want to define sensitivity and
 24 specificity. So sensitivity is the percentage of a

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1 positive test, percentage of positive test results
 2 obtained when evaluating only specimens that are
 3 truly positive. So ideally, every test--a test
 4 should identify every truly positive specimen. On
 5 the other hand, specificity is the percentage of the
 6 negative test results reported when only truly
 7 negative specimens are evaluated. Okay.
 8 So let's go back to the parameters of technical
 9 validation and some of the problems with it. In
 10 terms of sensitivity, there are several antibodies
 11 that are used to assess ER and PR and they differ in
 12 their sensitivities. These antibodies also differ
 13 in their specificities. When it comes to
 14 reproducibility, we have different
 15 immunohistochemical methods and as I mentioned,
 16 Trish will be going into details on these later in
 17 the week. But this certainly affects
 18 reproducibility of the test and finally,
 19 interpretation in a uniform manner, this is highly
 20 influenced by the arbitrary cutoffs that have been
 21 used and the methods of scoring these results, and
 22 I'm going to touch particularly on this last point.
 23 Another way to look at technical validation is
 24 to divide it into three parts, and all of these

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1 parts are very, very important. First of all, pre-
 2 analytical components. Then there's the analytical
 3 components and post-analytic components. I'm going
 4 to touch on the pre-analytic, but concentrate
 5 particularly on the post-analytic, as Trish will
 6 deal a lot with the analytic components of technical
 7 validation.
 8 So first of all, to pre-analytic components.
 9 This is extremely important to assure accuracy of a
 10 test, and this relates to tissue handling and
 11 fixation. So it's really vital that the time the
 12 specimen, the breast specimen spends out of
 13 formalin, after it's been removed from the patient,
 14 is minimized. This should be a very, very short
 15 period of time, and this involves the nursing, the
 16 OR nursing staff, the surgeons and the pathologists
 17 working very closely together to make sure that that
 18 specimen is placed in formalin as soon as possible.
 19 Another very important part of this process is
 20 that the specimen should be placed in a sufficient
 21 amount of formalin and we recommend at least seven
 22 times the volume of formalin to the volume of the
 23 specimen to allow adequate fixation. The third
 24 very, very important point to assure adequate

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1 fixation is that the specimen should be sectioned at
 2 fairly thin slices before, in fact, it is put into
 3 this formalin, because formalin diffuses through
 4 tissue very slowly and if the specimen is not
 5 sectioned, then the centre of that specimen will not
 6 be fixed at all.
 7 COFFEY, Q.C.:
 8 Q. So just on that point, in effect, I take it, a
 9 specimen, of course is a piece of human tissue?
 10 DR. O'MALLEY:
 11 A. Yes, that's right.
 12 COFFEY, Q.C.:
 13 Q. In this context.
 14 DR. O'MALLEY:
 15 A. It's the breast cancer with surrounding normal
 16 breast tissue.
 17 COFFEY, Q.C.:
 18 Q. And you use the word "diffuse" I believe?
 19 DR. O'MALLEY:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. In layman's terms, what does that mean?
 23 DR. O'MALLEY:
 24 A. To seep into, penetrate.

Page 21

1 COFFEY, Q.C.:

2 Q. To seep into or to penetrate.

3 DR. O'MALLEY:

4 A. Penetrate.

5 COFFEY, Q.C.:

6 Q. Okay, and you've indicated that formalin doesn't--if

7 a specimen, I take it, is put into formalin, it

8 doesn't immediately go all the way through it?

9 DR. O'MALLEY:

10 A. That's correct.

11 COFFEY, Q.C.:

12 Q. It takes a period of time for it to penetrate

13 through the cells and get deeper and deeper into it?

14 DR. O'MALLEY:

15 A. Absolutely.

16 COFFEY, Q.C.:

17 Q. Okay.

18 DR. O'MALLEY:

19 A. It does.

20 COFFEY, Q.C.:

21 Q. And the advantage then of this slicing then of the

22 tissue into, I take it, relatively thin pieces is

23 what?

24 DR. O'MALLEY:

Page 22

1 A. Yeah, five to ten millimetres.

2 COFFEY, Q.C.:

3 Q. Five to ten millimetres. Why is that advantageous,

4 Doctor? What happens?

5 DR. O'MALLEY:

6 A. Well, that allows immediate contact of the formalin

7 with every part of the specimen at these very thin

8 slices, so it means that the formalin can penetrate

9 into the specimen at many different parts along the

10 specimen. Some of these specimens can be quite

11 large. They can be several centimetres in maximum

12 dimension, so this is a very, very important step in

13 the process of fixation.

14 COFFEY, Q.C.:

15 Q. And I take it then that if a slice of tissue is only

16 five to ten millimetres, well, for example, if it

17 was ten millimetres thick, the formalin then is on

18 both sides of it, so it only--to get to the centre

19 of it, it only has to go five millimetres in each

20 direction?

21 DR. O'MALLEY:

22 A. That's right.

23 COFFEY, Q.C.:

24 Q. Or if it's five millimetres thick, it only has to go

Page 23

1 two and a half millimetres, and it just gets inside

2 all the way through faster?

3 DR. O'MALLEY:

4 A. That's right.

5 COFFEY, Q.C.:

6 Q. That's the -

7 DR. O'MALLEY:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. It's just a physical process, the thinner, all

11 things considered, the better?

12 DR. O'MALLEY:

13 A. Yes.

14 COFFEY, Q.C.:

15 Q. Okay.

16 DR. O'MALLEY:

17 A. Now this touches on one of the points you raised

18 about the time that formalin does take to fully

19 penetrate the tissue. So it's not only important to

20 have the specimen exposed to formalin, but it does

21 need to sit in formalin for several hours to allow

22 adequate penetration, and optimally, the specimens

23 should sit in formalin for somewhere between six to

24 48 hours. Now the six-hour, that very short time

Page 24

1 line really only applies to very, very small

2 specimens, such as core biopsies.

3 COFFEY, Q.C.:

4 Q. Could you explain what a core biopsy is?

5 DR. O'MALLEY:

6 A. So a core biopsy is a very, very thin piece of

7 tissue. It usually measures one centimetre by one

8 millimetre and these are specimens that are usually

9 obtained in radiology and they're usually for

10 diagnostic purposes to make a diagnosis of breast

11 cancer when an abnormality is seen, usually on

12 mammography.

13 COFFEY, Q.C.:

14 Q. So for such specimens, if it's one millimetre thick

15 or wide, I take it then you're already down to a

16 very thin specimen and therefore it just doesn't

17 require six hours to ensure that the formalin

18 penetrates through that one millimetre?

19 DR. O'MALLEY:

20 A. Exactly.

21 COFFEY, Q.C.:

22 Q. To its centre or core.

23 DR. O'MALLEY:

24 A. Exactly.

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1 THE COMMISSIONER:
 2 Q. So if one had a biopsy, would that--as opposed to a
 3 surgical removal of -
 4 DR. O'MALLEY:
 5 A. A surgical removal is the next point that I make.
 6 Those are larger specimens and they require at least
 7 24 to 48 hours of formalin fixation.
 8 COFFEY, Q.C.:
 9 Q. They'll require 24 to 48 hours, Doctor, having been
 10 sliced up into five to ten millimetre thick slices?
 11 DR. O'MALLEY:
 12 A. Yes, yes.
 13 COFFEY, Q.C.:
 14 Q. After you've done the appropriate sectioning, is the
 15 word, I gather?
 16 DR. O'MALLEY:
 17 A. Um-hm.
 18 COFFEY, Q.C.:
 19 Q. After it's appropriately sectioned and it still
 20 requires at least 24 hours and up to 48, somewhere
 21 between 24 and 48 would be optimum?
 22 DR. O'MALLEY:
 23 A. Yes, that's true. Now we do know from several
 24 studies that longer fixation is less of a problem,

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1 in terms of retaining antigenicity when
 2 immunohistochemistry is used on these specimens.
 3 The big problem is under fixation. If a specimen is
 4 fixed for less than six hours, that has a big impact
 5 on the accuracy of an immunohistochemical test.
 6 COFFEY, Q.C.:
 7 Q. Any kind of specimen under six or a core under six?
 8 DR. O'MALLEY:
 9 A. Well, even a core under six, but certainly a larger
 10 surgical specimen, if it is fixed for less than six
 11 hours, then the immunohistochemical test would be--
 12 the accuracy of such a test would be severely
 13 compromised, and in fact, this gets back to the
 14 issue of thinly slicing the specimen. It would be
 15 the same as under fixation, because if the formalin
 16 has not penetrated fully into that specimen, it
 17 would be basically under fixed.
 18 COFFEY, Q.C.:
 19 Q. And I take it under fixed, Doctor, again in--that's
 20 a term technologists and physicians use. The
 21 practical effect of under fixation is what, in
 22 layman's terms? What's the actual practical effect?
 23 DR. O'MALLEY:
 24 A. The tissue dies. The tissue dies.

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1 COFFEY, Q.C.:
 2 Q. And the effect of that is to do what? In terms of
 3 ER and PR testing, what's the practical effect of
 4 it?
 5 DR. O'MALLEY:
 6 A. The practical effect is that the test, no matter how
 7 sensitive or specific the antibodies are that are
 8 used in such a test, they won't work.
 9 COFFEY, Q.C.:
 10 Q. Okay, so that the cells--as you say, the tissue
 11 dies. The cells, I take it, their cellular
 12 structure comes apart, disintegrates?
 13 DR. O'MALLEY:
 14 A. Disintegrates. Disintegrates, so there's nothing to
 15 bind--the antibodies have nothing to bind to because
 16 the tissue basically has integrated, disintegrated,
 17 I should say.
 18 COFFEY, Q.C.:
 19 Q. So if I understand you correctly, Doctor, at this
 20 stage, in terms of tissue handling and fixation,
 21 important points are from the time of excision,
 22 which is, in effect, the cutting out of the tissue
 23 from the patient, to it being immersed in formalin
 24 is minimize the time?

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1 DR. O'MALLEY:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. All things considered, do it as quickly as possible,
 5 number one?
 6 DR. O'MALLEY:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. Number two, make sure that if it is any kind of--
 10 anything other really than a core biopsy, any kind
 11 of sizeable tissue at all, it'd to be sectioned,
 12 sliced?
 13 DR. O'MALLEY:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Appropriately, thinly, and it's to remain then
 17 within formalin for, if it's a core biopsy, a
 18 minimum of six hours, and if it's any other type or
 19 larger biopsy or any larger specimen, 24 to 48
 20 hours, having been appropriately sliced and put in
 21 quickly into the formalin?
 22 DR. O'MALLEY:
 23 A. Yes.
 24 THE COMMISSIONER:

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1 Q. Can I take it from this that the timing of what I
 2 think is called the grossing in the slicing process
 3 is important?
 4 DR. O'MALLEY:
 5 A. Yes, it is very important.
 6 COFFEY, Q.C.:
 7 Q. In terms of that, Doctor, as an example, an OR and a
 8 tumor is excised and the flesh surrounding the tumor
 9 or a woman's breast is removed and it's put in the
 10 container of formalin, the timing then, I take it,
 11 from that point, because the sectioning does not go
 12 in the OR?
 13 DR. O'MALLEY:
 14 A. No.
 15 COFFEY, Q.C.:
 16 Q. The actual slicing by a pathologist or pathologist's
 17 assistant doesn't go on there.
 18 DR. O'MALLEY:
 19 A. No.
 20 COFFEY, Q.C.:
 21 Q. That's done in the -
 22 DR. O'MALLEY:
 23 A. It happens in the pathology department.
 24 COFFEY, Q.C.:

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1 Q. So the timing then, in terms of the Commissioner's
 2 question, in terms of that between the actual
 3 surgery, as quickly as possible into a formalin
 4 container appropriately filled, and the time then at
 5 which the sectioning occurs, I take it that you'd
 6 want to get it sectioned as quickly as possible.
 7 What kind of time frames are we talking about there,
 8 Doctor? When would they become problematic, do you
 9 think?
 10 DR. O'MALLEY:
 11 A. Well, they become really problematic if, say, a
 12 breast, a patient has a mastectomy and that
 13 mastectomy is left in formalin over the weekend
 14 prior to sectioning, then that would certainly be
 15 problematic in terms of under fixation and the
 16 possibility of disintegration of the tissue.
 17 COFFEY, Q.C.:
 18 Q. And I take it that's because even though the breast
 19 is completely, as a whole, surrounded by formalin,
 20 that the interior of the breast, the flesh inside,
 21 the interior of the specimen, the formalin on the
 22 outside just can't penetrate fast enough in order to
 23 preserve the inner tissue?
 24 DR. O'MALLEY:

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1 A. That's right.
 2 COFFEY, Q.C.:
 3 Q. It just doesn't get there fast enough?
 4 DR. O'MALLEY:
 5 A. That's right.
 6 COFFEY, Q.C.:
 7 Q. Okay, and certainly, over a weekend is problematic?
 8 A Friday afternoon surgery and only doing the
 9 sectioning Monday morning could be problematic?
 10 DR. O'MALLEY:
 11 A. It could be problematic. It could be problematic,
 12 for sure.
 13 COFFEY, Q.C.:
 14 Q. Is that the point? Thank you. I'm sorry, Doctor,
 15 go ahead.
 16 DR. O'MALLEY:
 17 A. So back to the various parameters of technical
 18 validation. As I mentioned, I want to focus
 19 specifically now on the post-analytic component, as
 20 Trish will be dealing with the analytic component.
 21 So the post-analytic component has three main
 22 important steps and the first obviously is the
 23 interpretation of the stain by the pathologist. The
 24 second is the reporting of the staining that we see

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1 and the College of American Pathologists has
 2 published guidelines on what should actually be
 3 included in a pathology report in relation to ER and
 4 PR testing. And then the third huge issue is
 5 quality assurance and quality control.
 6 So just to touch on the issue of
 7 interpretation. Before we, pathologists, assess a
 8 test, ER and PR test, we have to make sure that the
 9 test is appropriate for evaluating, and this is
 10 particularly--this is a particular issue when there
 11 is no staining at all in the tumor. What I have,
 12 what I'm showing on the screen here is a histologic
 13 section of breast cancer where there is no staining
 14 whatsoever. All of the nuclei, as shown here,
 15 appear blue. If this was positive, we'd see some
 16 brine staining.
 17 COFFEY, Q.C.:
 18 Q. Doctor, while we're here, so this is, in effect, a
 19 photograph, photographic reproduction of a slide -
 20 DR. O'MALLEY:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. - with tumor tissue?
 24 DR. O'MALLEY:

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1 A. That's right.

2 COFFEY, Q.C.:

3 Q. And could you just use the cursor then to show the

4 Commissioner, for example, where the nucleus is in

5 these various cells?

6 DR. O'MALLEY:

7 A. So right here, this is a nucleus. Is that clear?

8 There's another nucleus. So these are all separate

9 tumor nuclei. Okay. So in a case like this where

10 the tumor is completely negative, to make sure that

11 the test has worked, of course, the technologist

12 will have assured that the controls, positive

13 controls have worked. But what we look for on the

14 slide is an internal positive control, and this is

15 shown here in the bottom right-hand corner. These

16 are normal ducts in the same specimen that are

17 showing positive staining with the estrogen receptor

18 and these should be positive in all cases. So these

19 are normal breast ducts and each of these nuclei, as

20 you can see, are staining positively.

21 COFFEY, Q.C.:

22 Q. And they're actually coloured here, well, I'm not

23 good with colours, but it looks brown, sort of brown

24 or dark brown.

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1 DR. O'MALLEY:

2 A. Yeah, they are brown, under the microscope they're

3 brown.

4 COFFEY, Q.C.:

5 Q. And the importance of this part of the process,

6 Doctor, is what? What, as a physician, what does

7 this tell you?

8 DR. O'MALLEY:

9 A. Well this tells me that the test has worked. On

10 this particular slide the normal epithelium has

11 stained so I can be confident that the tumor is

12 indeed estrogen receptor negative.

13 COFFEY, Q.C.:

14 Q. Because they normal tissue here in the, in this

15 insert on the bottom right, you would have expected

16 that if the process, physical process worked

17 properly, that these would stain, these sorts of

18 normal cells will stain in this context.

19 DR. O'MALLEY:

20 A. Yes. Okay. So once we are satisfied that the tests

21 can be interpreted, we then assess the percentage,

22 if there is positivity there, some of the tumor

23 cells are staining, we assess then how many of those

24 tumor cells are staining. And these gets into the

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1 cut off for what a positive test is, and this cut

2 off actually has varied in the literature. Most

3 labs, certainly in the past have used a cut off of

4 ten percent, so there must be at least ten percent

5 of tumor nuclei staining for that test to be called

6 ER or PR positive. Some labs have used a higher cut

7 off of 20 percent, but we now have fairly solid

8 clinical data from the Baylor Group by Harvey et al,

9 that in the adjunctive setting that as few as one

10 percent, as few as one to ten percent of ER positive

11 tumor cells predicts for a clinical response to

12 anti-estrogen therapy. And I want to spend some

13 time talking about this very important clinical data

14 because it really has impacted on certainly the cut

15 off that we use at Mount Sinai and certainly at

16 other hospitals. So what this study did was it

17 looked at ER in over 1900 patients with primary

18 breast cancer and they used an antibody known as

19 6F11. To score these results, they used the Allred

20 score and I'm going to go through that in detail and

21 the results were compared, these immunohistochemical

22 results were compared to the previous standard

23 biochemical method, the Ligand Binding Assay

24 results, but most importantly the results were

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1 compared to clinical outcome of these patients. So

2 just to go through in detail what the Allred score

3 entails, this is a semi-quantitative scoring system

4 that was developed by Craig Allred, the senior

5 pathologist in the Baylor group and it comprises of

6 two components. There's a proportion score and an

7 intensity score. The proportion score is divided

8 into five components, so a score of one is assigned

9 to a tumor where there is absolutely no tumor cells

10 staining or less than one percent of tumor cells--

11 well actually if there are no tumor cells staining,

12 then it gets a score of zero, but there there's less

13 than one percent of the cells staining, it gets a

14 score of one. If there is between one and ten

15 percent--actually, let me just rephrase that, so it

16 gets a score of zero if there is zero percent; less

17 than one percent, one; one to ten percent, two;

18 eleven to thirty-three percent, three; thirty-four

19 to sixty-seven percent, four; and greater than

20 sixty-seven percent, up to a hundred percent, five.

21 Okay? The intensity score is from zero to three, so

22 zero if there's absolutely no positive cells; one if

23 there is staining but it's of a weak intensity; two

24 if the intensity is moderate; and three if the

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1 intensity is strong. And those cases that I showed
 2 you before, those cells that were staining in the
 3 normal epithelium, that was staining at a strong
 4 intensity.
 5 COFFEY, Q.C.:
 6 Q. And intensity in this context means what, Doctor?
 7 Not the implication of it, how do you interpret
 8 something as intense?
 9 DR. O'MALLEY:
 10 A. It really--it has to do with the, really with the
 11 colour, I mean, if it's weak, it will be a very
 12 light brown, if it's strong, it will be a very dark
 13 brown, so it's really a difference in shades of
 14 brown and actually that can be certain, subjective
 15 at times, but this is a case that would be, I would
 16 expect would be uniformly interpreted, uniformly
 17 interpreted as a tumor that shows almost a hundred
 18 percent positivity with a strong intensity. So
 19 these are all tumor cells and even at this power you
 20 can see that there's a lot of brown staining
 21 throughout, okay. This blue stuff here, this is
 22 normal tissue, this is fat and this is normal
 23 stromal, these are normal stromal cells, so they are
 24 negative. Now, I'll just draw your attention to

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1 this small benign duct, you can see that here we
 2 have those normal epithelium cells staining as
 3 wells. Now, of course in this case we already know
 4 that the test has worked because the tumor is so
 5 strongly positive, but this is also nice reassurance
 6 that our internal positive control is behaving as it
 7 should, okay? So this is easy to interpret as a
 8 strongly positive tumor cell, it's this tumor that
 9 would be less, it would cause more variability in
 10 interpretation where a far fewer of the tumor cells
 11 are staining positively. So here you can see the
 12 positive cells as evidenced by these little brown
 13 dots, but you can see that there's much more blue in
 14 this slide indicating negative tumor cells. I
 15 believe I have a higher power, yes, here. Here you
 16 can see these positive tumor cells and many more
 17 negative tumor cells. Here this actually shows the
 18 varying intensity of staining that one can see, so
 19 where's a weakly positive cell and here's a strongly
 20 positive cell, okay. So I want to now return to the
 21 data by Harvey et al, and this slide summarizes all
 22 of the patients in the study that received endocrine
 23 therapy. There were over 770 patients in that
 24 cohort of 1900 patients that actually received

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1 endocrine therapy. So here we're looking at the
 2 predictive utility of the test and these--all of
 3 these curves summarize all of the possible total
 4 immunohistochemical scores for all of the patients
 5 tumors. On the X axis we have the time up to 72
 6 months, and the Y we have the disease free survival
 7 probability. And what you can see here is that
 8 there is a sharp difference between the survival,
 9 the disease free survival in the patients whose
 10 tumors had a score of zero to two, compared to those
 11 patients whose tumors had a score of three and up to
 12 eight. And so that was why the cut point of greater
 13 than two was used to assess what a positive result
 14 or what a positive ER result was. Okay, so is that
 15 clear? So a tumor with a composite score of zero or
 16 two, is a tumor that's deemed ER negative; whereas a
 17 tumor with a composite score of three to eight is a
 18 tumor that's ER positive.
 19 COFFEY, Q.C.:
 20 Q. And, Doctor, as well I take it the patients being
 21 studied here, are those, all of these patients have
 22 received some sort of endocrine therapy?
 23 DR. O'MALLEY:
 24 A. That's absolutely--and see here at the top of the

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1 slide, all of these 777 patients received endocrine
 2 therapy, the vast majority of these patients in fact
 3 received Tamoxifen. So again this is looking at the
 4 predictive utility of the test and we can see that
 5 the patients whose tumors were, did ER positive, did
 6 much better, responded to a greater degree to that
 7 endocrine therapy than those patients who had tumors
 8 that were ER negative. So it's because of this data
 9 that we use the greater than two, i.e. three or up
 10 as determining what a positive result is. Now let
 11 me bring you back to this semi-quantitative scoring
 12 system to put that into context. So that means that
 13 a tumor with as few as between one to ten percent of
 14 the tumor cells being positive, i.e. it gets a
 15 proportion score of two, with even a weak intensity,
 16 getting an intensity score of one, i.e. two plus one
 17 will be deemed ER positive.
 18 COFFEY, Q.C.:
 19 Q. And, Doctor, just looking at that slide, I take it
 20 that if you are at the--you've fallen into the
 21 category of proportion score, for example two, which
 22 falls somewhere between one and ten percent, that if
 23 there is between one and ten percent of cells
 24 staining that they must have some sort of intensity

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1 and even the lowest intensity is one -
 2 DR. O'MALLEY:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. A score of one, so two plus one is three and there
 6 you are.
 7 DR. O'MALLEY:
 8 A. Exactly.
 9 COFFEY, Q.C.:
 10 Q. Three and above.
 11 DR. O'MALLEY:
 12 A. Exactly.
 13 COFFEY, Q.C.:
 14 Q. You'd get a benefit.
 15 DR. O'MALLEY:
 16 A. So as I mentioned before, there certainly can be
 17 some subjectivity in determining the degree of
 18 intensity, but this data shows that it really isn't
 19 that important, it's determining the proportion of
 20 tumor cells that are positive at any degree of
 21 intensity that's the critical step in determining
 22 whether indeed a tumor is positive or negative. So
 23 back now to this data by Harvey et al and this is
 24 the clinical data showing very importantly that ER

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1 status determined by immunohistochemistry was in
 2 fact better at predicting disease free survival of
 3 these patients and equivalent at predicting overall
 4 survival compared to that standard biochemical test,
 5 the Ligand Binding Assay test, so this really does
 6 show that immunohistochemistry is a very, very good
 7 test when it's performed accurately in giving this
 8 important clinical information. And this is a
 9 summary of that information showing here that the
 10 patients whose tumors were ER negative had a much
 11 worse disease free survival than those patients who
 12 were ER positive; in fact, there was a 30 percent
 13 benefit at five years for the patients who had ER
 14 positive tumors. Again, remember this is the
 15 predict--these are all--all of these patients have
 16 been treated. This is not looking at the intrinsic
 17 biologic potential of ER status, this is looking at
 18 its predictive utility. Here we can see the data
 19 for the Ligand Binding Assay with a 25 percent
 20 disease free survival benefit of five years. Okay,
 21 so that data was data in early breast cancer, in the
 22 adjunctive setting. This data is in the metastatic
 23 breast cancer setting.
 24 COFFEY, Q.C.:

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1 Q. Now I take it early setting, I take it that's before
 2 the disease is spread.
 3 DR. O'MALLEY:
 4 A. That's right.
 5 COFFEY, Q.C.:
 6 Q. Beyond its original site.
 7 DR. O'MALLEY:
 8 A. That's right.
 9 COFFEY, Q.C.:
 10 Q. Doctor and this Harvey study was published when?
 11 DR. O'MALLEY:
 12 A. It was published in 1999.
 13 COFFEY, Q.C.:
 14 Q. I'm sorry, Doctor, go ahead, you were about to tell
 15 us about the more advanced -
 16 DR. O'MALLEY:
 17 A. Disease.
 18 COFFEY, Q.C.:
 19 Q. Disease, yes, go ahead.
 20 DR. O'MALLEY:
 21 A. Metastatic breast cancer, so this paper came out the
 22 year after the Harvey study and this was data from a
 23 clinical trial from South Western Oncology group and
 24 they looked at both ER and PR by both the

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1 biochemical Ligand Binding Assay and by
 2 immunohistochemistry. Again we're looking at
 3 predictive utility of the test because all of these
 4 patients were treated with Tamoxifen and there was a
 5 significant long-term follow up with a nine year
 6 median follow up. Now this summarizes the year of
 7 registration and the disease free survival and what
 8 we can see here is that not only was there a
 9 difference between ER positivity and ER negativity,
 10 for actually both ER, positivity and negativity, but
 11 also PR negativity and positivity, but the degree of
 12 positivity was associated with a greater response to
 13 Tamoxifen, so we can see here the red line
 14 represents the patients who had negative disease
 15 with a score of zero to one. Now what we're looking
 16 at here is just the proportion score. So I showed
 17 you the Allred score was a combination of both
 18 proportion and intensity with a composite score of
 19 being somewhere between zero and eight, here,
 20 because the intensity score didn't really add
 21 anything above and beyond any cell or cells being
 22 weakly positive, this study actually dropped the
 23 intensity score and just looked at the percentage
 24 score which was from zero to five. So here we can

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1 see those tumors that are negative, i.e. zero or
 2 less than one percent of the tumor cells positive
 3 had a much worse survival than those patients who
 4 had weak or--well not really weak positivity, but
 5 positivity somewhere between two and three. That
 6 translates to between one to ten percent and up to
 7 thirty percent positivity, compared to those who had
 8 greater than a third positivity, so all the way up
 9 to a hundred percent positivity. And again, there
 10 was that same linear relationship for progesterone
 11 receptor. So this data would indicate that we not
 12 only need to report whether a tumor is ER positive
 13 or negative, but that we really do need to include
 14 the actual percentage positivity that the tumor
 15 displays. Okay, now I want to turn to the very,
 16 very important issue of quality control and quality
 17 assurance for both ER and PR testing. Now quality
 18 assurance is really an indication of how accurate a
 19 test is from lab to lab and it really assesses the
 20 interlab variability and every lab that performs
 21 these tests should be participating in a quality
 22 assurance program. One of the best quality
 23 assurance programs to my mind is that run out of the
 24 UK. It's known as NEQAS and there's also a very,

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1 very good quality assurance program from the U.S.
 2 run by the College of American Pathologists. So,
 3 this a study published by the NEQAS Group where they
 4 assessed ER and PR staining. This is the ER
 5 staining from 200 labs in 26 countries, the vast
 6 majorities of these countries were in Europe, but
 7 there were a few labs from North America that were
 8 included in this study. What the NEQAS Group did
 9 was they circulated tumors to all of these
 10 participating 200 labs that had high, medium and low
 11 levels of estrogen receptor. And what they find was
 12 that greater than 80 percent of those labs were able
 13 to detect the tumors that had high and medium ER
 14 levels. They called--when they repeated the
 15 staining in their labs, they find the tumors were
 16 indeed positive. However, almost 40 percent of
 17 those labs failed to detect--only 40 percent of
 18 those labs detected the ER in the tumors that had
 19 low levels of ER. Okay. So, over 60 percent of
 20 those labs actually did not detect the ER in the
 21 circulated tumor that had low levels.
 22 So, what this group did was then it looked at
 23 the those labs, it looked at the cutoff that those
 24 labs used to determine what an ER positive result

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1 was. And what they find was that for the labs that
 2 used the ten percent cutoff, the false negativity
 3 rate was 66 percent. However, for the labs that
 4 used the 1 percent cutoff as validated by the Harvey
 5 Study, the false negativity was lower. It certainly
 6 wasn't zero, but it was much lower than those labs
 7 that used the higher cutoff.
 8 COFFEY, Q.C.:
 9 Q. It was down, I take it, about 30 percent?
 10 DR. O'MALLEY:
 11 A. Yes. Now, recently the Canadian Quality Control and
 12 Immunohistochemistry combined with the Canadian
 13 Association of Pathologists Group has struck this
 14 national standards committee. And a recent study
 15 was undertaken where 37 different tumors in the form
 16 of tissue micro-ray were circulated to 18 labs
 17 across Canada, looking at this issue of inter-
 18 observer reproducibility. And this is quite
 19 reassuring data that of those 18 labs, the
 20 concordance for ER was 98.5 percent with a
 21 sensitivity of 98.5 percent and the specificity of
 22 98.3 percent. And the concordance for PR was a
 23 little less, but still very, very good at 94.4
 24 percent. So, I think this does indicate that we

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1 can, when there is good quality control, quality
 2 assurance in place, that the reproducibility across
 3 labs can be very high.
 4 So, I just want to conclude by showing what we
 5 do at Mount Sinai. We fix all our specimens in 20
 6 percent neutral buffered formalin for at least 8 and
 7 up to 24 hours. Certainly it can be up to 48 hours,
 8 but this is the optimal fixation is somewhere
 9 between 8 and 24 hours. Obviously, following
 10 slicing to allow adequate fixation, as I've
 11 discussed earlier, we use the antibodies that were
 12 validated in that Harvey Study, that is we use the 6
 13 FL antibody for ER and the 1294 antibody for the PR
 14 and we used the Allred scoring system. This is the
 15 cutoffs that we used. So, obviously the tumor shows
 16 no staining, it's classified as negative. If
 17 they're somewhere between 1 and 9 percent, it's
 18 categorized as low positive and if there's between
 19 10 and 100 percent staining, then that tumor is
 20 categorized as ER and PR positive. And these
 21 cutoffs have been--they are certainly supported by
 22 the College of American Pathologists consensus
 23 document and other international documents.
 24 We use synoptic reporting to report these

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1 results and this is what our report would look like.
 2 So, if a tumor--so, we state whether a tumor is
 3 positive or negative. So, here you can see that
 4 this tumor is positive, then we report the
 5 percentage positive cells, here the tumor showed
 6 greater than 90 percent positivity. We include the
 7 antibody that was used and then you list the
 8 chemical procedure that was used for both ER and PR.
 9 We also include a statement about our positive and
 10 negative laboratory controls. And we include the
 11 data that our cutoff is based on, ie., the Harvey
 12 Study.
 13 Now, when I'm giving this talk to medical
 14 oncologists, I leave them with three points. I tell
 15 them that they shouldn't accept just a positive or
 16 negative result from their laboratories. That they
 17 really should insist on knowing what that percentage
 18 positivity is. And again, all labs who are
 19 following the CAP requirements should be including
 20 the antibodies used and the methodology used. And
 21 the third point is that the medical oncologists
 22 should be aware of the labs cutoff point and the
 23 data that that is based on. So, that concludes my
 24 presentation.

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1 COFFEY, Q.C.:
 2 Q. Doctor, the study that you referred to, the one
 3 involving Terry et al in the slide presentation, the
 4 most recent study involving the 18 labs, when was
 5 that conducted?
 6 DR. O'MALLEY:
 7 A. It was only conducted this year and it hasn't--if we
 8 can go back to that data--it has not been published
 9 yet. It is in the process of being submitted for
 10 publication. But I did check with the authors to
 11 make sure I could present this data.
 12 COFFEY, Q.C.:
 13 Q. And this is going on as it were in real time.
 14 DR. O'MALLEY:
 15 A. This is going on in real time. This is what's
 16 currently happening across Canada.
 17 COFFEY, Q.C.:
 18 Q. The cutoffs that you refer to that Mount Sinai uses,
 19 how long has Mount Sinai been using those?
 20 DR. O'MALLEY:
 21 A. We used those cutoffs--prior to the 1999 study, we
 22 actually did use a 10 percent cutoff, but I believe
 23 it was in 2000 that we then switched to the Baylor
 24 antibodies and used the lower cutoff.

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1 COFFEY, Q.C.:
 2 Q. Which is the -
 3 DR. O'MALLEY:
 4 A. Which is the percent -
 5 COFFEY, Q.C.:
 6 Q. One -
 7 DR. O'MALLEY:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Could you tell the Commissioner, please, because you
 11 did make reference in passing to the technologists
 12 checking controls.
 13 DR. O'MALLEY:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Okay. Could you tell the Commissioner what controls
 17 it is the technologists at Mount Sinai check?
 18 DR. O'MALLEY:
 19 A. So we use external controls, and this, we actually
 20 use a composite of controls that include a strong
 21 positive tumor, a tumor that's positive at a lower
 22 level and then a completely negative tumor. And
 23 these tumors actually were assessed by the Ligand
 24 Binding Assay. We have an archive of tumors that we

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1 know the results from the previous standard, Ligand
 2 Binding Assay, and so we include these in our runs.
 3 COFFEY, Q.C.:
 4 Q. And so the technologists are checking the external
 5 control slots?
 6 DR. O'MALLEY:
 7 A. External controls, yes.
 8 COFFEY, Q.C.:
 9 Q. Controls. And in terms of the division of
 10 responsibility at Mount Sinai, the pathologists
 11 check which controls?
 12 DR. O'MALLEY:
 13 A. Well, we check, obviously, the internal controls, as
 14 I mentioned, and we do check periodically the
 15 external controls, as well. Certainly if we were
 16 concerned, if we had any concerns with the assay, we
 17 would check the external controls.
 18 COFFEY, Q.C.:
 19 Q. And in terms of that, can you tell the Commissioner,
 20 please, describe for the Commissioner, what actually
 21 happens in terms of what has to happen before you,
 22 as a pathologist, actually see a tumor slide, I
 23 mean, who has checked it and for what before you
 24 ever get your hands on it?

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1 DR. O'MALLEY:
 2 A. A huge, a huge amount of work has gone into the
 3 performance of this test, making sure that it is
 4 stringently being performed and it is accurate
 5 before it ever reaches my desk, and that is really
 6 the analytical stage of the technical validation
 7 that I alluded to. So the sensitivity and
 8 specificities of the antibodies are checked, they
 9 have been validated, a large number of tumors have
 10 been validated to make sure that the antibodies are
 11 working appropriately before they're ever used in a
 12 clinical, in a clinical setting.
 13 COFFEY, Q.C.:
 14 Q. And we'll be hearing from Ms. Wegrynowski about
 15 that. But in terms of for any one patient, by the
 16 time the slide gets to you for an ER interpretation
 17 or PR interpretation, you understand what about what
 18 controls have been checked before the arrive, the
 19 slide arrives in your office?
 20 DR. O'MALLEY:
 21 A. Well, my understanding is that the positive,
 22 strongly positive, weakly positive and negative
 23 controls have been checked and they have stained and
 24 they are staining in the appropriate manner before -

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1 COFFEY, Q.C.:
 2 Q. Checked by whom?
 3 DR. O'MALLEY:
 4 A. Checked by the technologists, yes, the senior
 5 technologists.
 6 COFFEY, Q.C.:
 7 Q. So, that is the arrangement that exists at Mount
 8 Sinai?
 9 DR. O'MALLEY:
 10 A. Yes, and if there is any concern at all, then they
 11 are checked also by the pathologists.
 12 COFFEY, Q.C.:
 13 Q. And how long have the technologist been checking
 14 external controls at Mount Sinai?
 15 DR. O'MALLEY:
 16 A. Well, I've been there since 1998 and it certainly
 17 has been happening since then.
 18 COFFEY, Q.C.:
 19 Q. And we'll be hearing, Commissioner, more from Ms.
 20 Wegrynowski about that, but from your perspective
 21 then, Doctor, I take it as a practising pathologist
 22 there that you understand that it wouldn't come to
 23 you, the tumor tissue slide would not even arrive
 24 for you to interpret without external controls

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1 having been certified as it were by the
 2 technologists?
 3 DR. O'MALLEY:
 4 A. That's correct.
 5 COFFEY, Q.C.:
 6 Q. How about usage of internal controls as a
 7 pathologist. Can you tell the Commissioner, please,
 8 about that, how long that has been the practice?
 9 How long have you been looking for internal controls
 10 in ER and PR slides?
 11 DR. O'MALLEY:
 12 A. Since I've started practising, that's just standard
 13 procedure.
 14 COFFEY, Q.C.:
 15 Q. Okay. So, when you, for example--remind me, please,
 16 you were at -
 17 DR. O'MALLEY:
 18 A. Victoria -
 19 COFFEY, Q.C.:
 20 Q. Vanderbilt, when? When was that?
 21 DR. O'MALLEY:
 22 A. I was at Vanderbilt in 1991 and 1992.
 23 COFFEY, Q.C.:
 24 Q. Okay. And then when you returned to Canada, just

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1 after that, I'm sorry, the hospital was?
 2 DR. O'MALLEY:
 3 A. Victoria hospital in London.
 4 COFFEY, Q.C.:
 5 Q. Victoria. And at that time, were they using IHC for
 6 ER and PR there?
 7 DR. O'MALLEY:
 8 A. They were.
 9 COFFEY, Q.C.:
 10 Q. And at that time when you were processing patient
 11 slides, were you looking for internal controls then?
 12 DR. O'MALLEY:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Doctor, the usage of internal controls, in that
 16 context, are they peculiar to ER and PR or peculiar
 17 to IHC testing or where do they fit? Where do the
 18 idea of using internal controls fit in comparison to
 19 the uses of external controls? Perhaps you could
 20 put that -
 21 DR. O'MALLEY:
 22 A. Well, they certainly apply to ER and PR because we
 23 have that in-built normal epithelium that we know
 24 should be positive with both ER and PR, but it

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1 doesn't apply to every immunohistochemical test or
 2 isn't that in-built internal control.
 3 COFFEY, Q.C.:
 4 Q. So, internal controls, in that context, are peculiar
 5 to certain IHC tests?
 6 DR. O'MALLEY:
 7 A. Yes, that is correct, yes.
 8 COFFEY, Q.C.:
 9 Q. And the ER test and the PR test happen to be two
 10 that it applies to.
 11 DR. O'MALLEY:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Again, just to put this in some kind of context for
 15 the Commissioner, like, IHC stains,
 16 immunohistochemistry stains, approximately how many,
 17 for example, would there be being utilized right now
 18 at Mount Sinai, how many different ones? And I
 19 won't hold you to the actual number, but just -
 20 DR. O'MALLEY:
 21 A. Actually Trish will be the -
 22 COFFEY, Q.C.:
 23 Q. Trish would know.
 24 DR. O'MALLEY:

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1 A. Trish will have that data for you.
 2 COFFEY, Q.C.:
 3 Q. The actual amount, but I take it there's many, many
 4 stains.
 5 DR. O'MALLEY:
 6 A. Many, many stains.
 7 COFFEY, Q.C.:
 8 Q. I mean, it's not just three or four or five stains,
 9 it's -
 10 DR. O'MALLEY:
 11 A. No.
 12 COFFEY, Q.C.:
 13 Q. - probably well over a--and I anticipate she'll
 14 probably tell us well over a hundred. Doctor, in
 15 terms of--and I appreciate you practice breast
 16 pathology. If you could help the Commissioner
 17 please, in terms of these stains and there are many
 18 of them, I take it that they're not peculiar to
 19 breast pathology. They're used, these stains, IHC
 20 stains are used for a whole bunch of other types of
 21 sub specialities -
 22 DR. O'MALLEY:
 23 A. That's very, very true, but what's peculiar or
 24 different about ER and PR and indeed HER2 is that

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1 those immunohistochemical stains are used--a semi-
 2 quantitative result is given and they are used to
 3 drive therapy, rather than a lot of
 4 immunohistochemistry is used to just help sort out
 5 diagnosis, differential diagnosis. But for ER/PR
 6 and HER2, they re used very much to drive clinical
 7 decision making.
 8 COFFEY, Q.C.:
 9 Q. Now, is there, to your knowledge, any known
 10 correlation between ER positivity of a tumor and PR
 11 positivity?
 12 DR. O'MALLEY:
 13 A. Yes, the vast majority of tumors that are ER
 14 positive will also be PR positive. Occasionally,
 15 however, ER positive tumors will be PR negative.
 16 And this is probably due to the estrogen receptor
 17 being present, but actually not functional in those
 18 tumors. Now, conversely, ER positivity can occur in
 19 the face of ER negativity, but that's extremely
 20 rare. And -
 21 COFFEY, Q.C.:
 22 Q. Excuse me, what is extremely rare?
 23 DR. O'MALLEY:
 24 A. PR positivity in the face of ER negativity.

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1 COFFEY, Q.C.:
 2 Q. Is extremely rare.
 3 DR. O'MALLEY:
 4 A. It is and indeed it would be an indication that the
 5 ER has failed because we know that the PR, induction
 6 of PR is really driven by ER. So, the ER must be
 7 functional for the progesterone receptor to be
 8 turned on.
 9 COFFEY, Q.C.:
 10 Q. And that rarity, existence of that rarity, how long
 11 has that been known? How long have you -
 12 DR. O'MALLEY:
 13 A. I can't put a date--many years.
 14 COFFEY, Q.C.:
 15 Q. Many years, okay. It goes back to the time your
 16 training and certainly into the -
 17 DR. O'MALLEY:
 18 A. Certainly since I've been at Mount Sinai.
 19 COFFEY, Q.C.:
 20 Q. If you were to encounter such a result, you know,
 21 for a patient you saw what you interpreted or
 22 thought, looking through the microscope, at a slide
 23 and what you were seeing, thought, well, that's PR
 24 positive and the same tumor slide made from the same

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1 block and the ER result was negative, at least, to
 2 the best you could see. Would that cause you to do
 3 anything?
 4 DR. O'MALLEY:
 5 A. I would probably repeat the ER, but in terms of just
 6 at a pragmatic level, the clinician is going to
 7 treat that patient because the tumor is PR positive.
 8 COFFEY, Q.C.:
 9 Q. So, it's your understanding that the oncologist--if,
 10 for example, you report that PR is, I don't know, 20
 11 percent positive and even if it's, the ER is
 12 reported as 0, your understanding is that the
 13 oncologist will treat the patient in any case -
 14 DR. O'MALLEY:
 15 A. Yes, that is my understanding, -
 16 COFFEY, Q.C.:
 17 Q. - as if they're receptor positive and -
 18 DR. O'MALLEY:
 19 A. Yes, because as I mentioned, the PR can only be
 20 positive if the ER is functional.
 21 COFFEY, Q.C.:
 22 Q. What sorts of things, Doctor, would, from your
 23 perspective, cause you to perhaps question the
 24 accuracy of a test result, as you were saying? What

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1 sorts of things as clinician?
 2 DR. O'MALLEY:
 3 A. When I look down the microscope?
 4 COFFEY, Q.C.:
 5 Q. Yes.
 6 DR. O'MALLEY:
 7 A. Well, there are a number of things. Tumor type is
 8 one of them. So, while the vast majority of breast
 9 cancers are invasive ductal carcinomas, there are a
 10 certain number of special type cancers, invasive
 11 lobular cancers, invasive tubular cancers and
 12 invasive mucinous cancers are the three most common
 13 special type cancers. If one of those special type
 14 cancers was ER or PR negative, I would question the
 15 test result because the vast majority of those
 16 special type cancers are indeed ER and PR positive.
 17 COFFEY, Q.C.:
 18 Q. And questioning in that world means what? What
 19 would you do?
 20 DR. O'MALLEY:
 21 A. Well, I would--obviously I would have checked the
 22 internal controls and then I would go back and check
 23 the external controls, talk to the technologists
 24 about that particular run and ask for a repeat if

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1 necessary.
 2 COFFEY, Q.C.:
 3 Q. Repeat in the sense of have just have the slide or
 4 the tissue--another section -
 5 DR. O'MALLEY:
 6 A. Another section taken from the tumor and the testing
 7 -
 8 COFFEY, Q.C.:
 9 Q. The whole process gone through again.
 10 DR. O'MALLEY:
 11 A. Repeated, yes.
 12 COFFEY, Q.C.:
 13 Q. Now, Doctor, on that point, I take it though
 14 occasionally, example, lobular invasive carcinomas,
 15 have you ever encountered a lobular invasive that
 16 upon retest even, you were satisfied that it was a
 17 negative ER negative?
 18 DR. O'MALLEY:
 19 A. It's so rare that I can remember the one case that I
 20 did, that did come across my desk. It does happen,
 21 but it is very rare that a classic invasive lobular
 22 cancer would be negative for both ER and PR.
 23 COFFEY, Q.C.:
 24 Q. And, in fact, when did that occur? Do you recall

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1 when?
 2 DR. O'MALLEY:
 3 A. It actually occurred last year and it had been sent
 4 to three other labs before it arrived at Mount
 5 Sinai.
 6 COFFEY, Q.C.:
 7 Q. Doctor, do you know if Mount Sinai has tissue
 8 samples sent to it that are still in formalin from
 9 other hospitals? Like, sent across town, as it were
 10 in Toronto?
 11 DR. O'MALLEY:
 12 A. That would be quite unusual. The vast majority of
 13 the specimens that we receive have already been
 14 fixed and are in wax box, yes.
 15 COFFEY, Q.C.:
 16 Q. Okay. And in terms of if that was to occur, I take
 17 it, Trish would be at the technologists level even,
 18 that she would be perhaps aware of the pros and cons
 19 of doing that or the potential pitfalls of doing
 20 that?
 21 DR. O'MALLEY:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. I should take it up with her, right?

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1 DR. O'MALLEY:
 2 A. Yes, indeed, indeed.
 3 COFFEY, Q.C.:
 4 Q. I'm not suggesting it does happen at all, not at
 5 all, I just wanted to ask you about it for a reason
 6 that will become apparent to the Commissioner at
 7 some later stage. One example, that case that you
 8 did refer to that you understood had gone to a
 9 number of other labs and to hospitals before it
 10 ended up at Mount Sinai, that lobular invasive, at
 11 the time I take it, it was your understanding that
 12 was being kind of shipped around for second and
 13 third opinions because it was perceived to be just
 14 so unusual.
 15 DR. O'MALLEY:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. And in performing those, carrying out or giving a
 19 second or third opinion, you would do what? Go
 20 through the whole processing procedure in the lab
 21 for external controls, internal controls and -
 22 DR. O'MALLEY:
 23 A. Yes, external controls and yes, I mean, they're used
 24 in every run.

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1 COFFEY, Q.C.:
 2 Q. Yes. And if I could, Doctor, what I would like to
 3 do now, is I'm going to move on to the actual
 4 involvement such as it was that you had in the
 5 matter involving St. John's, in the hospitals here.
 6 THE COMMISSIONER:
 7 Q. Mr. Coffey, if I can interrupt just briefly before
 8 you do that, because there are a couple of things
 9 that I'm curious about -
 10 COFFEY, Q.C.:
 11 Q. I was going to say, in fact, in terms of -
 12 THE COMMISSIONER:
 13 Q. - on this, so it's just--while it's in my mind,
 14 things have a tendency to slip through. One is the
 15 business of the cutoff. I notice for example that,
 16 which as I understand it has been 10 percent or 1
 17 percent or in some cases, 20 percent or even 30
 18 percent, who in the specialties determines what is
 19 positive and what is negative? Is that something
 20 for pathologists?
 21 DR. O'MALLEY:
 22 A. That is decided by the pathologists, yes.
 23 THE COMMISSIONER:
 24 Q. And how does--is that something that is decided by

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1 each pathology department in each hospital?
 2 DR. O'MALLEY:
 3 A. It is, through their own validation and also review
 4 of the literature. So, why we chose the 1 percent
 5 is because we feel that that paper is the best
 6 evidence, both from a clinical and technical
 7 validation and we use those specific antibodies.
 8 THE COMMISSIONER:
 9 Q. So, is there a procedure at Mount Sinai where you
 10 regularly look at this or is it that some new study
 11 comes out and the leadership of pathology at Mount
 12 Sinai says, maybe we ought to think about it. How
 13 does that get done?
 14 DR. O'MALLEY:
 15 A. Well, it gets done through regularly reviewing the
 16 literature and for breast disease then, it would, I
 17 would make some of those decisions in conjunction
 18 with the leadership and the technical staff. So,
 19 the steps would be that we would, for example, with
 20 the 6F11, I had heard that they didn't even present
 21 it. I was particularly impressed by that data and
 22 then I discussed the, bringing those antibodies into
 23 the lab with the head of surgical pathology and then
 24 I discussed it with the senior technologists in

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1 immunohistochemistry.
 2 THE COMMISSIONER:
 3 Q. Okay. Now, that point about the particular
 4 antibodies and I noticed that in the last slide that
 5 you presented, in terms of the information that you
 6 provide to oncologists, you said that they should
 7 insist on the reporting of the percentage of
 8 positivity, the antibodies used and the methodology.
 9 Now, why is it that you tell the oncologists which
 10 antibodies you used? I can relate to why you tell
 11 them percentages. I'm just wondering why is it you
 12 tell them which antibodies you use?
 13 DR. O'MALLEY:
 14 A. Well, because different antibodies have been
 15 associated with different cutoffs. So, again it's
 16 just another step to make sure that--it's really
 17 following the College of American Pathologists
 18 guidelines. And it's just another validation step
 19 in the process.
 20 THE COMMISSIONER:
 21 Q. All right. So, the decision made by Mount Sinai
 22 respecting percentage of positivity, in turn is
 23 something that relates, in any event to the
 24 antibodies used, correct?

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1 DR. O'MALLEY:
 2 A. Well, it's related to the scoring of the antibodies.
 3 THE COMMISSIONER:
 4 Q. All right. So, really what you're trying to do in
 5 respect of communicating with the oncologists is to
 6 allow the oncologist to understand the basis for
 7 your cutoff, in terms of the science so that -
 8 DR. O'MALLEY:
 9 A. Exactly.
 10 THE COMMISSIONER:
 11 Q. - if they want to do an assessment, then they know
 12 your reference point is this particular science?
 13 DR. O'MALLEY:
 14 A. Exactly.
 15 THE COMMISSIONER:
 16 Q. All right, and the only other thing that I had a
 17 note of was this business of the lobular invasive
 18 and the expectation in respect of lobular--sorry,
 19 I'm having trouble getting my tongue around all
 20 these medical terms--would be negative?
 21 DR. O'MALLEY:
 22 A. The expectation is that an invasive lobular cancer,
 23 particularly a low grade classic invasive lobular,
 24 that it would be positive.

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1 THE COMMISSIONER:
 2 Q. I'm sorry, you're right.
 3 DR. O'MALLEY:
 4 A. Over 90 percent.
 5 THE COMMISSIONER:
 6 Q. I got positive written down, but I said negative.
 7 DR. O'MALLEY:
 8 A. Over 90 percent of ER -
 9 THE COMMISSIONER:
 10 Q. Ah, okay, that was my question. One, what the
 11 percentage was that you would--what percentage would
 12 one--might one expect would be negative.
 13 DR. O'MALLEY:
 14 A. Less, way less than ten percent. Way less than, in
 15 fact, five percent.
 16 THE COMMISSIONER:
 17 Q. Okay.
 18 DR. O'MALLEY:
 19 A. Would be negative. So we would expect, as I say, 90
 20 to 95 percent of classic ILC's to be ER positive.
 21 THE COMMISSIONER:
 22 Q. And how long has that been known?
 23 DR. O'MALLEY:
 24 A. I can't put a date to that, but I've certainly known

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1 about that for years.
 2 THE COMMISSIONER:
 3 Q. And well, can we relate it to the same thing that
 4 you related earlier, you said that since you--you
 5 made the reference to since you've been practising
 6 at Mount Sinai, which would have been since '98?
 7 DR. O'MALLEY:
 8 A. '98, well, I probably would have known that when I
 9 was practising in Victoria, at Victoria Hospital in
 10 London, which was '93 to '98.
 11 THE COMMISSIONER:
 12 Q. All right. So that would have been known in that
 13 period of time, and the other thing is, is this data
 14 tracked in your lab?
 15 DR. O'MALLEY:
 16 A. Yes, we do track the percentage positive and
 17 percentage negative ER and PR results that we have.
 18 THE COMMISSIONER:
 19 Q. In general, and also in respect of the different
 20 kinds of breast cancer, or that's what I'm--you
 21 know, there's -
 22 DR. O'MALLEY:
 23 A. In general. In general. If we wanted to look at
 24 specific, we can do that, but it's not as easily

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1 retrieved as the overall percentage positivity.
 2 THE COMMISSIONER:
 3 Q. So within Mount Sinai, you would know, with the push
 4 of a button, what your yearly statistics were in
 5 terms of percentages of positive and negative
 6 results?
 7 DR. O'MALLEY:
 8 A. Yes.
 9 THE COMMISSIONER:
 10 Q. All right. Thank you. Sorry to interrupt, Mr.
 11 Coffey, but while it was on my mind I thought I'd
 12 better.
 13 COFFEY, Q.C.:
 14 Q. Doctor, while I'm on it, as clarifying something
 15 again, which is, I gather, second nature to
 16 yourself. A synoptic report, what does synoptic
 17 mean?
 18 DR. O'MALLEY:
 19 A. It just means a very formatted report. So the
 20 information is in the same place in the same sort of
 21 format throughout the report.
 22 COFFEY, Q.C.:
 23 Q. And you also, in the last slide, made reference to
 24 in its title, in fact, information for medical

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1 oncologists and you indicated that when you do speak
 2 to medical oncologists as a group, as it were, or
 3 groups of them, that there are certain things you
 4 try to ensure that you tell them, to in effect
 5 demand of the pathologists that you're dealing with.
 6 Could you tell the Commissioner, and ask you just a
 7 couple of questions about kind of the relationships
 8 with other professionals. Technologists at Mount
 9 Sinai, what interaction do you have on a routine
 10 basis with technologists and who reports to whom?
 11 Could you just lay that out?
 12 DR. O'MALLEY:
 13 A. We work very, very closely with technologists when
 14 it comes to immunohistochemical staining, on a daily
 15 basis actually.
 16 COFFEY, Q.C.:
 17 Q. And who reports to--like in terms of the
 18 immunohistochemistry, who reports to whom?
 19 DR. O'MALLEY:
 20 A. We have a head of immunohistochemistry.
 21 COFFEY, Q.C.:
 22 Q. Is that a doctor?
 23 DR. O'MALLEY:
 24 A. That's a doctor, yes. So actually Dr. Pritzker will

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1 be able to address those reporting issues.
 2 COFFEY, Q.C.:
 3 Q. Okay, the organizational thing.
 4 DR. O'MALLEY:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. And so I'll take him through that, but in terms of
 8 yourself and your own interaction with
 9 technologists, I take it if you weren't here today,
 10 you were at work in Toronto, it would not be at all
 11 unusual for you to interact with the IHC techs
 12 routinely?
 13 DR. O'MALLEY:
 14 A. Absolutely. As I say, on a daily basis.
 15 COFFEY, Q.C.:
 16 Q. And with respect to oncologists, how much
 17 interaction at Mount Sinai do you have, as a
 18 pathologist, as a breast pathologist, with
 19 oncologists?
 20 DR. O'MALLEY:
 21 A. A lot of interaction. Maybe not on a daily basis,
 22 but certainly on a weekly basis. We have multi-
 23 disciplinary tumor boards where we discuss all of
 24 the patients that have been diagnosed with invasive

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1 breast cancer that week, and those conferences
 2 include medical oncologists, surgical oncologists,
 3 nurses, sometimes radiation oncologists come along
 4 too, and of course, ourselves.
 5 COFFEY, Q.C.:
 6 Q. And that practice has been going on for how long?
 7 DR. O'MALLEY:
 8 A. Since I've been at Mount Sinai.
 9 COFFEY, Q.C.:
 10 Q. Commissioner, I'm going to--as I'm going to pass on
 11 to something else and -
 12 THE COMMISSIONER:
 13 Q. Would you like to take the morning break?
 14 DR. O'MALLEY:
 15 A. - perhaps we can take the morning break, and I'll
 16 come back and finish my questions.
 17 THE COMMISSIONER:
 18 Q. Yes, of course.
 19 COFFEY, Q.C.:
 20 Q. Thank you.
 21 THE COMMISSIONER:
 22 Q. Take 15 minutes.
 23 (RECESS)
 24 THE COMMISSIONER:

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1 Q. Please be seated. Mr. Coffey, before you proceed,
 2 if you don't mind, I'm going to interrupt again.
 3 COFFEY, Q.C.:
 4 Q. Sure.
 5 THE COMMISSIONER:
 6 Q. Dr. O'Malley, at the end of your presentation, you
 7 did speak a little about those occasions when you
 8 might meet with oncologists and other professionals
 9 regarding the patient. Can you just give me a
 10 little more detail about under what circumstances
 11 the pathologist and oncologist might meet?
 12 DR. O'MALLEY:
 13 A. Certainly. These are regular meetings. They occur
 14 once a week in our breast centre, and the patients
 15 that we discuss are all of those patients that have
 16 come to Mount Sinai and have had a diagnosis of
 17 invasive breast cancer that week. So all of the
 18 patients have already had a diagnosis, either a core
 19 biopsy diagnosis or they've already undergone a
 20 lumpectomy or a mastectomy. So the discussions with
 21 the radiologists, the medical oncologists, surgical
 22 oncologists, are really around what type of
 23 chemotherapy these patients are going to have, and
 24 that's where they want to know the ER and the PR and

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1 the HER2 status of the tumors of those patients.
 2 THE COMMISSIONER:
 3 Q. So it's at treatment stage, rather than diagnosis
 4 stage?
 5 DR. O'MALLEY:
 6 A. It's at treatment stage, yes.
 7 THE COMMISSIONER:
 8 Q. And in your world at Mount Sinai, is there a place
 9 for a joint effort by pathologists and oncologists
 10 at the diagnosis stage?
 11 DR. O'MALLEY:
 12 A. The communication would really more often happen
 13 between the pathologist and the radiologist when
 14 they're performing the core biopsy for diagnosis and
 15 we would often meet and discuss those patients.
 16 THE COMMISSIONER:
 17 Q. All right. But I take it that primarily, on the
 18 diagnosis end of things, your communication is the
 19 written report that you provide to people?
 20 DR. O'MALLEY:
 21 A. That's right.
 22 THE COMMISSIONER:
 23 Q. Okay. Thank you.
 24 DR. O'MALLEY:

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1 A. We're ultimately responsible for making that -
 2 THE COMMISSIONER:
 3 Q. Yes.
 4 DR. O'MALLEY:
 5 A. - the definitive call of cancer or not.
 6 THE COMMISSIONER:
 7 Q. Okay, thank you. Mr. Coffey.
 8 COFFEY, Q.C.:
 9 Q. Thank you, Commissioner. Now Doctor, if I could
 10 please, Registrar, Exhibit P-1698? Now, Doctor, I
 11 bring up this exhibit just simply because, although
 12 it's not--it didn't come from you, nor was it sent
 13 to you, you are referenced in it, okay, and it
 14 relates to another exhibit which is a letter which
 15 was sent to you on the same day, so I'm just going
 16 to take you to a little bit of this first. It's
 17 July 14th 2005. It's a letter to Dr. Donald Cook.
 18 It's from Dr. Beverley Carter. Do you know Dr.
 19 Carter?
 20 DR. O'MALLEY:
 21 A. I do.
 22 COFFEY, Q.C.:
 23 Q. How do you know Dr. Carter?
 24 DR. O'MALLEY:

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1 A. I know Dr. Carter for many years. We both trained
 2 with Dr. David Page and we went through residency
 3 programs in Ontario. So we met as residents, and so
 4 we've known each other since our residency days.
 5 COFFEY, Q.C.:
 6 Q. Which would be, I take it, now getting onto a couple
 7 of decades.
 8 DR. O'MALLEY:
 9 A. Many years.
 10 COFFEY, Q.C.:
 11 Q. And this is where Dr. Carter is writing to Dr. Cook
 12 and she is suggesting here that certain measures be
 13 undertaken, okay, to conduct an investigation and
 14 she'll be telling us about that in due course, but
 15 toward the--in the second paragraph, she says--she
 16 begins by saying "as quickly as possible, I would
 17 like to know the estrogen receptor status of every
 18 patient tested in our laboratory between 1997 and
 19 2004," and then she goes on from there, and toward
 20 the bottom of the paragraph says "all slides then
 21 have to be reviewed. They need to be reviewed by
 22 me, both estrogen receptor negative and estrogen
 23 receptor positive patients. Estrogen receptor
 24 negative patients should be given priority. Blocks

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1 will be pulled from those cases and estrogen
 2 receptor progesterone receptor status reordered.
 3 This test should be carried out as quickly as
 4 possible. Ten percent of cases should be randomly
 5 selected for outside quality assurance consultation.
 6 Dr. Frances O'Malley at Mount Sinai Hospital has
 7 agreed to act in this capacity. Problematic cases,
 8 as defined by a multiplicity of reasons, should also
 9 be sent for outside testing." And then she goes on
 10 to speak about a computerized database.
 11 So Doctor, if we could bring up then, please,
 12 Exhibit P-1697? And this is a letter dated July
 13 14th, 2005. It's addressed to yourself and the
 14 Department of Pathology, Mount Sinai Hospital, and
 15 if we look at the second page, it's from Dr. Carter,
 16 and she writes "Dear Dr. O'Malley, as per our
 17 telephone discussion on July 13th, 2005, could you
 18 please have ER/PR staining done on the following and
 19 also provide interpretation for same." And then
 20 there's a listing of a number of surgical block
 21 numbers, patient's name and date of birth, the MCP
 22 number and the specimen, what it's described as.
 23 Do you recall speaking with Dr. Carter in July?
 24 DR. O'MALLEY:

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1 A. I do recall.
 2 COFFEY, Q.C.:
 3 Q. Could you tell us then about what you recall about
 4 that?
 5 DR. O'MALLEY:
 6 A. Yes. I recall Dr. Carter calling me and telling me
 7 that she was concerned about the ER and PR testing
 8 in her lab and just wondered if we would be amenable
 9 to retesting a small number of cases, I think 10 or
 10 15 cases, and I said I didn't think that would be a
 11 problem. I would talk to our head of surgical
 12 pathology, but that I certainly didn't think that
 13 that would be a problem.
 14 COFFEY, Q.C.:
 15 Q. And who was the head of surgical pathology?
 16 DR. O'MALLEY:
 17 A. Back then, well, I guess it was Ken Pritzker.
 18 COFFEY, Q.C.:
 19 Q. Ken Pritzker. Then eventually it ended up with Ken
 20 Pritzker.
 21 DR. O'MALLEY:
 22 A. It eventually ended up very fast to Dr. Pritzker.
 23 COFFEY, Q.C.:
 24 Q. And what then happened, in terms of that particular

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1 aspect of the matter?
 2 DR. O'MALLEY:
 3 A. Well, what happened was I believe that Dr. Cook
 4 called Dr. Pritzker and I'm not privy to that
 5 conversation, but my understanding is that many more
 6 cases--Dr. Cook wanted to send many more cases to
 7 Mount Sinai for testing and really, I didn't have
 8 much involvement in the whole process after that.
 9 COFFEY, Q.C.:
 10 Q. Doctor, with respect to the initial phone call from
 11 Dr. Carter, did she initially want you to get
 12 involved in this?
 13 DR. O'MALLEY:
 14 A. Just insofar as retesting a small number of cases.
 15 COFFEY, Q.C.:
 16 Q. And we understand that Trish Wegrynowski -
 17 DR. O'MALLEY:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. - got involved, and she will be testifying in the
 21 coming days. Do you know anything about how she
 22 ended up getting involved?
 23 DR. O'MALLEY:
 24 A. Yes. Dr. Carter did talk about some of the issues

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1 surrounding the ER/PR testing and my understanding
 2 from what she relayed to me was that the problems
 3 were probably at the analytic stage, involving the
 4 technical procedure of the immunohistochemical test.
 5 So I suggested that it would be better to have a
 6 senior, very experienced technologist, such as Trish
 7 Wegrynowski, to review the process.
 8 COFFEY, Q.C.:
 9 Q. So Dr. Carter was in effect asking you if it is at
 10 the analytic stage, a problem that she, at the time,
 11 was conveying to you, she thought perhaps it was, it
 12 was your view expressed to her that "look, well if
 13 it involves that, talk to Trish," as it were?
 14 DR. O'MALLEY:
 15 A. Exactly.
 16 COFFEY, Q.C.:
 17 Q. And "I'll put you in touch with her or her in touch
 18 with you" and it went on from there?
 19 DR. O'MALLEY:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. And now who is Trish Wegrynowski, just so--you've
 23 referred to her a number of times this morning. Who
 24 is she?

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1 DR. O'MALLEY:
 2 A. She is one of our senior immunohistochemical
 3 technologists at Mount Sinai, very, very experienced
 4 technologist.
 5 COFFEY, Q.C.:
 6 Q. And was she there when you first arrived at Mount
 7 Sinai?
 8 DR. O'MALLEY:
 9 A. I believe she came in 1999, so a year after I
 10 arrived.
 11 COFFEY, Q.C.:
 12 Q. Now with respect to others who might or who ended up
 13 involved, Dr. Brendan Mullen, who is Dr. Brendan
 14 Mullen?
 15 DR. O'MALLEY:
 16 A. Dr. Mullen is a staff pathologist at Mount Sinai
 17 with a lot of experience in many areas of pathology
 18 and in breast pathology as well.
 19 COFFEY, Q.C.:
 20 Q. And in terms of the retesting process that the
 21 Commissioner is going to hear more about in the
 22 coming days, Dr. Mullen, as opposed to yourself, who
 23 ended up being most heavily involved in it?
 24 DR. O'MALLEY:

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1 A. Dr. Mullen.
 2 COFFEY, Q.C.:
 3 Q. Okay, and in terms of that, what level within the
 4 Mount Sinai's organization decided that? Who ended
 5 up making that decision?
 6 DR. O'MALLEY:
 7 A. My understanding is that it was made by Dr.
 8 Pritzker, in conjunction with Dr. Mullen, obviously.
 9 COFFEY, Q.C.:
 10 Q. If we could, please, Exhibit P-1703? Now Dr.
 11 O'Malley, this is a series of e-mails but the first
 12 of them, at the bottom of the first page of the
 13 exhibit, is from George Tilley, October 20th, 2005,
 14 at 2:38 p.m. to a Dr. Robert Bell. It's copied to
 15 Dr. Bob Williams, Robert Williams, and there's a
 16 reference at the bottom of that page by Mr. Tilley
 17 saying "our laboratory clinical chief will be
 18 contacting the two individuals you referenced to
 19 also see what insight they can offer in terms of
 20 national follow," and he says "it appears that there
 21 is a gap in terms of a national entity who can take
 22 the lead with this issue, so we will likely have to
 23 take a shotgun approach to the follow up and hope
 24 that there is someone who can keep it moving. In

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1 the meantime, we will write the Canadian Association
 2 of Pathologists and others that we may subsequently
 3 identify. I will also seek Phil's help at the
 4 CPSI." Signed George.
 5 Then above, there's an e-mail following that
 6 from Dr. Robert Bell, October 23rd, 2005, 8:13 p.m.
 7 to George Tilley. He's copied it though to Bruce
 8 Youngson and yourself, Dr. Frances O'Malley, and he
 9 says "thanks, George. The two individuals with the
 10 most expertise around ER testing in Toronto are Drs.
 11 Frances O'Malley and Dr. Bruce Youngson," and then
 12 Dr. Bell writes "Bruce and Frances, you have
 13 probably heard about the issue of retesting breast
 14 cancer specimens in Newfoundland. Some ER negative
 15 specimens have been reinterpreted as positive. The
 16 chief of pathology from Newfoundland may contact you
 17 as to any advice regarding reliability of ER
 18 testing," and then you, the next day, October 24th
 19 forwarded that to Dr. Pritzker for his information.
 20 So in October, late October 2005, from your
 21 perspective, Doctor, who at Mount Sinai was
 22 addressing the matter with Newfoundland?
 23 DR. O'MALLEY:
 24 A. Dr. Pritzker.

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1 COFFEY, Q.C.:
 2 Q. Pritzker. And I take it on a day-to-day level, Dr.
 3 Mullen, in the sense of actually getting the
 4 retesting done?
 5 DR. O'MALLEY:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And the technologist arranging to have the tissues,
 9 the slides processed?
 10 DR. O'MALLEY:
 11 A. Um-hm.
 12 COFFEY, Q.C.:
 13 Q. Okay. So, Doctor, other than being interviewed by
 14 Sandra Chaytor and myself, okay, which happened
 15 sometime late last year, actually, late 2007, and
 16 coming here to testify, have you had any other
 17 involvement in this matter?
 18 DR. O'MALLEY:
 19 A. I've had minimal involvement, which really the only
 20 involvement that I can remember is sometimes when
 21 Dr. Mullen had a difficult case from a diagnostic
 22 point of view or a case that he find difficult to
 23 interpret, he would ask for my opinion. And there
 24 were a few occasions, very few occasions when he was

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1 on vacation when he would ask me to sign out some of
 2 the prospective ongoing cases that came from
 3 Newfoundland.
 4 COFFEY, Q.C.:
 5 Q. They would be the current cases?
 6 DR. O'MALLEY:
 7 A. The current cases, but I -
 8 COFFEY, Q.C.:
 9 Q. Current, ongoing?
 10 DR. O'MALLEY:
 11 A. Yeah.
 12 COFFEY, Q.C.:
 13 Q. Okay. Commissioner, they're the questions I have.
 14 Doctor, there may be other lawyers who have some
 15 questions.
 16 COMMISSIONER:
 17 Q. Mr. Pritchard, do you have any questions?
 18 COFFEY, Q.C.:
 19 Q. I'm going to move aside.
 20 MR. PRITCHARD:
 21 Q. Thank you, Commissioner, I don't have any questions
 22 of this witness. Thank you -
 23 COMMISSIONER:
 24 Q. Mr. Simmons?

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1 DR. FRANCES O'MALLEY, EXAMINATION BY MR. DANIEL SIMMONS
 2 MR. SIMMONS:
 3 Q. Thank you, Commissioner. Good morning, Dr.
 4 O'Malley, my name is Dan Simmons and I'm here
 5 representing Eastern Health. Just some background
 6 questions first for you on, about Mount Sinai and
 7 its lab. The Mount Sinai as an institution, does it
 8 operate from a single location in Toronto?
 9 DR. O'MALLEY:
 10 A. Yes, it does.
 11 MR. SIMMONS:
 12 Q. It is. Is it affiliated in any formal way with any
 13 other hospitals operating from any other locations
 14 from which it provides services to those?
 15 DR. O'MALLEY:
 16 A. It's affiliated with the university health network
 17 in terms of many of our clinicians work at both
 18 sites.
 19 MR. SIMMONS:
 20 Q. Right, okay. And we've heard some mention along the
 21 way in this Inquiry of the concept of a reference
 22 laboratory. Does Mount Sinai operate what would be
 23 referred to as a reference laboratory?
 24 DR. O'MALLEY:

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1 A. Yes, it does. It operates a reference, it functions
 2 as a reference laboratory for Her2 testing
 3 specifically.
 4 MR. SIMMONS:
 5 Q. Okay. And what does it mean then to be a reference
 6 laboratory?
 7 DR. O'MALLEY:
 8 A. We receive so we're part of a quality assurance
 9 program within the province, and we receive cases
 10 from other labs that are performing Her2 testing for
 11 retesting in our lab to ensure that there is good
 12 interlab concordance.
 13 MR. SIMMONS:
 14 Q. Okay. And in--with this particular matter we know
 15 that many ER/PR cases were retested at Mount Sinai
 16 from Newfoundland and that there were also current
 17 cases from Newfoundland that went there for
 18 retesting, and you referred to those, some of those
 19 a moment ago. Does Mount Sinai lab provide that
 20 sort of service to any other hospitals as well, to
 21 do testing for other people?
 22 DR. O'MALLEY:
 23 A. Yes, we do. Yes, we provide that service for many
 24 other hospitals.

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1 MR. SIMMONS:
 2 Q. Right, okay. And do I understand that within Mount
 3 Sinai there's actual two separate laboratories where
 4 IHC or immunohistochemical testing can be performed,
 5 there's a research laboratory and then there's the
 6 clinical laboratory?
 7 DR. O'MALLEY:
 8 A. Yes, yes, but they work very, very closely together.
 9 The same procedures, the same SOPs are in effect in
 10 both parts of the lab.
 11 MR. SIMMONS:
 12 Q. Okay. Why the division, what's done differently in
 13 the research laboratory versus the clinical
 14 laboratory?
 15 DR. O'MALLEY:
 16 A. It's just a streamlining of work, so research
 17 studies are just funnelled through the research
 18 laboratory and all of the service cases are dealt
 19 with in the clinical lab.
 20 MR. SIMMONS:
 21 Q. Okay. In the research laboratory is there a service
 22 there provided to industry to carry out contract
 23 testing for drug companies and things such as that?
 24 DR. O'MALLEY:

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1 A. Yes.
 2 MR. SIMMONS:
 3 Q. Yes.
 4 DR. O'MALLEY:
 5 A. Dr. Pritzker will be able to elaborate on that.
 6 MR. SIMMONS:
 7 Q. Yes, okay. You told us about the method that was
 8 used prior to immunohistochemical testing for
 9 assessing the presence of estrogen receptors and
 10 progesterone receptors and I think you called that
 11 the Ligand Binding Assay?
 12 DR. O'MALLEY:
 13 A. Yes.
 14 MR. SIMMONS:
 15 Q. LBA?
 16 DR. O'MALLEY:
 17 A. Um-hm.
 18 MR. SIMMONS:
 19 Q. And that it was a method that had been in use, I
 20 gather, for some time before the
 21 immunohistochemistry methods were developed?
 22 DR. O'MALLEY:
 23 A. That's true.
 24 MR. SIMMONS:

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1 Q. Okay. You mentioned that when you--when the Ligand
 2 Binding Assay was in use in Ontario, I believe you
 3 said there were five laboratories that were somehow
 4 sponsored or approved -
 5 DR. O'MALLEY:
 6 A. Licensed, approved, yes.
 7 MR. SIMMONS:
 8 Q. - or licensed by the government for carrying out
 9 that testing?
 10 DR. O'MALLEY:
 11 A. Um-hm.
 12 MR. SIMMONS:
 13 Q. So within Ontario at that time were those the only
 14 five institutions that were -
 15 DR. O'MALLEY:
 16 A. Performing those tests, yes. That, to my
 17 understanding, yes, that was the case.
 18 MR. SIMMONS:
 19 Q. Do you know anything about how much government
 20 supervision there was or regulation there was over
 21 the activities of those laboratories in performing
 22 those tests?
 23 DR. O'MALLEY:
 24 A. I don't know a lot because I wasn't directly

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1 involved in any of those laboratories, but my
 2 understanding is that direct funding came from the
 3 provincial government to support the activities in
 4 those laboratories and there was strict quality
 5 assurance and quality control procedures between all
 6 labs.
 7 MR. SIMMONS:
 8 Q. That were mandated, I guess, in that case, were
 9 they?
 10 DR. O'MALLEY:
 11 A. That were mandated as part of the funding, yes.
 12 MR. SIMMONS:
 13 Q. Okay. Now, when the move came to switch from the
 14 Ligand Binding Assay to the IHC method, if I
 15 understand correctly, there were advantages to
 16 moving to the IHC, naturally, or it wouldn't have
 17 been done, and one of the significant advantages was
 18 that the Ligand Binding Assay required a relatively
 19 large volume of tissue in order to carry out the
 20 test?
 21 DR. O'MALLEY:
 22 A. That's right.
 23 MR. SIMMONS:
 24 Q. And that as detection of breast cancer became

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1 possible in earlier and earlier stages, in many
 2 cases there would not be a tissue sample large
 3 enough to provide that?
 4 DR. O'MALLEY:
 5 A. Exactly.
 6 MR. SIMMONS:
 7 Q. Sample size?
 8 DR. O'MALLEY:
 9 A. Um-hm.
 10 MR. SIMMONS:
 11 Q. And that that was one of the reasons for moving
 12 towards the IHC test. When that happened in
 13 Ontario, was there the same approach taken to
 14 confine the IHC testing to certain approved
 15 laboratories the way it had been for the Ligand
 16 Binding Assay?
 17 DR. O'MALLEY:
 18 A. No, no, that did not happen, that did not happen.
 19 Each laboratory--because most of these laboratories
 20 were already performing immunohistochemical tests.
 21 MR. SIMMONS:
 22 Q. I see, yes.
 23 DR. O'MALLEY:
 24 A. So it just became incorporated into that process.

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1 But unfortunately, there wasn't, standardization was
 2 not introduced at that time.
 3 MR. SIMMONS:
 4 Q. Right.
 5 DR. O'MALLEY:
 6 A. So each laboratory was responsible for their own
 7 validation and standardization of the ER and PR
 8 tests.
 9 MR. SIMMONS:
 10 Q. Okay. And so different laboratories, any
 11 laboratory, I guess, that wanted to add the ER and
 12 the PR antibodies to their arsenal of
 13 immunohistochemistry tests could choose to do so and
 14 it was up to them to determine exactly how they
 15 implemented it?
 16 DR. O'MALLEY:
 17 A. That is my understanding.
 18 MR. SIMMONS:
 19 Q. Right, okay. Now, has that changed in Ontario now,
 20 has there been anything happen in Ontario to bring
 21 back any kind of mandated QA or QC for this type of
 22 testing?
 23 DR. O'MALLEY:
 24 A. Not in Ontario, but there is now this national

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1 initiative. And I showed some of the early data
 2 from that.
 3 MR. SIMMONS:
 4 Q. Yes.
 5 DR. O'MALLEY:
 6 A. Which will hopefully bring in national standards.
 7 But all laboratories who--all laboratories that are
 8 performing these tests are really are recommended to
 9 take part in a quality assurance program such as the
 10 UK program that I discussed, and the US or College
 11 of American Pathologists program. We at Mount Sinai
 12 participate in both of those quality assurance
 13 programs.
 14 MR. SIMMONS:
 15 Q. Right, okay. Now, there are, I understand,
 16 different antibodies available that can be used in
 17 the technical performance of the ER and the PR
 18 testing?
 19 DR. O'MALLEY:
 20 A. That's correct.
 21 MR. SIMMONS:
 22 Q. And they come from different manufacturers?
 23 DR. O'MALLEY:
 24 A. Um-hm.

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1 MR. SIMMONS:
 2 Q. And are there known to be different sensitivities
 3 and specificities from those different antibodies?
 4 DR. O'MALLEY:
 5 A. Absolutely.
 6 MR. SIMMONS:
 7 Q. Okay. And in addition to the antibodies, and we'll
 8 hear more, I know, from Ms. Wegrynowski about the
 9 technical side of the testing, but are there also
 10 differences in the types of materials, things like
 11 what we may hear of as detection systems and so on
 12 that can be used in performing the ER and the PR
 13 tests?
 14 DR. O'MALLEY:
 15 A. There are, yes.
 16 MR. SIMMONS:
 17 Q. And do you know from, I guess, from your
 18 interactions with other counterparts of yours in
 19 Ontario, in the Toronto area, are there differences
 20 among the different labs even now in the Toronto
 21 area of which antibodies they choose to use and
 22 which other procedural components they choose to use
 23 in performing these tests?
 24 DR. O'MALLEY:

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1 A. There are.
 2 MR. SIMMONS:
 3 Q. Okay. Is there any, has there been since this
 4 testing was transferred over from Ligand Binding
 5 Assay to IHC, has there been any source that labs
 6 can go to in Ontario or in Canada to give them a set
 7 of approved recommendations for choice of antibody,
 8 chose of detection system, method of performing the
 9 test, method of interpreting the test and all those
 10 different elements?
 11 DR. O'MALLEY:
 12 A. Well, there are many publications reporting results
 13 for different antibodies in different detection
 14 system, etcetera, but it's really up to the
 15 individual lab to, you know, the pathologists and
 16 technologists working together to make the final
 17 decision regarding the specific antibodies that are
 18 used in the specific detection systems that are
 19 used. But when that decision is made then, there is
 20 a rigorous validation process that must be put in
 21 place to make sure that those results are giving an
 22 accurate -
 23 MR. SIMMONS:
 24 Q. Right, okay.

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1 DR. O'MALLEY:
 2 A. - those tests are giving an accurate result.
 3 MR. SIMMONS:
 4 Q. And is that validation process something that is an
 5 external requirement imposed upon laboratories and
 6 health care institutions or is it just part of good
 7 practice to do that?
 8 DR. O'MALLEY:
 9 A. Well, in the setting Her2 it is mandated and for ER.
 10 MR. SIMMONS:
 11 Q. Okay.
 12 DR. O'MALLEY:
 13 A. And PR too.
 14 MR. SIMMONS:
 15 Q. How is it mandated for ER and PR now, who mandates
 16 it?
 17 DR. O'MALLEY:
 18 A. Well, it's not currently mandated, but through--I
 19 mean, it's highly, highly recommended, but through
 20 the national standards committee that has just been
 21 struck, my understanding is that it will be
 22 mandated.
 23 MR. SIMMONS:
 24 Q. Okay. Can you tell me a little more about that

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1 national standards committee, who makes it up and
 2 what its task is to be or do you know?
 3 DR. O'MALLEY:
 4 A. I don't know a lot about it, but I do know that it
 5 is based in Saskatchewan.
 6 MR. SIMMONS:
 7 Q. Yes.
 8 DR. O'MALLEY:
 9 A. And Nina Toilacovik (phonetic) is heading up this
 10 initiative.
 11 MR. SIMMONS:
 12 Q. Are there any organizations or groups that are
 13 sponsoring that effort or standing behind it?
 14 DR. O'MALLEY:
 15 A. Yes. The Canadian Association of Pathologists.
 16 MR. SIMMONS:
 17 Q. Okay. Are there any governmental agencies or
 18 regulators that you are aware of that have set any
 19 kind of standards in Canada for the performance of
 20 this type of testing and the interpretation of it?
 21 DR. O'MALLEY:
 22 A. I'm not aware of any governmental agency.
 23 MR. SIMMONS:
 24 Q. And aside from the work currently under way

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1 sponsored by Canadian Association of Pathologists,
 2 are you aware as to whether there's been any other
 3 kind of national standard available to turn to in
 4 Canada for this type of testing?
 5 DR. O'MALLEY:
 6 A. No.
 7 MR. SIMMONS:
 8 Q. So from the point of view of individual laboratories
 9 then, is it fair to say that there has been and
 10 continues to be a choice of different antibodies,
 11 materials and procedures that can used for ER and PR
 12 testing?
 13 DR. O'MALLEY:
 14 A. Yes.
 15 MR. SIMMONS:
 16 Q. And that there's no mandated choices to be made,
 17 each lab has to use its best processes to determine
 18 what to do?
 19 DR. O'MALLEY:
 20 A. That's correct.
 21 MR. SIMMONS:
 22 Q. And is there an understanding that sometimes what
 23 works in one lab may not be the best for another
 24 lab?

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1 DR. O'MALLEY:
 2 A. That is absolutely correct.
 3 MR. SIMMONS:
 4 Q. Can you tell me something more about that, about why
 5 that would be the case?
 6 DR. O'MALLEY:
 7 A. Well, again, Trish can elaborate on that. But it
 8 definitely is the case that one antibody in a
 9 particular lab with a different detection system
 10 will be more sensitive than the same antibody in
 11 another lab with a different detection system, for
 12 example.
 13 MR. SIMMONS:
 14 Q. Okay. Now, you've given us some very helpful
 15 evidence about the cutoffs and determining the
 16 cutoff points for designating a test result as
 17 either positive or negative. And the first question
 18 I wanted to ask you is kind of a follow up on one
 19 that the Commissioner asked you. Because if I
 20 understand correctly, it is the oncologists who
 21 ultimately determine the treatment for the patient
 22 and whether or not an adjuvant therapy such as
 23 Tamoxifen will be recommended for that patient or
 24 not?

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1 DR. O'MALLEY:
 2 A. Yes.
 3 MR. SIMMONS:
 4 Q. That's right? And but you as a pathologist would be
 5 aware that there are pros and cons to do those
 6 decisions because there are adverse effects that can
 7 result from Tamoxifen therapy as well as beneficial
 8 effects? You would be aware of that in a general
 9 sense?
 10 DR. O'MALLEY:
 11 A. Yes, yes.
 12 MR. SIMMONS:
 13 Q. Yeah, okay. And I'm just curious as to why it would
 14 be expected for a pathologist in the laboratory
 15 setting to have to designate a test as positive or
 16 negative at all rather than just give the percentage
 17 to the oncologist and leave it entirely to the
 18 oncologist to determine what course of treatment to
 19 take based on that percentage and the other factors
 20 that they have to take into account?
 21 DR. O'MALLEY:
 22 A. Well, no, it's not quite as simple as that.
 23 MR. SIMMONS:
 24 Q. Okay.

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<p>1 DR. O'MALLEY:</p> <p>2 A. Because the cutoff is really dependent on the</p> <p>3 antibody used and because of the issues of</p> <p>4 sensitivities and specificities, so you know, while</p> <p>5 we use a one percent cutoff because we have those</p> <p>6 very sensitive antibodies, another lab still may be</p> <p>7 using a ten percent cutoff, so it would not be the</p> <p>8 best practice for a clinician to be deciding what</p> <p>9 the cutoff is for a particular lab.</p> <p>10 MR. SIMMONS:</p> <p>11 Q. Um-hm.</p> <p>12 DR. O'MALLEY:</p> <p>13 A. Having said that, the NIH in the States has</p> <p>14 recommended, indeed, that any tumor positivity for</p> <p>15 both ER and PR should be considered positive.</p> <p>16 MR. SIMMONS:</p> <p>17 Q. Yes.</p> <p>18 DR. O'MALLEY:</p> <p>19 A. But again, that's consistent with, really, the</p> <p>20 Allred score.</p> <p>21 MR. SIMMONS:</p> <p>22 Q. Right. NIH, I think, is National Institutes of</p> <p>23 Health in the United States?</p> <p>24 DR. O'MALLEY:</p>	<p>1 adopted the one percent cutoff.</p> <p>2 MR. SIMMONS:</p> <p>3 Q. How recent is that?</p> <p>4 DR. O'MALLEY:</p> <p>5 A. In the last few years.</p> <p>6 MR. SIMMONS:</p> <p>7 Q. Okay. And are you aware of whether or not there</p> <p>8 have been other institutions in--that you would be</p> <p>9 familiar with in the Toronto area that haven't moved</p> <p>10 to the one percent and have stayed at the ten</p> <p>11 percent for their results?</p> <p>12 DR. O'MALLEY:</p> <p>13 A. I couldn't comment on every lab, but I would not be</p> <p>14 surprised if some of those labs are still at the ten</p> <p>15 percent. But remember, they may be using different</p> <p>16 antibodies and that's ten percent may be relevant</p> <p>17 for those particular antibodies.</p> <p>18 MR. SIMMONS:</p> <p>19 Q. Right. Are you familiar with an organization called</p> <p>20 ASCP?</p> <p>21 DR. O'MALLEY:</p> <p>22 A. Yes.</p> <p>23 MR. SIMMONS:</p> <p>24 Q. And that's the American Society of?</p>
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<p>1 A. Yes.</p> <p>2 MR. SIMMONS:</p> <p>3 Q. Is there any comparable recommendation from any</p> <p>4 comparable body in Canada that you're aware of?</p> <p>5 DR. O'MALLEY:</p> <p>6 A. Not that I'm aware of.</p> <p>7 MR. SIMMONS:</p> <p>8 Q. Okay. So from what you've said then, because at</p> <p>9 Mount Sinai you're using a particular antibody,</p> <p>10 you're satisfied that you know what the sensitivity</p> <p>11 and specificity of it is in your lab's hands, you've</p> <p>12 adopted the one to ten percent as being something</p> <p>13 that would be positive enough to merit a</p> <p>14 recommendation for treatment?</p> <p>15 DR. O'MALLEY:</p> <p>16 A. That is correct, yes.</p> <p>17 MR. SIMMONS:</p> <p>18 Q. Are you aware if that is the case in other</p> <p>19 comparable institutions in the area where you are in</p> <p>20 Toronto, if they've adopted that or if there's</p> <p>21 variation in the cutoffs?</p> <p>22 DR. O'MALLEY:</p> <p>23 A. There certainly has been variation, but my</p> <p>24 understanding is that certainly Sunnybrook has</p>	<p>1 DR. O'MALLEY:</p> <p>2 A. Clinical Pathology.</p> <p>3 MR. SIMMONS:</p> <p>4 Q. Clinical Pathologists. And ASO I think is the</p> <p>5 American Society of Oncologists?</p> <p>6 DR. O'MALLEY:</p> <p>7 A. ASCO, yeah.</p> <p>8 MR. SIMMONS:</p> <p>9 Q. Okay. Do you know whether--and they are</p> <p>10 organizations in the United States, I guess, one of</p> <p>11 them might be the comparative group to the Canadian</p> <p>12 Association of Pathologists, would it?</p> <p>13 DR. O'MALLEY:</p> <p>14 A. College of American Pathologists would be equivalent</p> <p>15 to the Canadian Association of Pathologists.</p> <p>16 MR. SIMMONS:</p> <p>17 Q. Okay. Are you aware of whether ACSP and ASO have</p> <p>18 done or been doing any work to develop any</p> <p>19 guidelines for ER and PR testing?</p> <p>20 DR. O'MALLEY:</p> <p>21 A. Actually, ASCO and CAP, so the oncology group and</p> <p>22 the pathology group in the States recently published</p> <p>23 guidelines on Her2 testing. I do know that while</p> <p>24 there are no published recommendations on ER and PR,</p>

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1 they are in the works, that is my understanding.
 2 MR. SIMMONS:
 3 Q. Okay. So in the United States, then, the
 4 organizations that would typically be taking the
 5 responsibility for publishing these sorts of
 6 guidelines have done so for the Her2 testing but
 7 note yet for ER and PR?
 8 DR. O'MALLEY:
 9 A. That's correct.
 10 MR. SIMMONS:
 11 Q. You mentioned some of the work that had been done in
 12 Europe and you mentioned the NEQAS program, which I
 13 understand is something that was developed in the UK
 14 in response to the interlaboratory variability
 15 studies that had been done in Europe.
 16 DR. O'MALLEY:
 17 A. That is my understanding too.
 18 MR. SIMMONS:
 19 Q. Do you know whether in UK and Europe there is
 20 anything equivalent to a set standard for the
 21 performance of ER and PR testing, something which we
 22 don't have yet in Canada and the United States?
 23 DR. O'MALLEY:
 24 A. Well through that program, a certain competency has

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1 to be reached in terms of concordance with the
 2 reference lab.
 3 MR. SIMMONS:
 4 Q. Okay, and the program you refer to is the quality
 5 assurance program sponsored by the NEQAS
 6 organization, is it?
 7 DR. O'MALLEY:
 8 A. Yes.
 9 MR. SIMMONS:
 10 Q. Now we've heard mention along the way a proficiency
 11 testing, is that you're referring to there something
 12 similar to that?
 13 DR. O'MALLEY:
 14 A. That's exactly--it's just another term for what
 15 we're talking about.
 16 MR. SIMMONS:
 17 Q. And as I understand it, the NEQAS organization, if
 18 you enrol with that, it will send a sample to your
 19 laboratory for you to process onto a slide and stain
 20 and then have your pathologist interpret it. The
 21 results in the slide are sent back to the NEQAS
 22 organization in the UK and they grade you on how
 23 well you've done with it.
 24 DR. O'MALLEY:

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1 A. That's correct.
 2 MR. SIMMONS:
 3 Q. And how long has that been available, that service,
 4 would you know?
 5 DR. O'MALLEY:
 6 A. I don't actually know offhand, many years, I
 7 believe, but I can't give a specific date.
 8 MR. SIMMONS:
 9 Q. In one of your slides where you mentioned that, you
 10 had footnoted, I think, a study from Rhodes there
 11 from 2000? Does that sound familiar?
 12 DR. O'MALLEY:
 13 A. Uh-hm. Yes.
 14 MR. SIMMONS:
 15 Q. Would that be around the time of the study, one of
 16 these studies of the interlaboratory variability?
 17 DR. O'MALLEY:
 18 A. Yes, it was, but NEQAS has been in existence, you
 19 know, before that.
 20 MR. SIMMONS:
 21 Q. Okay, all right. And do you know how long Mount
 22 Sinai has been enrolled in the NEQAS program?
 23 DR. O'MALLEY:
 24 A. Just in the last few years, we've been enrolled in

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1 the CAP program, the College of American
 2 Pathologist's program for many years, but we just
 3 joined NEQAS in the last few years.
 4 MR. SIMMONS:
 5 Q. So aside from the College of American Pathologist's
 6 program available from the United States and--oh, by
 7 the way, that -
 8 DR. O'MALLEY:
 9 A. Oh there's also a provincial QMPLS -
 10 MR. SIMMONS:
 11 Q. In Ontario.
 12 DR. O'MALLEY:
 13 A. Yes, yes.
 14 MR. SIMMONS:
 15 Q. Do they do proficiency testing or do they--are they
 16 the equivalent of an accreditation body for
 17 provincial laboratories in Ontario?
 18 DR. O'MALLEY:
 19 A. No, not--to my understanding the equivalent of an
 20 accreditation program, but again, Dr. Pritzker
 21 should be able to address that more fully.
 22 MR. SIMMONS:
 23 Q. Good, thank you. Now immunohistochemistry in
 24 general and the ER/PR testing here in particular,

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1 which is what we're concerned with, can you tell me
 2 if there's been any process of evolution in
 3 understanding of how this test works and on
 4 understanding the most effective ways to do it and
 5 interpret it over time, since you first became
 6 familiar with it?
 7 DR. O'MALLEY:
 8 A. I would--yes, there definitely has been an
 9 evolution.
 10 MR. SIMMONS:
 11 Q. Uh-hm. I'm putting you on the spot now I know, but
 12 can you give me some sort of overview of what sorts
 13 of things might have changed over time regarding the
 14 usefulness of it and how reliable it is?
 15 DR. O'MALLEY:
 16 A. Well the usefulness has been known for many, many
 17 years as I allude to that it has been a clinically
 18 validated test for a long time. I guess what we
 19 have learned over the years is that, you know, we've
 20 learned that the different antibodies have very,
 21 very different sensitivities and specificities and
 22 we have to pay very particular attention to that, as
 23 well as the different detection systems giving,
 24 affecting the sensitivity and specificity of the

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1 test as well.
 2 MR. SIMMONS:
 3 Q. Have some of the potential problems with the test
 4 become better known and more clearly understood over
 5 time?
 6 DR. O'MALLEY:
 7 A. I would think so, but Trish will be able to
 8 elaborate on that.
 9 MR. SIMMONS:
 10 Q. Right, okay. You were asked some questions
 11 concerning external controls and just to make sure I
 12 understand what you're referring to there, if I
 13 understand it correctly, when a batch, a group of ER
 14 or PR tests are performed, a series of twenty or
 15 forty of fifty slides will be processed together at
 16 the same time, they'll go through the process with
 17 the antibodies and the different chemical reagents
 18 being applied and the different steps being done.
 19 That's generally the way they are processed in the
 20 laboratories, right?
 21 DR. O'MALLEY:
 22 A. Yes.
 23 MR. SIMMONS:
 24 Q. And that typically one of the slides will have a

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1 piece of tissue with a known outcome and in your
 2 case, you described there being a strong positive, a
 3 weak positive and a negative.
 4 DR. O'MALLEY:
 5 A. Uh-hm.
 6 MR. SIMMONS:
 7 Q. And that that slide would be processed as part of
 8 the same batch?
 9 DR. O'MALLEY:
 10 A. Yes.
 11 MR. SIMMONS:
 12 Q. And that slide is what's being referred to as the
 13 external control, I believe?
 14 DR. O'MALLEY:
 15 A. That's right.
 16 MR. SIMMONS:
 17 Q. So the purpose of that then is to ensure that the
 18 external control slides stains the way it's supposed
 19 to, because if it doesn't, it's an indicator that
 20 maybe the process didn't work.
 21 DR. O'MALLEY:
 22 A. That's absolutely correct.
 23 MR. SIMMONS:
 24 Q. Okay, now in Mount Sinai it's the technologists who

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1 assess the external control slide to see if the test
 2 worked before released the patient slides to the
 3 pathologists for them to look at?
 4 DR. O'MALLEY:
 5 A. Yes.
 6 MR. SIMMONS:
 7 Q. Is there any particular advantage to having a
 8 technologist review the external control slide
 9 instead of having a designated pathologist review
 10 the external control slide?
 11 DR. O'MALLEY:
 12 A. Well, I mean, as long as the technologist is highly
 13 trained then, you know, it can be completely
 14 adequately performed by the technologist. If
 15 there's any concern, then the pathologist will
 16 review those external controls as well.
 17 MR. SIMMONS:
 18 Q. I understand that for the technologist to be the one
 19 to review the external control, they require the
 20 degree of training, understanding and proficiency to
 21 be able to do it reliably, but on the other hand, is
 22 there any--would there be anything that would be
 23 problematic about having a pathologist perform that
 24 part of the process, instead of a technologist?

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1 DR. O'MALLEY:
 2 A. No, no, just as a time issue.
 3 MR. SIMMONS:
 4 Q. Okay. The fact that I have to take time to review
 5 my notes is a good sign, it means I don't have much
 6 more to ask you. You've referred a number of times
 7 to a particular antibody that Mount Sinai uses which
 8 is the 6F11 antibody.
 9 DR. O'MALLEY:
 10 A. Yes.
 11 MR. SIMMONS:
 12 Q. And I've seen reference to that as a mouse
 13 monoclonal antibody, I think.
 14 DR. O'MALLEY:
 15 A. Uh-hm.
 16 MR. SIMMONS:
 17 Q. We've also heard this inquiry of another antibody
 18 that's available for ER testing designated, I think,
 19 SP1.
 20 DR. O'MALLEY:
 21 A. Rabbit.
 22 MR. SIMMONS:
 23 Q. Yeah, rabbit something or another.
 24 DR. O'MALLEY:

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1 A. Yes.
 2 MR. SIMMONS:
 3 Q. Has Mount Sinai moved to the SP1 antibody?
 4 DR. O'MALLEY:
 5 A. No, we haven't because we're very confident and
 6 comfortable with the performance of the 6F11.
 7 MR. SIMMONS:
 8 Q. When the pathologist gets the final slide and is
 9 satisfied that it's interpretable and does the
 10 interpretation, scores it, uses whichever method is
 11 going to be used, the pathologist, of course, has to
 12 prepare a report in some written form, to pass that
 13 information on to the oncologist and so it forms
 14 part of the permanent patient record.
 15 DR. O'MALLEY:
 16 A. Uh-hm.
 17 MR. SIMMONS:
 18 Q. And you've referred to synoptic reporting, which I
 19 take it to mean for at least some parts of this
 20 process, using standardized language -
 21 DR. O'MALLEY:
 22 A. That's correct.
 23 MR. SIMMONS:
 24 Q. - for reporting it. Can you give me some idea of

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1 what sort of process is available at your
 2 institution for automating or this process of
 3 preparing pathology reports, are they just dictated
 4 and someone types them up? Are they entered
 5 directly into a computer system? How do you--what
 6 do you do in a hands-on way when you have to do one
 7 of those reports?
 8 DR. O'MALLEY:
 9 A. Well through our lab information system both can be
 10 done, but many times we enter the data right on the
 11 screen.
 12 MR. SIMMONS:
 13 Q. Uh-hm, okay, is there any narrative portion in those
 14 reports or is it all filling in fields where there
 15 are set terminology to be used for every field?
 16 DR. O'MALLEY:
 17 A. The gross description of the specimen is still in a
 18 narrative form, but the actual microscopic portion
 19 of the report, which includes the ER and PR and
 20 HER/2neu results is all now in synoptic format.
 21 MR. SIMMONS:
 22 Q. And has that process been in use at your institution
 23 since you've been there or introduced along the way
 24 somewhere?

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1 DR. O'MALLEY:
 2 A. No, it was introduced along the way. I believe we
 3 moved to synoptic reports in 2005.
 4 MR. SIMMONS:
 5 Q. In 2005.
 6 DR. O'MALLEY:
 7 A. Yeah, I believe that is correct.
 8 MR. SIMMONS:
 9 Q. So prior to 2005 then, was there any fixed
 10 standardization in the pathology reports about how
 11 the results of the ER and PR tests were recorded?
 12 DR. O'MALLEY:
 13 A. Generally they were reported in very similar manner
 14 from one pathologist to the next -
 15 MR. SIMMONS:
 16 Q. Yes.
 17 DR. O'MALLEY:
 18 A. There might have been a slight variation, but it was
 19 pretty standard, even before that time.
 20 MR. SIMMONS:
 21 Q. And was that reporting done in the narrative portion
 22 of the report or in particular fields of the report?
 23 DR. O'MALLEY:
 24 A. It was in the microscopic portion of the report.

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1 MR. SIMMONS:
 2 Q. In the microscopic, so the pathologists would have
 3 to dictate the ER--or type, the ER/PR results as
 4 part of the narrative portion and there was some
 5 potential then for different pathologists to use
 6 some variation in the way, the language they used to
 7 report that, was there?
 8 DR. O'MALLEY:
 9 A. That's correct, yes.
 10 MR. SIMMONS:
 11 Q. Positivity rates on an annual basis, how does your
 12 lab handle designating someone to monitor and
 13 collect that data for what portion of ER and PR
 14 tests are positive on an annual basis?
 15 DR. O'MALLEY:
 16 A. Well that is generated through the
 17 immunohistochemistry lab.
 18 MR. SIMMONS:
 19 Q. Uh-hm, okay, so that's done within the lab itself,
 20 is it?
 21 DR. O'MALLEY:
 22 A. Yes.
 23 MR. SIMMONS:
 24 Q. And is there anyone designed on the, any physician

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1 designed to take responsibility for assessing those
 2 results, those positivity rates looking for trends,
 3 those sorts of things from a management perspective?
 4 DR. O'MALLEY:
 5 A. Well the head of the immunolab would look at those
 6 rates.
 7 MR. SIMMONS:
 8 Q. Okay. So you wouldn't have been involved, I guess,
 9 over the years in monitoring those rates yourself?
 10 DR. O'MALLEY:
 11 A. Well actually, yes, I'm involved as well.
 12 MR. SIMMONS:
 13 Q. Okay, and what's your involvement in it, how does
 14 that work?
 15 DR. O'MALLEY:
 16 A. Well I'm just, you know, very interested in what
 17 goes on, so yeah, I would make it my business to
 18 know what those rates are.
 19 MR. SIMMONS:
 20 Q. Okay. We've heard some mention here of type of
 21 diagnosis that has been abbreviated DCIS, which I
 22 think is ductal carcinoma in situ?
 23 DR. O'MALLEY:
 24 A. That's correct.

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1 MR. SIMMONS:
 2 Q. Are ER and PR tests normally done for those cases?
 3 DR. O'MALLEY:
 4 A. At Mount Sinai we do not routinely perform ER and PR
 5 on DCIS.
 6 MR. SIMMONS:
 7 Q. Any particular reason why that would be the case?
 8 DR. O'MALLEY:
 9 A. We don't feel that the data is strong enough to
 10 support that. The data actually that has really
 11 driven the performance of ER and PR is the setting
 12 of ductal carcinoma in situ is one study that's been
 13 only published in abstract form, so we certainly
 14 wouldn't change procedure based on that limited
 15 data.
 16 MR. SIMMONS:
 17 Q. Okay.
 18 DR. O'MALLEY:
 19 A. On the other hand, if a medical oncologist asks us
 20 specifically to perform ER and PR on a case of DCIS,
 21 we obviously will do that.
 22 MR. SIMMONS:
 23 Q. Right, so from the pathologist's point of view then
 24 in getting a new case into the lab for assessment,

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1 while it would be standard and routine in a breast
 2 cancer case to order an ER and PR on any type of an
 3 invasive cancer, it would not be the pathologist's
 4 routine to order the test if it's a ductal carcinoma
 5 in situ?
 6 DR. O'MALLEY:
 7 A. At Mount Sinai that's the practice, yes.
 8 MR. SIMMONS:
 9 Q. Right, which is, I guess, a type of non evasive
 10 cancer?
 11 DR. O'MALLEY:
 12 A. It's a non-evasive breast cancer and Tamoxifen is
 13 really used in that case as a chemo-preventative
 14 agent because the therapy for DCIS is excision and
 15 radiation.
 16 MR. SIMMONS:
 17 Q. Okay. We've--I understand that there is some new
 18 technology on the horizon or may be available now to
 19 assist pathologists with the assessment of the
 20 percentage of positivity?
 21 DR. O'MALLEY:
 22 A. Image analysis.
 23 MR. SIMMONS:
 24 Q. Image analysis, yes. Have you had any experience

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1 with that at Mount Sinai?

2 DR. O'MALLEY:

3 A. Yes, we do have an image analysis system, but we use

4 it in the research setting. We have not moved it

5 into the clinical setting.

6 MR. SIMMONS:

7 Q. Okay, is there any particular reason why you haven't

8 moved it into the clinical setting?

9 DR. O'MALLEY:

10 A. Cost, expertise needed.

11 MR. SIMMONS:

12 Q. Uh-hm.

13 DR. O'MALLEY:

14 A. And also the vast majority of ER and PR are really

15 quite easy to read manually. So it wouldn't save us

16 time reading the vast majority. I see its role is

17 really assessing those cases where the percentage of

18 positivities are around the one to ten percent range

19 and that's where it could be quite useful.

20 MR. SIMMONS:

21 Q. So it's used in the research laboratory, which is a

22 physically separate laboratory from the clinical

23 laboratory at your institution?

24 DR. O'MALLEY:

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1 A. That's--yes.

2 MR. SIMMONS:

3 Q. And not for the clinical cases. Okay. Thank you

4 very much, Dr. O'Malley, I don't have anything else

5 for you.

6 THE COMMISSIONER:

7 Q. Mr. Browne?

8 DR. FRANCES O'MALLEY, EXAMINATION BY MR. PETER BROWNE

9 MR. BROWNE:

10 Q. Good morning, Dr. O'Mally.

11 DR. O'MALLEY:

12 A. Good morning.

13 MR. BROWNE:

14 Q. My name is Peter Browne. I represent a number of

15 individual physicians who have been asked to

16 testify, including pathologists and oncologists.

17 You'll be glad to know that Mr. Simmons has covered

18 some of the areas that I was planning on questioning

19 you on. I'd like to begin with, however, your

20 curriculum vitae, I have a number of just sort of

21 curious questions and one of which relates to, it

22 looks to be either an abstract or an article and

23 it's at page 26, item No. 93. It's an abstract that

24 you were involved in in 2005 and it's entitled

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1 "Standardization of Estrogen and Progesterone

2 receptor assay values." Do you recall that

3 publication?

4 DR. O'MALLEY:

5 A. Just -

6 MR. BROWNE:

7 Q. Number 93 I have, and it's page 26, Chapman, Jasani,

8 Miller and yourself.

9 DR. O'MALLEY:

10 A. Yes, that's just an abstract, it has not been

11 published as a peer review article yet.

12 MR. BROWNE:

13 Q. Is there any relevance to, I guess some of the

14 issues we talked about this morning in this abstract

15 and if so, could you explain that to the

16 Commissioner?

17 DR. O'MALLEY:

18 A. Well really it was just looking at variability from

19 different labs, the variation that occurs between

20 labs.

21 MR. BROWNE:

22 Q. Okay, just here in Canada or worldwide?

23 DR. O'MALLEY:

24 A. It was looking at the situation worldwide, well

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1 mostly between Canada and the UK.

2 MR. BROWNE:

3 Q. And some of the individuals in fact who you've

4 partnered with on this abstract are members of the

5 UK NEQAS program, is that correct?

6 DR. O'MALLEY:

7 A. That's correct.

8 MR. BROWNE:

9 Q. Now if I could, please, just to go back on some of

10 the general areas and beginning with, I guess some

11 of the basic biology of estrogen receptor

12 expression, ER is that--ER expression, is that

13 something that increases with the patient's age and

14 following menopause?

15 DR. O'MALLEY:

16 A. That's correct, most, many more post menopausal

17 tumors are tumors that occur in women who are post

18 menopausal will be ER positive than the situation of

19 pre-menopausal setting, but it's also related very

20 closely to grade of the tumor, so the vast majority

21 of grade, low grade cancers and as I mentioned

22 before, special type cancers will be ER and PR

23 positive as opposed to high grade cancers.

24 MR. BROWNE:

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1 Q. Right, and just talking about the low--and does it
 2 also include moderate grade as well or just low
 3 grade?
 4 DR. O'MALLEY:
 5 A. Low and moderate grade.
 6 MR. BROWNE:
 7 Q. Low and moderate. And they also, in my note here
 8 says these types of tumors also display some degree
 9 of tubal formulation. Can you explain what that
 10 means to the Commissioner as well?
 11 DR. O'MALLEY:
 12 A. Well that's just one of the parameters that we
 13 assess when we're grading a tumor, so the more tubal
 14 formation there is in a cancer, the more likely it
 15 is to be low grade, so it sort of recapitulating
 16 what the normal breast looks like, compared to a
 17 high grade cancer that just grows in solid sheets
 18 and I showed you the immunohistochemistry in such a
 19 case that was ER negative where the tumor was just
 20 growing in a solid sheet.
 21 MR. BROWNE:
 22 Q. Okay, and I think we've heard, at least in my
 23 recollection is the term heterogenicity and
 24 homogenicity in relation to ER/PR. Am I correct in

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1 understanding that generally ER expresses in a
 2 homogeneous fashion, but there are a subset of
 3 tumors that express heterogeneously and if you can
 4 explain the difference to the Commissioner, what
 5 that means?
 6 DR. O'MALLEY:
 7 A. So homogeneity means that the tumor is staining in a
 8 very uniformed fashion. So I showed an example of
 9 that where almost a hundred percent of the tumor
 10 cells were staining positively, but heterogeneity
 11 does occur and in fact, I did show an example where
 12 only about ten percent of the tumor cells were
 13 actually staining positively, so that's
 14 heterogeneity, so one can understand that if a
 15 portion of that tumor, only a portion of that tumor
 16 was assessed, it may be assessed as negative because
 17 the portion is actually positive, it would be missed
 18 in the assessment or in the testing.
 19 MR. BROWNE:
 20 Q. Now again going back to the low and intermediate
 21 range tumors of ER expression, has there been
 22 studies in literature which correlate that these
 23 types of tumors have a low response to Tamoxifen?
 24 DR. O'MALLEY:

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1 A. I showed you the data from Elledge's Group showing
 2 that indeed there was a linear relationship between
 3 the response to Tamoxifen and the percentage of
 4 positivity of the tumor cells. So there certainly
 5 is that data available in the literature.
 6 MR. BROWNE:
 7 Q. And if we look at, I guess the history of
 8 immunohistochemistry and ER/PR and look at, I guess,
 9 HER2neu, has there been a different approach in
 10 terms of, again, the worldwide pathology world in
 11 sort of rolling out, and I use the term "rolling
 12 out", say HER2neu testing verses IHC testing, and
 13 if so, is there a marked difference between how, in
 14 terms of standards and recognition of validation of
 15 the various tests that have occurred, vis-a-vis each
 16 other? It's a convoluted question -
 17 DR. O'MALLEY:
 18 A. Yes.
 19 MR. BROWNE:
 20 Q. But I see a difference at least in the literature
 21 that the approach that's being adopted with HER2/neu
 22 verses what was done with ER/PR when it first was
 23 introduced.
 24 DR. O'MALLEY:

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1 A. Yeah, there definitely is a difference in approach.
 2 Now I just want to clarify the vast majority of HER2
 3 testing is also an immunohistochemical test.
 4 MR. BROWNE:
 5 Q. Yes.
 6 DR. O'MALLEY:
 7 A. We use FISH, florescence in situ hybridization in
 8 setting HER2 testing as well, but yes, it's
 9 absolutely correct that HER2 immunohistochemical
 10 tests were rolled out in a very, very different
 11 fashion than ER and PR. Standards were implemented
 12 much faster and in fact, we not only have the ASCO
 13 CAP guidelines for HER2 testing, but we also have
 14 Canadian national standards for HER2 testing as
 15 well.
 16 MR. BROWNE:
 17 Q. Whereas we don't with ER/PR?
 18 DR. O'MALLEY:
 19 A. Whereas we don't for ER and PR.
 20 MR. BROWNE:
 21 Q. Yes. ER/PR has been around much longer than
 22 HER2/neu.
 23 DR. O'MALLEY:
 24 A. Yes, absolutely true.

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1 MR. BROWNE:
 2 Q. Okay, and as a result there is an abundance of
 3 literature, would you agree, expressing concerns
 4 over the high rate of false, potentially false
 5 negative testing in ER/PR? Well let me rephrase the
 6 question -
 7 DR. O'MALLEY:
 8 A. Well I guess the date I showed you from the NEQAS
 9 program showed a quite high false positive--sorry,
 10 false negativity rates for those tumors that were
 11 low expressing.
 12 MR. BROWNE:
 13 Q. Right.
 14 DR. O'MALLEY:
 15 A. Yeah.
 16 MR. BROWNE:
 17 Q. And in terms of the, I guess the variability,
 18 there's been a number of suggestions in the
 19 literature what may be at the root cause of that
 20 variability, has there not?
 21 DR. O'MALLEY:
 22 A. That's correct, yes.
 23 MR. BROWNE:
 24 Q. And that includes choice of antibody, antigen

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1 retrieval controls and interpretation and then pre-
 2 analytical variables, those points?
 3 DR. O'MALLEY:
 4 A. Absolutely, absolutely correct.
 5 MR. BROWNE:
 6 Q. Now you mentioned, just again on the subject matter
 7 of interlab variability, the NEQAS program, which
 8 you have some familiarity and I think in one of your
 9 slides, as you mentioned here this morning in
 10 reference was the Rhodes article in 2000.
 11 DR. O'MALLEY:
 12 A. Uh-hm.
 13 MR. BROWNE:
 14 Q. Was there a second study that followed that again
 15 which, by NEQAS, which looked at tumors that were
 16 fixed and processed by the NEQAS labs and then
 17 participants, I guess, reviewed those results and
 18 then were scored on it? Are you familiar -
 19 DR. O'MALLEY:
 20 A. NEQAS have published many, many studies and I just
 21 can't recall off the top of my head all of those
 22 studies.
 23 MR. BROWNE:
 24 Q. Okay. In terms of some of their findings, was

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1 there--had there been any NEQAS publications which
 2 suggest that pre-analytical variables, such as
 3 tissue handling and fixation do not greatly affect
 4 ER/PR testing and that their focus tends to be the
 5 correlation which affects ER testing the most is
 6 antigen retrieval, has there been a -
 7 DR. O'MALLEY:
 8 A. Well, no, that's definitely not correct. In fact,
 9 there is good data in the literature looking at the
 10 pre-analytic component of the testing to show how
 11 important that is. There's a study by Goldstein -
 12 MR. BROWNE:
 13 Q. Yes.
 14 DR. O'MALLEY:
 15 A. - looking at different times and fixative and that
 16 study showed that if a tumor had been fixed for less
 17 than six hours in formalin, that the false
 18 negativity rate for ER and PR was very high.
 19 MR. BROWNE:
 20 Q. Now I'm focusing more on the NEQAS studies in terms
 21 of their findings tend to relate a correlation to
 22 antigen retrieval; whereas Dr. Goldstein's studies
 23 tend to place a lot of emphasis on fixation.
 24 DR. O'MALLEY:

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1 A. Well I can't comment specifically on that NEQAS
 2 study because I just can't recall it.
 3 MR. BROWNE:
 4 Q. Can ER testing results, in terms of, I guess
 5 positivity rates and so on, be affected by the
 6 characteristics of a patient population? For
 7 instance, certain -
 8 DR. O'MALLEY:
 9 A. In terms of pre-post menopausal?
 10 MR. BROWNE:
 11 Q. Yes.
 12 DR. O'MALLEY:
 13 A. Status? Well we talked about that, that it's more
 14 likely that post menopausal woman with breast cancer
 15 would have an ER positive tumor.
 16 MR. BROWNE:
 17 Q. Okay, and just looking at, you mentioned Dr.
 18 Goldstein, the US experience, if I could just switch
 19 to that for a minute, I noticed among your
 20 curriculum vitae as well that you published another
 21 article with Professor--or Dr. Layfield, Lester
 22 Layfield?
 23 DR. O'MALLEY:
 24 A. Yes.

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1 MR. BROWNE:
 2 Q. Has he done a number of studies involving various
 3 labs in terms of cut off values used across the
 4 United States?
 5 DR. O'MALLEY:
 6 A. I'm aware of one study. I was not involved in that
 7 study, where he did look at a very limited number of
 8 labs, looked at interlab variability with respect to
 9 ER testing and showed quite a significant
 10 discordance between the labs.
 11 MR. BROWNE:
 12 Q. And do you recall, again just to--maybe some times
 13 as you looked through this article, whether or not
 14 it included, I think some of the labs had cut offs
 15 anywhere between one percent and thirty percent?
 16 DR. O'MALLEY:
 17 A. I can't recall that paper, all of the details in
 18 that paper. Thirty percent would be a bit high,
 19 usually it's around ten percent, a few labs have
 20 used twenty percent.
 21 MR. BROWNE:
 22 Q. Now, you touched on the issue of fixation this
 23 morning in your presentation, can I ask whether
 24 long-term storage of unstained paraffin sections,

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1 can that alter the immunoreactivity of the ER?
 2 DR. O'MALLEY:
 3 A. Yes, that can alter the immunoreactivity, we've done
 4 our own studies on that, but ER actually is more
 5 robust than, for example, HER2, the antigenicity is
 6 lost much quicker for HER2 when a section is being
 7 cut and left at room temperature, than it is for ER,
 8 but it's certainly, it certainly is lost for both ER
 9 and PR, so we try and cut our sections, you know,
 10 freshly when they are being submitted for ER and PR
 11 testing and HER2 testing, and if they are cut and
 12 there's going to be some delay before performance of
 13 the test, then we refrigerate those cut slides.
 14 MR. BROWNE:
 15 Q. Has there been, you talked about, as I understand at
 16 Mount Sinai you use a combination of staining
 17 intensity and percentages to the Allred score, is
 18 that -
 19 DR. O'MALLEY:
 20 A. That's correct.
 21 MR. BROWNE:
 22 Q. Has there been a study which has sort of, other than
 23 Professor's Allred's work in this area, which has
 24 conventionally demonstrated a clinical importance of

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1 measuring staining intensity or heterogeneity?
 2 DR. O'MALLEY:
 3 A. No, actually, it really, it showed, I mean, the
 4 follow-up study by Ellege, for example, just
 5 reported on the percentage because they didn't--well
 6 it was a study performed by the same group of
 7 people, so they were using that data to support the
 8 dropping the evaluation of intensity. But, no, the
 9 vast majority of studies look just at the
 10 percentage.
 11 MR. BROWNE:
 12 Q. In percentages.
 13 DR. O'MALLEY:
 14 A. Rather than intensity, yes.
 15 MR. BROWNE:
 16 Q. Okay. Now as I understand, in terms of the
 17 evolution and Mr. Simmons asked you about the
 18 evolution of this test this morning, initially most
 19 of the studies focused on ER, it was much later in,
 20 I guess, the process that PR was looked at and
 21 validated independently, is that correct?
 22 DR. O'MALLEY:
 23 A. That is correct, yes.
 24 MR. BROWNE:

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1 Q. And now I think, is it fair to say that the
 2 literature supports that PR status is independently
 3 associated with disease free survival and overall
 4 survival?
 5 DR. O'MALLEY:
 6 A. Yes, that study did show that, the study I believe
 7 by Moshin et al that you're referring to?
 8 MR. BROWNE:
 9 Q. Yes. And as a result for, I guess, from that one
 10 could suggest that ER positive and PR positive
 11 tumors have a better prognosis than ER positive and
 12 PR negative?
 13 DR. O'MALLEY:
 14 A. Yes.
 15 MR. BROWNE:
 16 Q. And then, I guess, in turn, PR positive and ER
 17 negative have better prognosis than ER negative and
 18 PR negative?
 19 DR. O'MALLEY:
 20 A. That is correct, yes.
 21 MR. BROWNE:
 22 Q. Okay. Now as well, we spoke or you spoke about the
 23 internal and external controls utilized by the
 24 pathologists this morning. Can an external control

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1 stain stronger than an internal control?

2 DR. O'MALLEY:

3 A. Yes, yes, I guess it could.

4 MR. BROWNE:

5 Q. And would that relate back to the type of tumor

6 that's used in a number of labs? I know in your

7 lab, you use, I think three different types, a

8 negative, a moderate, and a high.

9 DR. O'MALLEY:

10 A. Um-hm.

11 MR. BROWNE:

12 Q. Are there a number of labs that use, for controls,

13 simply high expressing tumors?

14 DR. O'MALLEY:

15 A. I believe so.

16 MR. BROWNE:

17 Q. And would that cause then probably a higher staining

18 external versus if you had a low or moderate

19 expressing internal, would that cause that result?

20 DR. O'MALLEY:

21 A. Well, what we're looking at for--we're not grading

22 the intensity. It may lead to a variation in

23 intensity, but what's more important is that there

24 are positive tumor cells present or positive in

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1 terms of the internal control, positive normal

2 epithelium.

3 MR. BROWNE:

4 Q. Okay, and again, Mr. Simmons asked you about

5 positivity rates. Just generally, in the

6 literature, what sort of--from about around about

7 2005-2007, there is a number of articles published

8 on positivity rates around the world. What is

9 generally an accepted positivity rate?

10 DR. O'MALLEY:

11 A. About 75 percent for ER, up to 80 percent in some

12 studies.

13 MR. BROWNE:

14 Q. And as well, you were asked about--by Mr. Coffey

15 this morning about certain tumors which are more

16 predictive of, I guess, or there's an expectation

17 that PR, or excuse me, ER positivity. One example

18 was the classic, I think you described the classic

19 ductal -

20 DR. O'MALLEY:

21 A. Infiltrating lobular.

22 MR. BROWNE:

23 Q. Infiltrating lobular. Is there such a, I guess,

24 variation on that where you have an infiltrating

Page 143

1 ductal with a prominent lobular feature?

2 DR. O'MALLEY:

3 A. A lot of those will be positive, for sure.

4 MR. BROWNE:

5 Q. Are they the same as your classic?

6 DR. O'MALLEY:

7 A. No, in terms of -

8 MR. BROWNE:

9 Q. What would be the percentage differences?

10 DR. O'MALLEY:

11 A. In terms of prognosis, the prognosis isn't just

12 quite as good for no special type with lobular

13 features as it is for a classic or pure infiltrating

14 lobular.

15 MR. BROWNE:

16 Q. And the frequencies, are they the same, in terms of

17 when you talk about classic lobular, when you have

18 an infiltrating ductal with lobular features?

19 DR. O'MALLEY:

20 A. Well, it'll be dependent on the grade of that tumor

21 and so a ductal no special type with lobular

22 features could be grade one to grade three, and that

23 will obviously affect the ER status.

24 MR. BROWNE:

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1 Q. And then in terms of, just to go back on the

2 internal control for a minute, and that's you

3 mention the inclusion of normal breast epithelium as

4 an internal control. While that's desirable, is it

5 always possible in every case to get an internal

6 control?

7 DR. O'MALLEY:

8 A. It's not always possible in every single case, but

9 it is certainly highly desirable.

10 MR. BROWNE:

11 Q. What sort of instances can you think of where an

12 internal control may not be--you may not be able to

13 get an internal control?

14 DR. O'MALLEY:

15 A. Where we have a section right through the centre of

16 the tumor. You're not going to have any normal

17 tissue on that section.

18 MR. BROWNE:

19 Q. And finally, the last couple of questions, you

20 mentioned Dr. Goldstein's work. Has he recently

21 published an article about ER staining and antibody

22 incubation and antigen retrieval?

23 DR. O'MALLEY:

24 A. He may have, but I haven't done a recent literature

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1 search of him.

2 MR. BROWNE:

3 Q. I think that may be all my questions for Dr.

4 O'Malley. They are. Thank you very much.

5 DR. O'MALLEY:

6 A. You're welcome.

7 THE COMMISSIONER:

8 Q. Mr. Pritchett?

9 MR. PRITCHETT:

10 Q. We have no questions, Madam Commissioner.

11 DR. FRANCES O'MALLEY, EXAMINATION BY MS. JENNIFER NEWBURY

12 MS. NEWBURY:

13 Q. Good afternoon, Dr. O'Malley. My name is Jennifer

14 Newbury and I represent the Canadian Cancer Society,

15 Newfoundland and Labrador division. I just have a

16 couple of topics for you this morning. First of

17 all, I was interested in exploring with you a little

18 bit how a pathology lab maintains best practices in

19 the absence of national and international standards,

20 and I take it that what you do in your lab and what

21 your lab does is to conduct your own validation

22 studies and conduct your own literature review, and

23 I take it that you do have to conduct the literature

24 review first as to, you know, make sure that you

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1 know what types of validation studies to conduct.

2 Is that -

3 DR. O'MALLEY:

4 A. Well, what types of antibodies to use in validation

5 studies, yes.

6 MS. NEWBURY:

7 Q. And that changes from time to time, I take it?

8 DR. O'MALLEY:

9 A. It does.

10 MS. NEWBURY:

11 Q. As new equipment and new antibodies become

12 available, and that's based on research, I guess?

13 DR. O'MALLEY:

14 A. Yes, keeping abreast of what's happening.

15 MS. NEWBURY:

16 Q. Okay, and I'm just wondering, what sort of a time

17 and resource commitment would there be for a lab to

18 maintain those best practices, to keep pace with the

19 literature, to conduct validation studies?

20 DR. O'MALLEY:

21 A. Trish Wegrynowski will be able to address the

22 specific time, but it is time consuming. It

23 absolutely is time consuming.

24 MS. NEWBURY:

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1 Q. Okay, and what part is more time consuming than the

2 other? Can you say whether it's more the literature

3 review or the validation studies itself?

4 DR. O'MALLEY:

5 A. Well, the literature review isn't that time

6 consuming. It's the validation. It's all of those

7 technical steps that are quite time consuming.

8 MS. NEWBURY:

9 Q. Okay, and in terms of your role as a pathologist and

10 perhaps the role of pathologists in your lab

11 generally, what sort of a time commitment would

12 there be to keep pace with, you know, the types of

13 antibodies available, the types of equipment that

14 might be on the market? Just to give a picture for

15 the Commissioner, you know, how many conferences

16 might you go to a year or how many journals do you

17 have to read, what sort of continuing education

18 seminars might you have to attend in the course of a

19 year, and is there much variation from year to year?

20 DR. O'MALLEY:

21 A. There definitely is variation from year to year and

22 from person to person. I attend a lot of

23 conferences, so I mean, I can't give you a specific

24 number that would be appropriate for every lab.

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1 MS. NEWBURY:

2 Q. Okay. Is there a designation of an individual or a

3 couple of individuals within a lab to take on that

4 role in terms of keeping pace with research and new

5 developments?

6 DR. O'MALLEY:

7 A. Well, in an academic setting, we're all expected to

8 keep pace with current developments.

9 MS. NEWBURY:

10 Q. And how about in a lab that may not be affiliated

11 with a teaching hospital or may not have the

12 academic component, would you have any idea what

13 might be involved in that situation?

14 DR. O'MALLEY:

15 A. Well, there still is a requirement to keep, you

16 know, knowledgeable about what is happening and, in

17 fact, the MOCComp program demands that through the

18 Royal College of Physicians and Surgeons, that one

19 must keep up with current knowledge.

20 MS. NEWBURY:

21 Q. Okay, and that's a Canadian -

22 DR. O'MALLEY:

23 A. Yes, that's a national requirement.

24 MS. NEWBURY:

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1 Q. Okay, and within your lab, as a group, do you try to
 2 cover off all key conferences or all key areas? Is
 3 there any sort of formal structure in place or do
 4 you just go by your areas of interest?
 5 DR. O'MALLEY:
 6 A. We go generally by our areas of expertise.
 7 MS. NEWBURY:
 8 Q. Okay, and are most of the resources available in
 9 Canada for you to do this or do you often have to
 10 travel to other jurisdictions to maintain, I guess,
 11 your best knowledge or keeping pace with the new
 12 developments?
 13 DR. O'MALLEY:
 14 A. Often it requires travelling internationally.
 15 MS. NEWBURY:
 16 Q. Okay.
 17 DR. O'MALLEY:
 18 A. Mainly to the U.S.
 19 MS. NEWBURY:
 20 Q. Okay, and in terms of the absence of national and
 21 international standards for ER/PR testing, I take it
 22 this isn't unique for that particular type of
 23 testing?
 24 DR. O'MALLEY:

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1 A. That's true.
 2 MS. NEWBURY:
 3 Q. Okay, and are there--would you say that there are
 4 many other types of laboratory testing that don't
 5 have national standards? I mean, how unusual is it?
 6 DR. O'MALLEY:
 7 A. Yes, yes.
 8 MS. NEWBURY:
 9 Q. There are many of them?
 10 DR. O'MALLEY:
 11 A. There are many, yes.
 12 MS. NEWBURY:
 13 Q. So it would be, I guess, typical for pathologists,
 14 for example, to keep pace with new developments and
 15 to keep pace with new types of testing procedures by
 16 attending these various conferences? You wouldn't
 17 just have to do it to learn about what's happening
 18 with ER/PR? You would be doing this in the normal
 19 course of your profession? Is that correct?
 20 DR. O'MALLEY:
 21 A. Yes, yes.
 22 MS. NEWBURY:
 23 Q. And do I assume that it would still be preferable to
 24 have national standards applicable to ER/PR?

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1 DR. O'MALLEY:
 2 A. It would absolutely be preferable. I look forward
 3 to these being published.
 4 MS. NEWBURY:
 5 Q. Okay, and it seems that there is a fair bit of
 6 flexibility by labs in terms of choosing the types
 7 of procedures that they want to use, the types of
 8 equipment, the types of antibodies. Do you expect
 9 that the national standards would allow that
 10 flexibility? Would there be some -
 11 DR. O'MALLEY:
 12 A. Well, there needs to be that flexibility because
 13 each lab does function differently, but within that,
 14 there won't be flexibility around the validation
 15 process itself.
 16 MS. NEWBURY:
 17 Q. Okay, and how would that be implemented, do you
 18 expect?
 19 DR. O'MALLEY:
 20 A. Well, through this national committee that has been
 21 struck, I would think.
 22 MS. NEWBURY:
 23 Q. Okay. So the national standards committee, you
 24 expect, would focus on validation studies or would

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1 they also deal with the various types of equipment
 2 and testing?
 3 DR. O'MALLEY:
 4 A. I would think that they will cover, in a broad
 5 stroke, the pre-analytic, analytic and post-analytic
 6 aspects of the testing, but I wouldn't expect them
 7 to mandate that a specific machine should be used
 8 for performing immunohistochemistry. They won't get
 9 into that sort of minute detail.
 10 MS. NEWBURY:
 11 Q. Okay.
 12 DR. O'MALLEY:
 13 A. So as I say, that's really a decision that each lab
 14 must make.
 15 MS. NEWBURY:
 16 Q. Okay, and for labs to be able to make those
 17 decisions, to choose the type of antibody or the
 18 type of equipment, would it still be necessary for
 19 pathologists to, you know, maintain or keep pace
 20 with conferences and continuing education and
 21 journal resources?
 22 DR. O'MALLEY:
 23 A. Absolutely.
 24 MS. NEWBURY:

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1 Q. You've spoken a bit about the national standards
 2 initiative and I think you mentioned it was an 18-
 3 lab study conducted in relation to that. Was the
 4 purpose of that study to get an overview of how labs
 5 are performing? Were labs randomly chosen for that
 6 particular study?
 7 DR. O'MALLEY:
 8 A. No, the labs were not randomly chosen. The labs
 9 that were--labs were invited to participate in that
 10 study and most of the labs actually had participated
 11 in the national HER2 program, development of those
 12 national guidelines. So they were hand-picked to--
 13 and most of them were very large labs and many of
 14 them functioned as reference labs.
 15 MS. NEWBURY:
 16 Q. Okay. So then was the purpose of the study to
 17 determine what level of concordance, whether or not
 18 you can have good concordance between labs for this
 19 particular type of testing?
 20 DR. O'MALLEY:
 21 A. Yes, it was a pilot study to see how the process
 22 could be implemented really.
 23 MS. NEWBURY:
 24 Q. Okay, and not to necessarily say that most labs, if

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1 you've picked them randomly, would necessarily
 2 perform at the same level? It wasn't that type of a
 3 study?
 4 DR. O'MALLEY:
 5 A. No, no, it wasn't. No, and in fact, it would be--I
 6 think this is the best case scenario. Those
 7 concordance rates were incredibly high.
 8 MS. NEWBURY:
 9 Q. Okay, and why would that be a best case scenario?
 10 DR. O'MALLEY:
 11 A. Well, because of the labs that were chosen, they all
 12 have a lot of experience. They're all very large
 13 labs.
 14 MS. NEWBURY:
 15 Q. And how then would that, those good results be
 16 available or translate to the smaller labs that are
 17 not considered to be reference labs? How would you
 18 be able to translate that ability?
 19 DR. O'MALLEY:
 20 A. Well, those labs should participate. Once this
 21 program is in place, is rolled out, then those labs
 22 should participate in the process and so any
 23 problems with a particular lab then will be
 24 identified early.

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1 MS. NEWBURY:
 2 Q. Okay, and will there be a process in place then that
 3 these other labs can improve their procedures? Will
 4 there be resources available to, I guess, modify the
 5 test as need be to reach the same level of
 6 concordance as the larger reference labs?
 7 DR. O'MALLEY:
 8 A. I don't know, but I certainly hope so.
 9 MS. NEWBURY:
 10 Q. Okay. You were asked a couple of questions this
 11 morning that relate to, I guess, monitoring of
 12 trends in terms of the ER/PR results, and you've
 13 mentioned there's one of several types of cancer
 14 that are expected to be ER positive. That's the
 15 invasive lobular, the classic invasive lobular
 16 carcinoma, and I believe you also indicated that
 17 with increasing age or post-menopausal, you would
 18 expect a higher rate of ER positivity, and is that
 19 knowledge used to actually be an extra check on the
 20 results that you have?
 21 DR. O'MALLEY:
 22 A. Well, not really because there is variability. What
 23 is more an extra check is looking at the type and
 24 the grade of the tumor.

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1 MS. NEWBURY:
 2 Q. Okay, so the type and the grade of the tumor.
 3 DR. O'MALLEY:
 4 A. Rather than on the menopausal status of the patient.
 5 MS. NEWBURY:
 6 Q. Okay, so that wouldn't be used as a check, but the
 7 type and grade of tumor would be?
 8 DR. O'MALLEY:
 9 A. Yes.
 10 MS. NEWBURY:
 11 Q. And I take it that was the reason, in the one case
 12 that you did have experience with, it was sent to
 13 four different labs. Was that because of a lack of
 14 confidence in the accuracy of the first couple of
 15 test results?
 16 DR. O'MALLEY:
 17 A. Well, it was just a concern because of the type of
 18 cancer. It was a classic infiltrating lobular
 19 cancer, so even though many of those labs had
 20 repeated the test and were quite happy with their
 21 controls, it was still a concern just because of the
 22 type of the cancer.
 23 MS. NEWBURY:
 24 Q. Okay, and are there any other trends, in terms of

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1 the ER/PR testing, that you can use to help, I
 2 guess, be an extra check in terms of the
 3 expectations that you would have for your ER/PR
 4 testing?
 5 DR. O'MALLEY:
 6 A. Trends beyond the type and the grade?
 7 MS. NEWBURY:
 8 Q. Yes, beyond the type and the grade.
 9 DR. O'MALLEY:
 10 A. No, I can't think of any additional steps.
 11 MS. NEWBURY:
 12 Q. Is gender ever an issue with -
 13 DR. O'MALLEY:
 14 A. No, male breast cancers are often ER positive.
 15 MS. NEWBURY:
 16 Q. Okay, and within your lab, is there any formal
 17 process in place to make sure that all of these
 18 trends are monitored on a regular basis or is it
 19 just left to the individual?
 20 DR. O'MALLEY:
 21 A. Yes, we have standard operating procedures.
 22 MS. NEWBURY:
 23 Q. Okay, and perhaps you can just explain how that
 24 works.

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1 DR. O'MALLEY:
 2 A. Well, actually Trish will probably go into detail on
 3 those SOPs.
 4 MS. NEWBURY:
 5 Q. In terms of the monitoring, and so that would be
 6 left to technologists, as opposed to pathologists,
 7 in terms of monitoring?
 8 DR. O'MALLEY:
 9 A. Well, no, the pathologists oversee that.
 10 MS. NEWBURY:
 11 Q. Right, okay, but she'll know the details on the
 12 standard operating procedures?
 13 DR. O'MALLEY:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. Okay. Great, thank you. Those are all the
 17 questions, I have. Thank you.
 18 THE COMMISSIONER:
 19 Q. Mr. Crosbie?
 20 DR. FRANCES O'MALLEY, EXAMINATION BY CHESLEY CROSBIE, Q.C.:
 21 CROSBIE, Q.C.:
 22 Q. Thank you, Commissioner. Thank you, Doctor, Ches
 23 Crosbie. You told us that you have at least weekly
 24 tumor boards or panels, you said board, I think?

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1 DR. O'MALLEY:
 2 A. Yes.
 3 CROSBIE, Q.C.:
 4 Q. And this is an interdisciplinary team of
 5 oncologists, pathologists and others who--do they
 6 only look at difficult cases? Do they look at all
 7 cases routinely? How does that work?
 8 DR. O'MALLEY:
 9 A. We look at all invasive breast cancer cases, but we
 10 spend more time on the difficult cases. But we do
 11 bring--but each patient is discussed, yes.
 12 CROSBIE, Q.C.:
 13 Q. Is the oncologist, I'm assuming most or maybe all
 14 patients would have an oncologist. Is that fair?
 15 DR. O'MALLEY:
 16 A. Yes.
 17 CROSBIE, Q.C.:
 18 Q. Is the treating oncologist involved in these boards?
 19 DR. O'MALLEY:
 20 A. Yes, yes.
 21 CROSBIE, Q.C.:
 22 Q. So that's a feature of a board when you have an
 23 interdisciplinary look at a case that the treater is
 24 present?

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1 DR. O'MALLEY:
 2 A. Yes.
 3 CROSBIE, Q.C.:
 4 Q. Does the decision making--perhaps I'm overstepping.
 5 Is it usual then that a consensus is arrived at that
 6 assists the treater in how to approach the case?
 7 DR. O'MALLEY:
 8 A. Yes.
 9 CROSBIE, Q.C.:
 10 Q. But these boards, they don't make actual treatment
 11 decisions. That's always a matter for the primary
 12 responsible physician who's treating, is it?
 13 DR. O'MALLEY:
 14 A. Well, actually, the boards do function in a
 15 consensus fashion and in the difficult cases where
 16 the treatment may not be straightforward, there may
 17 be options in terms of the chemotherapeutic
 18 regiment. So the medical oncologist will ask his or
 19 her colleagues for their opinions on which
 20 treatment, given the tumor type, size, all of the
 21 other prognostic factors that we look at, given
 22 those characteristics. So we actually do, as a
 23 group, reach a consensus at those meetings.
 24 CROSBIE, Q.C.:

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1 Q. Is it recorded?
 2 DR. O'MALLEY:
 3 A. Yes, it is recorded.
 4 CROSBIE, Q.C.:
 5 Q. Would it be true to say, harkening back to the sign
 6 that Harry Truman was supposed to have on his desk,
 7 you know, the buck stops here, that ultimately that
 8 decision is between the treating--if that's the
 9 primary treater, the oncologist and the patient?
 10 DR. O'MALLEY:
 11 A. That is true. That is true, but often what happens
 12 is the medical oncologist will say "this is my
 13 recommendation and I have--we have discussed your
 14 case at tumor board and it's also the recommendation
 15 of the group," for example.
 16 CROSBIE, Q.C.:
 17 Q. I seem to have picked up somewhere along the way,
 18 and you did testify that PR status can be used
 19 independently of ER status, as an indication for
 20 hormone therapy?
 21 DR. O'MALLEY:
 22 A. That's correct.
 23 CROSBIE, Q.C.:
 24 Q. Is there some standard regarding that, like PR-40?

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1 DR. O'MALLEY:
 2 A. I'm not sure exactly what you mean. You mean the
 3 cutoffs?
 4 CROSBIE, Q.C.:
 5 Q. Yes.
 6 DR. O'MALLEY:
 7 A. The cutoffs for PR are the same as ER, so in our
 8 lab, anyway, so one percent is accepted as a
 9 positive result for both ER and PR.
 10 CROSBIE, Q.C.:
 11 Q. Now what the treating oncologist chooses to do with
 12 the information in discussion with the patient, I
 13 guess we'd have to learn more from an oncologist
 14 about that?
 15 DR. O'MALLEY:
 16 A. Certainly.
 17 CROSBIE, Q.C.:
 18 Q. Do you know what the annual positivity/negativity
 19 ratio was for ER/PR testing at, well, I guess we
 20 have to look at it in--I guess we should talk ER and
 21 then PR, you'll have to tell me. Do you know what
 22 it was for last year at Mount Sinai, your
 23 institution?
 24 DR. O'MALLEY:

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1 A. I believe it was around 75 percent, somewhere around
 2 there, 75 to 77 percent for ER and about 65 percent
 3 for PR.
 4 CROSBIE, Q.C.:
 5 Q. And for ER do you know what those numbers may have
 6 been for, say, the last five years?
 7 DR. O'MALLEY:
 8 A. I don't. I'd have to look at the data.
 9 CROSBIE, Q.C.:
 10 Q. Would you--I'm assuming it's no big imposition if I
 11 were to ask you this, but if it is, you can tell me,
 12 would you be able to look at your data going back to
 13 1997, simply tell us per year at Mount Sinai what
 14 were the ratios for ER and PR?
 15 DR. O'MALLEY:
 16 A. Yes, it would take a bit of work. It's only in the
 17 last few years that it's become an automated
 18 process, but it could be, it could be retrieved.
 19 CROSBIE, Q.C.:
 20 Q. Okay. Well, I don't want to burden you, as I say.
 21 When did it become automated?
 22 DR. O'MALLEY:
 23 A. Just in the last few years.
 24 CROSBIE, Q.C.:

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1 Q. Well, perhaps as far back as you have the automated
 2 data and can relatively easily access it? Sounds
 3 like it's several years for the data.
 4 DR. O'MALLEY:
 5 A. Since the synoptic reporting, that has made it
 6 easier to retrieve that data.
 7 CROSBIE, Q.C.:
 8 Q. So is that a reasonable question for me to ask of
 9 you?
 10 DR. O'MALLEY:
 11 A. To pull that data?
 12 CROSBIE, Q.C.:
 13 Q. Yes.
 14 DR. O'MALLEY:
 15 A. Certainly it is.
 16 CROSBIE, Q.C.:
 17 Q. Okay. And I guess you can send that along through
 18 the channels of communication you've been using with
 19 the Commission?
 20 DR. O'MALLEY:
 21 A. Yes.
 22 CROSBIE, Q.C.:
 23 Q. No one's -
 24 DR. O'MALLEY:

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1 A. Yes.

2 CROSBIE, Q.C.:

3 Q. I think the answer is yes.

4 COMMISSIONER:

5 Q. On the understanding that what we're retrieving is

6 the easily retrievable material on the automated

7 system.

8 DR. O'MALLEY:

9 A. Okay, but that--yeah, okay.

10 COMMISSIONER:

11 Q. That's, as I understand, is what Mr. Crosbie is

12 seeking. While I'm sure he'd love to have the

13 other, he's not asking you to do major research for

14 him.

15 CROSBIE, Q.C.:

16 Q. That's exactly right, Commissioner.

17 COMMISSIONER:

18 Q. Thank you.

19 CROSBIE, Q.C.:

20 Q. Can we bring up, Registrar, 0067, please? Scroll

21 down to about the middle. And this letter, for your

22 information, was written in 2005 by Dr. Cook, a

23 pathologist here, to the VP medical services. And

24 I'm looking in the paragraphs that--paragraph that

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1 commences, "May 17, 2005," and you go to the middle

2 of that, you see the statement in the middle, "It is

3 estimated that"?

4 DR. O'MALLEY:

5 A. Um-hm.

6 CROSBIE, Q.C.:

7 Q. "Approximately 50 to 85 percent of all breast

8 cancers exhibit estrogen receptors." That's a sort

9 of broad band. Would you accept that as a

10 reasonable statement?

11 DR. O'MALLEY:

12 A. Yes, 50 percent is a little bit on the low side.

13 CROSBIE, Q.C.:

14 Q. If an institution were running a positivity rate for

15 PR--for ER, rather, of 50 percent, would that raise

16 any questions in your mind?

17 DR. O'MALLEY:

18 A. It would, it would, for sure. That's too low for an

19 ER positivity rate.

20 CROSBIE, Q.C.:

21 Q. At what stages does it become too low?

22 DR. O'MALLEY:

23 A. Well, for ER I would be concerned at anything lower

24 than 70 percent, certainly 65 percent.

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1 CROSBIE, Q.C.:

2 Q. Here in Newfoundland I understand we were in the

3 habit of sending out slides for purpose of doing

4 these reading of ER/PR positivity to smaller centres

5 outside of St. John's, outside of the lab at the

6 Health Sciences. Are there pitfalls in sending

7 slides out to smaller centres where they might have

8 only one or two pathologists?

9 DR. O'MALLEY:

10 A. Yes, yes. Certainly I can speak from the Her2

11 experience that, in fact, the guidelines recommend

12 that to perform Her2 testing a minimum of 250 immuno

13 tests per year should be--Her2, specifically, immuno

14 tests should be performed in a lab, so it's certain

15 accuracy is related to volume, for sure.

16 CROSBIE, Q.C.:

17 Q. That's what I was going to say, is there a

18 relationship to volume?

19 DR. O'MALLEY:

20 A. Yes.

21 CROSBIE, Q.C.:

22 Q. Is there also a benefit to being in, you know, a lot

23 of what pathologists do, I take it, involves things

24 that are in a grey zone. Is that true?

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1 DR. O'MALLEY:

2 A. We wouldn't like to think that a lot of what we do

3 is in a grey zone. I think we can -

4 CROSBIE, Q.C.:

5 Q. Some of it?

6 DR. O'MALLEY:

7 A. But some, yes, certainly some cases are very

8 difficult to make a definitive diagnosis of invasive

9 cancer, but the vast majority are easy to, it's easy

10 to make that definitive call.

11 CROSBIE, Q.C.:

12 Q. Is it fair to infer there's a benefit to having

13 colleagues available to consult with and share notes

14 with?

15 DR. O'MALLEY:

16 A. Definitely.

17 CROSBIE, Q.C.:

18 Q. If you have any degree of uncertainty about how to

19 make a call?

20 DR. O'MALLEY:

21 A. Yes, yes. And indeed, at Mount Sinai we often show

22 cases to one another, consult with one another on

23 difficult cases.

24 CROSBIE, Q.C.:

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1 Q. Can you expand a bit, please, on the concept of a
 2 reference lab, what characteristics would a
 3 reference lab have? You spoke of it in terms to
 4 Her2/neu and Mount Sinai functioning in that manner
 5 with regard to that test, but I assume it's a
 6 concept that has application with regard to other
 7 tests or processes, as well?
 8 DR. O'MALLEY:
 9 A. That's true. Again, the lab must--they're generally
 10 labs that deal with very large volumes of tests and
 11 they would have rigid quality control procedures in
 12 place, SOPs, they would have to fulfil many, many
 13 criteria to be assigned that, as a reference lab.
 14 CROSBIE, Q.C.:
 15 Q. So who is it that says you're a reference lab, is
 16 that a consensus kind of thing?
 17 DR. O'MALLEY:
 18 A. Well, in Ontario it was a decision made by the
 19 ministry, ministry of health and long-term care.
 20 CROSBIE, Q.C.:
 21 Q. And so you told us that your institution in relation
 22 to Her2/neu is "the" reference lab?
 23 DR. O'MALLEY:
 24 A. It's one. There are two references -

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1 CROSBIE, Q.C.:
 2 Q. Two?
 3 DR. O'MALLEY:
 4 A. Two reference labs in Ontario and we are one of
 5 those labs.
 6 CROSBIE, Q.C.:
 7 Q. And that was determined by the ministry?
 8 DR. O'MALLEY:
 9 A. It was.
 10 CROSBIE, Q.C.:
 11 Q. What about for ER/PR testing?
 12 DR. O'MALLEY:
 13 A. As I say, we don't have either provincial or
 14 national standards for ER/PR testing. They are in
 15 process.
 16 CROSBIE, Q.C.:
 17 Q. Okay. So then that requires some kind of agreed
 18 generalizably--generally applicable standard for the
 19 concept of reference lab to make sense the way
 20 you're explaining it? There should be some
 21 consensus as to what standards are and then the
 22 reference lab is selected by somebody as
 23 representing the embodiment of that standard against
 24 which other labs are to be measured?

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1 DR. O'MALLEY:
 2 A. Yes. Although I see that the program based on the
 3 pilot study from this national body, it would be
 4 more of a--it would be more like the NEQAS program.
 5 CROSBIE, Q.C.:
 6 Q. Well, what I get from that is there's external
 7 proficiency reviewing going on?
 8 DR. O'MALLEY:
 9 A. That's a quality assurance program.
 10 CROSBIE, Q.C.:
 11 Q. Um-hm. So is my statement roughly accurate, you
 12 need a body of agreed standards in order to have a
 13 reference lab?
 14 DR. O'MALLEY:
 15 A. Oh, definitely, yes.
 16 CROSBIE, Q.C.:
 17 Q. All right. To say that there's no generally agreed
 18 set of standards for, or, you know, national
 19 standards or even provincial standards for ER/PR
 20 testing, that's not to say that there are no
 21 standards at all?
 22 DR. O'MALLEY:
 23 A. Absolutely, absolutely.
 24 CROSBIE, Q.C.:

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1 Q. In fact, every competent institution has its own set
 2 of standards, right?
 3 DR. O'MALLEY:
 4 A. That's very true.
 5 CROSBIE, Q.C.:
 6 Q. And you would normally expect to find those
 7 standards in something called a standard operating
 8 procedures manual?
 9 DR. O'MALLEY:
 10 A. Yes.
 11 CROSBIE, Q.C.:
 12 Q. That's where you'd find them, the institution's own
 13 standards?
 14 DR. O'MALLEY:
 15 A. Um-hm.
 16 CROSBIE, Q.C.:
 17 Q. Can you tell us a bit more about validation, for
 18 example, in relation to antibodies? Say you get a
 19 new antibody or batch of antibody, just relate it to
 20 that?
 21 DR. O'MALLEY:
 22 A. Well, what we do is we have--we know how a previous
 23 antibody have behaved in terms of the staining that
 24 it gave with previous cases, so we like to--we, when

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1 we're bringing in new antibody, we like to validate
 2 it on at last 100 previously stained cases. So the
 3 validation process involves assessing these
 4 previously stained tumors with the new antibody and
 5 looking at the concordance between the staining that
 6 had been previously obtained and with the staining
 7 that obtained with the new antibody. And Trish will
 8 be able to go into the details later in the week.
 9 CROSBIE, Q.C.:
 10 Q. I'm sure. Just trying to get the basic idea. You
 11 don't just take a new batch of antibody and run
 12 samples through and, you know, rely on your
 13 controls, for example, to tell you whether you
 14 getting problems with it, you do it, in effect, side
 15 by side, you retest other samples with a known
 16 outcome by a process that you trust, right?
 17 DR. O'MALLEY:
 18 A. Yes.
 19 CROSBIE, Q.C.:
 20 Q. And she can tell us more about that. At this point
 21 in time IHC external proficiency testing, would you
 22 say, recommended, highly recommended, optional?
 23 DR. O'MALLEY:
 24 A. I would say that it is mandatory and I would expect

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1 that the standards, the national standards will make
 2 that statement. Certainly for Her2 our guidelines,
 3 our national guidelines as well as the CAP ASCO
 4 guidelines say that external quality assurance be
 5 involved in an external quality assurance program is
 6 mandatory.
 7 CROSBIE, Q.C.:
 8 Q. What about for ER/PR, say, in 2005, how would you
 9 characterize it?
 10 DR. O'MALLEY:
 11 A. Well, again, I mean, it's highly recommended to--I
 12 mean, it hasn't been stated as mandatory because we
 13 don't have those national standards, but as I say,
 14 for most laboratories they should be involved in a
 15 quality assurance if they are performing these
 16 tests.
 17 CROSBIE, Q.C.:
 18 Q. What about in 1997?
 19 DR. O'MALLEY:
 20 A. The same, I would say the same statement applies.
 21 CROSBIE, Q.C.:
 22 Q. Is it within your knowledge that the institution
 23 here, as they began to send up samples to your
 24 institution for retesting, did it come to your

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1 knowledge that they had been actually testing for
 2 ER/PR status their DCIS cases?
 3 DR. O'MALLEY:
 4 A. I can't comment on that because I really wasn't
 5 directly involved in the retesting. Dr. Mullen
 6 will, I presume, be able to answer that question for
 7 you.
 8 CROSBIE, Q.C.:
 9 Q. You were asked about a section coming through
 10 without an internal control and your comment was
 11 it's highly desirable to have the internal control
 12 present, which is essentially a piece of normal
 13 tissue which accompanies the tumor slice?
 14 DR. O'MALLEY:
 15 A. Well, it's actually in the slice, it's actually part
 16 of the section. So you've got the tumor, as I
 17 showed -
 18 CROSBIE, Q.C.:
 19 Q. But it's not a separate piece of tissue, it -
 20 DR. O'MALLEY:
 21 A. It's not a separate piece, it's actually -
 22 CROSBIE, Q.C.:
 23 Q. It's a margin around the tumor?
 24 DR. O'MALLEY:

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1 A. That's right, that's right.
 2 CROSBIE, Q.C.:
 3 Q. And what you're looking for there is you're looking
 4 to see a few dots in that normal tissue because
 5 ordinarily and even in postmenopausal women those
 6 receptors will be present if the tumor itself is
 7 positive, is that the general idea?
 8 DR. O'MALLEY:
 9 A. No. They will be--the whole point of that internal
 10 control is that they are positive independent of the
 11 ER and PR status of the tumor.
 12 CROSBIE, Q.C.:
 13 Q. Oh, okay. Excuse me.
 14 DR. O'MALLEY:
 15 A. Yes.
 16 CROSBIE, Q.C.:
 17 Q. So if you got a negative tumor plus positive
 18 receptors in the internal -
 19 DR. O'MALLEY:
 20 A. Normal -
 21 CROSBIE, Q.C.:
 22 Q. - control, you know something is wrong?
 23 DR. O'MALLEY:
 24 A. No, no. You know that the test has actually worked.

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1 The problem would be if the tumor was completely
 2 negative for ER and your internal controls in normal
 3 epithelium was negative, that would be a problem.
 4 That test should not be interpreted because the
 5 normal epithelium is negative, so one couldn't be
 6 sure that the test has worked in that particular
 7 slide.
 8 CROSBIE, Q.C.:
 9 Q. Yeah, I'm sorry, I had all this reversed. But the
 10 point I'm wanting to get around to is if indeed the
 11 slide had no normal tissue on it and the reading
 12 pathologist had any concern about that, he or she
 13 could ask for another slide?
 14 DR. O'MALLEY:
 15 A. Yes, yes.
 16 CROSBIE, Q.C.:
 17 Q. And a slide which did, was accompanied by normal
 18 tissue?
 19 DR. O'MALLEY:
 20 A. Yes. I mean, it's more difficult if the case is
 21 coming from outside, it's easier if the case is
 22 being--is in house because one can just quickly look
 23 at the other sections of tumor, but it's more tricky
 24 if the case is being sent from outside.

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1 COMMISSIONER:
 2 Q. Is it also not more tricky if it's a biopsy that's
 3 been done and sometimes the little piece that's
 4 taken doesn't necessarily get a lot of normal
 5 tissue?
 6 DR. O'MALLEY:
 7 A. Yes, yes, absolutely, because often the core biopsy,
 8 the radiologist targets the centre of the tumor, so
 9 many times a core biopsy may not have normal tissue.
 10 CROSBIE, Q.C.:
 11 Q. You're not usually relying on a core biopsy for
 12 definitive treatment, though, are you?
 13 DR. O'MALLEY:
 14 A. Well, that's a good point. I mean, we are--the
 15 core--the function of the core biopsy to make a
 16 diagnosis of invasive breast cancer. We don't
 17 routinely do ER/PR on the core biopsy, we wait until
 18 we received the surgical, surgically excised
 19 specimen. We do it in some circumstances, but
 20 generally we want for the surgically excised
 21 specimen.
 22 CROSBIE, Q.C.:
 23 Q. And so, and this is my final question, which is just
 24 as well, although there may be more. What I want to

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1 ask you is if the pathologist is reading the
 2 internal and external controls, then the reliability
 3 of the specimen itself for giving you an accurate
 4 reading in relation to positivity, negativity, that
 5 should be in place, is that right? The controls
 6 ought to catch any problem in the preparation of
 7 that specimen up to that point?
 8 DR. O'MALLEY:
 9 A. Oh, yeah. Yes, they should, they should. But -
 10 CROSBIE, Q.C.:
 11 Q. They really should?
 12 DR. O'MALLEY:
 13 A. - I mean, it takes--you know, it is dependent on
 14 having a senior experienced pathologist or
 15 technologist to oversee all of those technical steps
 16 that go into the test to ensure that the positive
 17 and negative controls behave as they should.
 18 CROSBIE, Q.C.:
 19 Q. So if we have a large or an inordinately large
 20 number of misreads, then we may want to have a look
 21 at what was going on to ensure the suitability of
 22 the controls and what was happening with the
 23 controls?
 24 DR. O'MALLEY:

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1 A. I would expect that the controls are archived, the
 2 control sections are--to my understanding. I don't
 3 know how long they're archived for. Again, Trish
 4 will be able to answer that.
 5 CROSBIE, Q.C.:
 6 Q. But that might be a possible source of trouble?
 7 DR. O'MALLEY:
 8 A. To pull those -
 9 CROSBIE, Q.C.:
 10 Q. Issues with controls -
 11 DR. O'MALLEY:
 12 A. - external controls?
 13 CROSBIE, Q.C.:
 14 Q. If you're getting a lot of reversals when another
 15 institution is reading your slides for you?
 16 DR. O'MALLEY:
 17 A. I'm not entirely sure that I'm getting what you're
 18 asking, I'm clear about what you're asking.
 19 CROSBIE, Q.C.:
 20 Q. Well, for example, we heard from a gentleman by the
 21 name of Dr. Ejeckam who--have you heard that name in
 22 -
 23 DR. O'MALLEY:
 24 A. I have heard that name. I don't know that

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1 individual.

2 CROSBIE, Q.C.:

3 Q. He had involvement back in 2003 where he suspended

4 testing for five or six weeks and he intervened and

5 in a troubleshooting capacity, it's fair to say, and

6 Dr. Ejeckam did emphasise that to him the internal

7 control is critical, but in general having workable

8 controls was very important for ensuring that you

9 got a valid reading on the patient's tissue sample.

10 And everything I just said is a reasonable

11 statement, is it?

12 DR. O'MALLEY:

13 A. Well, they're vital, yes.

14 CROSBIE, Q.C.:

15 Q. So if it turns out that an institution was not

16 getting reliable reading of the patient's tissue

17 sample, stands to reason we should look for problems

18 with the controls?

19 DR. O'MALLEY:

20 A. Definitely, yes.

21 CROSBIE, Q.C.:

22 Q. That's all I wanted to bring out. Thank you.

23 COMMISSIONER:

24 Q. Mr. Pike, do you have any questions?

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1 MR. PIKE:

2 Q. No questions, thank you.

3 COMMISSIONER:

4 Q. Mr. Clements?

5 MR. CLEMENTS:

6 Q. No questions.

7 COMMISSIONER:

8 Q. Do you have anything arising, Ms. Coffey?

9 DR. FRANCES O'MALLEY, RE-EXAMINATION BY BERNARD COFFEY, Q.C.:

10 COFFEY, Q.C.:

11 Q. Yes, just a couple of questions, if I could, Doctor.

12 Doctor, just if you could for the Commissioner, just

13 to elaborate a little bit on an answer you just gave

14 Mr. Crosbie. You indicated that, well, if it's an

15 in-house case and when you look at a slide and

16 there's not enough tissue there, from your

17 perspective, to consider it as an internal control,

18 what--if it's an in-house case, what's the advantage

19 of it being an in-house case, what do you then

20 actually do?

21 DR. O'MALLEY:

22 A. Well, if the other blocks from that tumor are

23 readily accessible, we can just go into the lab and

24 pull those sections and review them very, very

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1 quickly and choose a more suitable block, if need

2 be.

3 COFFEY, Q.C.:

4 Q. Yeah. Look at the HNE (phonetic) slide for a

5 particular block?

6 DR. O'MALLEY:

7 A. Look at the HNE slide.

8 COFFEY, Q.C.:

9 Q. And get one with tumor and normal tissue and say,

10 well, I want ER on that one?

11 DR. O'MALLEY:

12 A. Exactly.

13 COFFEY, Q.C.:

14 Q. Okay. I just want to clarify that. And, of course,

15 if it's not an in-house case, you might not have all

16 the blocks, I take it?

17 DR. O'MALLEY:

18 A. We often don't. In fact, many of the labs that send

19 us cases, just send us one block of tumor.

20 COFFEY, Q.C.:

21 Q. In terms of the block itself that's to be utilized,

22 you know, for the ER test or PR test, who chooses

23 the block, who identifies which block?

24 DR. O'MALLEY:

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1 A. From externally or internally?

2 COFFEY, Q.C.:

3 Q. Well for the internal control, who would -

4 DR. O'MALLEY:

5 A. Oh, for the internal controller, the case that's

6 actually assessed?

7 COFFEY, Q.C.:

8 Q. Well, for example, if you're going to do--you're

9 called upon, you go back tomorrow, you're at work

10 and you're doing your case and you have to choose

11 which block to do the ER test on, is it your choice

12 as to which block to choose?

13 DR. O'MALLEY:

14 A. Yes, it's the pathologist responsible for that

15 particular case -

16 COFFEY, Q.C.:

17 Q. Okay.

18 DR. O'MALLEY:

19 A. - decides on which block is assessed.

20 COFFEY, Q.C.:

21 Q. That's one. Could you tell us please too, because

22 Mr. Browne, I think, asked you about abstract versus

23 published. You started -

24 DR. O'MALLEY:

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1 A. It's a published abstract, but it hasn't been
 2 published--the entire article hasn't been published.
 3 So, I was just making a distinction between a
 4 published abstract and the actual peer reviewed
 5 paper, publication of the paper.
 6 COFFEY, Q.C.:
 7 Q. So, in the context, when it were, like, abstract is
 8 used there, for example, in your CV, that indicates
 9 that it hasn't been peer reviewed?
 10 DR. O'MALLEY:
 11 A. Oh no, no, no, it has. Those abstracts are peer
 12 reviewed to undergo publication and presentation at
 13 the particular conference that it is being sent to.
 14 No, they have been absolutely peer reviewed. It's
 15 just that all of the--it's so--an abstract is
 16 basically just a synopsis of the data and then the
 17 paper contains all of the details.
 18 COFFEY, Q.C.:
 19 Q. Sure. Doctor, I think Mr. Simmons asked you about
 20 reactivity and long term storage of paraffin blocks.
 21 DR. O'MALLEY:
 22 A. Um-hm.
 23 COFFEY, Q.C.:
 24 Q. And then your answer was framed in terms of well, if

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1 we have--if a slide is prepared in the sense of a
 2 very thin slice is taken off the paraffin block and
 3 it's put on the slide, that it's not desirable to
 4 leave the slide lying around unrefrigerated.
 5 DR. O'MALLEY:
 6 A. That is correct.
 7 COFFEY, Q.C.:
 8 Q. Because it can have a negative effect on the ability
 9 when it's processed -
 10 DR. O'MALLEY:
 11 A. The accuracy of the test.
 12 COFFEY, Q.C.:
 13 Q. What about the block itself, like paraffin blocks
 14 themselves in the whole, how about them?
 15 DR. O'MALLEY:
 16 A. No, they can be stored for many, many years and
 17 antigenicity can still be retained many, many years
 18 later.
 19 COFFEY, Q.C.:
 20 Q. Okay. And there was as well--Mr. Simmons asked you
 21 some questions about had you testified to the effect
 22 that what HER2/neu, there are national guidelines -
 23 DR. O'MALLEY:
 24 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. - standards, I think is the word you used, for the
 3 HER2/neu tests. And you've indicated that it's only
 4 now that ER/PR national standards, you anticipate,
 5 will hopefully be in place shortly. Do I understand
 6 that correctly?
 7 DR. O'MALLEY:
 8 A. That is correct.
 9 COFFEY, Q.C.:
 10 Q. But HER2/neu compared to ER/PR, HER2/neu is
 11 relatively new compared to ER/PR, IHC tests.
 12 DR. O'MALLEY:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Can you tell the Commissioner, as a practising
 16 pathologist, why it is that HER2/neu has national
 17 standards now as opposed to ER/PR which has existed
 18 for, I gather, more than a decade.
 19 DR. O'MALLEY:
 20 A. A lot had to do with the cost of the drug that's
 21 used in HER2 positive tumors, Trastuzumab or
 22 Herceptin, it costs about \$45,000.00 per patient per
 23 year of treatment. So, there are major cost
 24 implications in the case of a false positive result,

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1 ie., a patient's tumor is called HER2 positive, when
 2 indeed it's not positive. So, that patient has
 3 undergone significant--has been treated with a very,
 4 very expensive drug that is not going to benefit the
 5 patient. So, it was really the cost of that drug
 6 that drove the issue for bringing in standards
 7 sooner in the setting of HER2, than for ER and PR.
 8 The endocrine drugs are a lot cheaper.
 9 COFFEY, Q.C.:
 10 Q. Okay. And finally then, Doctor, Mr. Simmons asked
 11 you about the, or referred you to the fact that
 12 there are different antibodies which have different
 13 specificities and different sensitivities known and,
 14 of course, there are different detection systems and
 15 different antibodies used by different laboratories
 16 and different detection systems used by different
 17 laboratories and each lab has to decide for itself,
 18 what's the appropriate mix and procedures. Okay.
 19 In relation to that, if whatever the particular lab
 20 decides to choose, which antibody to choose, decides
 21 to use for ER/PR and which detection systems or
 22 system it finally decides upon, from your
 23 perspective, if the lab in doing so appropriately
 24 optimizes the process and carefully follows the

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1 procedures it has established, worked out for itself
 2 and established, should the ER and PR results be
 3 accurate?
 4 DR. O'MALLEY:
 5 A. I would think so.
 6 COFFEY, Q.C.:
 7 Q. Okay. And therefore, usable clinically for
 8 treatment -
 9 DR. O'MALLEY:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Thank you, Commissioner.
 13 EXAMINATION PER CURIAM
 14 THE COMMISSIONER:
 15 Q. Thank you, Mr. Coffey. Doctor O'Malley,
 16 occasionally people refer to something called a
 17 false negative. Is it expected that there would be
 18 a certain number of false negative in ER testing?
 19 DR. O'MALLEY:
 20 A. Well, ideally, we want to--the whole point of
 21 optimization is to significantly decrease the
 22 possibility of either a false negative or a false
 23 positive.
 24 THE COMMISSIONER:

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1 Q. But is it more likely or less likely that--is it
 2 more or less likely that you would have a false
 3 positive, for example, than a false negative?
 4 DR. O'MALLEY:
 5 A. Well again, that depends on all of the factors that
 6 we've talked about. If a tumor has been sub-
 7 optimally fixed, if it hasn't been handled in the
 8 manner that I spoke about, then the chances of
 9 having a false negative result are high. On the
 10 other hand, if an antibody is highly, highly
 11 sensitive and used in conjunction with a highly
 12 sensitive detection system, this particularly
 13 pertains to the situation of HER2, then there's a
 14 greater chance of a false positive result.
 15 THE COMMISSIONER:
 16 Q. Well, if one were looking at the results of a
 17 particular laboratory or laboratories, indeed,
 18 across the whole country, is there a commonly
 19 accepted number in North America, for example, would
 20 you say--you know, I would expect that two percent,
 21 three percent, five percent, ten percent of those
 22 test results would be false results.
 23 DR. O'MALLEY:
 24 A. Well, again -

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1 THE COMMISSIONER:
 2 Q. I know you would hope that it wouldn't be.
 3 DR. O'MALLEY:
 4 A. Exactly, exactly, but even less than five percent
 5 would be a concern.
 6 THE COMMISSIONER:
 7 Q. Okay. Thank you very much.
 8 DR. O'MALLEY:
 9 A. Well, I should say even less than ten percent. Less
 10 than five percent may happen, because when we look
 11 at that external quality assurance in inter-observer
 12 variability, if we get 95 percent concordance, that
 13 is acceptable.
 14 THE COMMISSIONER:
 15 Q. And do I take it then that where you think that
 16 differences--you see, to me, what you might call a
 17 false negative might arise for a different purpose,
 18 and I frankly, I'm not quite sure, how does one
 19 figure out that there is a false negative, by the
 20 way? Is it just that two or three tests down the
 21 road somebody finds a different result, so -
 22 DR. O'MALLEY:
 23 A. Something would have to prompt that.
 24 THE COMMISSIONER:

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1 Q. Okay.
 2 DR. O'MALLEY:
 3 A. Yes, because we wouldn't be reporting it out if we
 4 thought that there was a chance that it could be
 5 falsely negative.
 6 THE COMMISSIONER:
 7 Q. Okay, and it seems to me that there is a difference
 8 in the circumstance where you have the difficult
 9 case and you might have a reasonable difference of
 10 view between pathologists as to how you should
 11 interpret something, and a case where sort of one
 12 pathologist might view it one way and then there's
 13 the other ten in the room who says no, that's not
 14 what it is at all. It's something entirely
 15 different.
 16 DR. O'MALLEY:
 17 A. Well, no, in a situation of--we could look at two
 18 different situations. There's the diagnostic
 19 dilemma or there's the difficulty in scoring in ER
 20 cases. So it's the latter, I think, that you're
 21 asking?
 22 THE COMMISSIONER:
 23 Q. Yes. Well, in this case, although my mind sometimes
 24 drifts to the other, I confess.

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1 DR. O'MALLEY:
 2 A. Yes. Well, I mean, in that situation, it's just
 3 really a matter of what is the percentage. There
 4 might be some variability in what one pathologist
 5 assesses as the percentage positive tumor cells
 6 versus another, but that really is only relevant for
 7 cases, one of which I showed, where the degree of
 8 positivity is at the low end. For the vast majority
 9 of cases, and speaking specifically about ER,
 10 they're either completely negative or highly--or
 11 very strongly positive. So it's only about six
 12 percent or so, certainly less than ten percent,
 13 where the degree of positivity is around that
 14 borderline level where there might be a little bit
 15 of variability in terms of interpreting.
 16 THE COMMISSIONER:
 17 Q. Okay. So that should not be a major problem?
 18 DR. O'MALLEY:
 19 A. It should not be a major problem.
 20 THE COMMISSIONER:
 21 Q. Okay. Mr. Crosbie, you're -
 22 CROSBIE, Q.C.:
 23 Q. Commissioner, with great respect, your question
 24 about rates of false negatives is a very contentious

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1 issue, which you've raised now -
 2 THE COMMISSIONER:
 3 Q. Well, we have it in the literature that there is
 4 such a thing. So are you saying that there's a
 5 problem with my question or you want to ask a follow
 6 up one?
 7 CROSBIE, Q.C.:
 8 Q. The problem is that it would make some of the other
 9 lawyers in the room want to explore the topic
 10 further. Now that may not be necessary, but she
 11 made a very quick comment on it, and it's a very key
 12 issue for some of us.
 13 THE COMMISSIONER:
 14 Q. In another setting or in this one?
 15 CROSBIE, Q.C.:
 16 Q. I believe in this setting, yes. I can only assume
 17 that when we talk of false negative rates, there
 18 will be other individuals from your institution,
 19 like Dr. Pritzker, who would be able to address that
 20 this afternoon. Is that so?
 21 DR. O'MALLEY:
 22 A. You can certainly bring it up with him, yes.
 23 CROSBIE, Q.C.:
 24 Q. Yes.

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1 COFFEY, Q.C.:
 2 Q. And well, actually, Dr. Mullen.
 3 DR. O'MALLEY:
 4 A. And Dr. Mullen.
 5 THE COMMISSIONER:
 6 Q. Dr. Mullen, yes. Frankly, I started down this road
 7 just for an explanation of what it was and how one
 8 figured out what it was. But I perhaps got
 9 diverted. Are you content then with the idea that
 10 there will be others, Mr. Crosbie, or are you
 11 suggesting there is another question or two you want
 12 to ask of this witness?
 13 CROSBIE, Q.C.:
 14 Q. No, I'm content.
 15 THE COMMISSIONER:
 16 Q. All right. Well, on that basis then, only left for
 17 me to thank you very much for coming all this way
 18 and for giving us what I, at least, have found an
 19 extremely interesting morning. Thank you.
 20 DR. O'MALLEY:
 21 A. Thank you.
 22 THE COMMISSIONER:
 23 Q. We'll adjourn until--we're a little late today.
 24 Let's make it 2:20.

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1 (LUNCH BREAK)
 2 THE COMMISSIONER:
 3 Q. Please be seated. Mr. Coffey.
 4 COFFEY, Q.C.:
 5 Q. Thank you, Commissioner. The next witness is Dr.
 6 Kenneth Pritzker.
 7 DR. KENNETH PRITZKER (AFFIRMED) EXAMINATION BY BERNARD COFFEY,
 8 Q.C.
 9 REGISTRAR:
 10 Q. Would you please state and spell your complete name
 11 for the Commission.
 12 DR. PRITZKER:
 13 A. My name is Kenneth Phillip Henry Pritzker. K-E-N-N-
 14 E-T-H P-H-I-L-L-I-P H-E-N-R-Y P-R-I-T-Z-K-E-R.
 15 REGISTRAR:
 16 Q. Thank you.
 17 COFFEY, Q.C.:
 18 Q. Dr. Pritzker, can you give the Commissioner please a
 19 brief overview of your education and your
 20 professional background. And I emphasis "brief"
 21 because in your case, I think it goes on for some
 22 period of time.
 23 DR. PRITZKER:
 24 A. Sure. I graduated in medicine at the University of

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1 Toronto in 1967 and at the same time I received a
 2 Bachelor of Science in medicine in Pharmacology.
 3 After that I did a rotating internship and a year of
 4 internal medicine, followed by pathology studies at
 5 McGill University. And in 1972 I became a fellow of
 6 the Royal College of Physicians/Surgeons of Canada
 7 in Pathology and commenced work at Mount Sinai
 8 Hospital, had an appointment at Mount Sinai Hospital
 9 in Toronto.
 10 CROSBIE, Q.C.:
 11 Q. Will we be seeing an exhibit, Mr. Coffey?
 12 COFFEY, Q.C.:
 13 Q. Yes, I'll be doing that in a second. Go ahead,
 14 sorry, Doctor.
 15 DR. PRITZKER:
 16 A. I've been at Mount Sinai--Mount Sinai has been my
 17 base for my entire career and in the early years, I
 18 was a general pathologist, but I had a special
 19 interest in bones and joints and developed a
 20 research group interested in diseases such as
 21 osteoarthritis and osteoporosis. And in 1986 I
 22 became chief of the department in Mount Sinai and I
 23 have had that role since that time. Over the years
 24 and since the start of my career, I've been involved

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1 with various specialities, societies, local,
 2 provincial, national and international in pathology.
 3 And I guess, one of the highlights was presidency of
 4 the Canadian Association of Pathologists which was
 5 in the early 1980s.
 6 COFFEY, Q.C.:
 7 Q. Commissioner, if I could please, I have some
 8 exhibits I'm going to ask to be entered. They would
 9 be exhibits P-1706 through P-1717 inclusive and P-
 10 1726.
 11 THE COMMISSIONER:
 12 Q. Entered.
 13 EXHIBITS P-1706 THROUGH P-1717 INCLUSIVE, ENTERED AND MARKED
 14 EXHIBIT P-1726 ENTERED AND MARKED.
 15 COFFEY, Q.C.:
 16 Q. Registrar, could you bring up, please, Exhibit P-
 17 1726? Doctor, this is a document entitled
 18 curriculum vitae for Kenneth Phillip Henry Pritzker.
 19 I take it that that is your CV?
 20 DR. PRITZKER:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. And on my account, it goes on for 109 pages, looking
 24 at the numbering system here. Doctor, could you

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1 tell the Commissioner, please, as you indicated, you
 2 were, as you put it, a practising pathologist in the
 3 sense of on a day-to-day basis for years.
 4 DR. PRITZKER:
 5 A. I still am.
 6 COFFEY, Q.C.:
 7 Q. And I was going to ask you about that. Are you
 8 still -
 9 DR. PRITZKER:
 10 A. Yes, I am.
 11 COFFEY, Q.C.:
 12 Q. Okay. And you are also, though, since about 1986,
 13 did I get that right, and what is your job title
 14 there?
 15 DR. PRITZKER:
 16 A. At the present time, my job title is Pathologist in
 17 Chief and I'm also Director of the Department of
 18 Pathology and Laboratory Medicine.
 19 COFFEY, Q.C.:
 20 Q. And as a practical matter, in those roles, what does
 21 each of those roles mean?
 22 DR. PRITZKER:
 23 A. Well, Pathologist in Chief is responsible for the
 24 medical aspects of the department including the

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1 quality and the quantity and the nature of all
 2 services. And in the context of our hospital which
 3 is a teaching hospital, it's only the services, but
 4 it's also the academic output, the teaching and the
 5 research. So, my overall responsibility that that's
 6 of high grade and adequate quantity. The
 7 directorship indicates I'm responsible for the
 8 support infrastructure which is really the technical
 9 operations as well. I'm responsible for that in
 10 reporting to the president for the entire outcome of
 11 the department.
 12 COFFEY, Q.C.:
 13 Q. And so in that capacity, I take it in the former
 14 capacity you have physicians report to you?
 15 DR. PRITZKER:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. And in the latter capacity what type of other
 19 occupations report to you?
 20 DR. PRITZKER:
 21 A. Well, it's technologists, technicians, clerical
 22 staff, principally.
 23 COFFEY, Q.C.:
 24 Q. Anybody who works in the department, I take it?

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1 DR. PRITZKER:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Doctor, and you've indicated, as well, though,
 5 you're still a practising pathologist and have
 6 remained so. What does--what type of pathology do
 7 you practice?
 8 DR. PRITZKER:
 9 A. Well, my special interest is in diseases of bones
 10 and joints, and because of all the other
 11 responsibilities I have, I confine my practice, at
 12 this time, to that subject. It's things such as
 13 bone and tumors of bone and soft tissue and it's
 14 also the examination of specimens that have various
 15 forms of arthritis.
 16 COFFEY, Q.C.:
 17 Q. And, Doctor, are you still yourself involved in
 18 academic publications?
 19 DR. PRITZKER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. And, Doctor, could perhaps describe--first of all
 23 I'll ask you, Mount Sinai Hospital, is it--you've
 24 indicated it's associated--it's a teaching hospital,

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1 it's associated with which university?
 2 DR. PRITZKER:
 3 A. The University of Toronto.
 4 COFFEY, Q.C.:
 5 Q. And are there any other--as a relationship, then,
 6 with UFT's medical school, does it have, Mount
 7 Sinai, have a relationship or participate with any
 8 other groups within Ontario?
 9 DR. PRITZKER:
 10 A. Oh, yes, we do. But there are--and beyond Ontario.
 11 But these are informal relationship which would be
 12 developed on a departmental basis or even on an
 13 individual basis.
 14 COFFEY, Q.C.:
 15 Q. And within the pathology and laboratory medicine
 16 program at Mount Sinai, could you tell us, please,
 17 how it's structured perhaps in terms of, you know,
 18 the relationship between the physicians, the
 19 pathologists and the technologists and technicians
 20 and the administrative staff, how is that all laid
 21 out, perhaps?
 22 DR. PRITZKER:
 23 A. Okay. The first thing you should be aware is it's
 24 quite a large operation. There are a total of about

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1 300 people on staff, plus about 100 students on site
 2 at any one time. And it's also quite a varied
 3 operation. We would have somewhere around 30
 4 different centres of activity, technical centres of
 5 activity. So it's clear that in order to operate
 6 such a centre, it has to be, the organization has to
 7 be reasonable complex. Now, what we have is a site
 8 of organization in which there sections, medical
 9 sections which would be for a particular subject,
 10 such as surgical pathology, cytology, biochemistry
 11 and within those sections there may be folks who
 12 have specific responsibilities, medical
 13 responsibilities for the oversight related to
 14 particular subjects which require it, such as
 15 immunohistochemistry, that was--and on a technical
 16 side we have units and, we call it units to define
 17 it, these centres, and they may have, a unit might
 18 be--an example of a unit would be histology and an
 19 area of focused activity within that unit might be
 20 the immunohistochemistry, it would be
 21 immunohistochemistry. So if we look at it at the
 22 local base, the local centre of activity, we would
 23 have a technical person who would be the lead and we
 24 would have a medical person that would be at the

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1 lead, and they would be expected to work together to
 2 produce the results and to have oversight and
 3 supervision of the activity. In organization chart
 4 terms the technical person reports upwards to their
 5 supervisor, who reports upwards to the
 6 administrative director and the medical person
 7 usually would report to me directly or they may
 8 report to another physician, depending on the
 9 circumstance. The--if and when there are issues,
 10 and there always issues, as you can expect in a
 11 complex operation, one that requires deliberation.
 12 It's expected that the medical people involved and
 13 the technical people involved and sometimes with
 14 other resource people, some staff people, the
 15 quality individual or whoever, would study the
 16 problem and recommend to the administrative director
 17 or myself solutions. And what would happen then is
 18 we would have a discussion around that report, often
 19 with the folks and determine a course of action.
 20 That's a microcosm of how the place works.
 21 COFFEY, Q.C.:
 22 Q. Now, just to take the IHC -
 23 DR. PRITZKER:
 24 A. Yes.

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1 COFFEY, Q.C.:

2 Q. - activity, that exists within which unit? The -

3 DR. PRITZKER:

4 A. So, the IHC, immunohistochemistry exists within the

5 centre, the unit of histology. And Trish

6 Wegrynowski is our lead technologist there and Dr.

7 Robert Riddell is the lead physician for the

8 immunohistochemistry.

9 COFFEY, Q.C.:

10 Q. And the lead physician for immunohistochemistry, for

11 IHC, what is--it's Doctor, I'm sorry, Doctor?

12 DR. PRITZKER:

13 A. Dr. Robert Riddell.

14 COFFEY, Q.C.:

15 Q. Riddell. What is, in that context, Dr. Riddell's

16 responsibilities are what?

17 DR. PRITZKER:

18 A. It's primarily strategic in terms of reporting. His

19 role would be to tell us normally what they're doing

20 each, for each period of time. But we have many

21 requests to expand the service; he would be part of

22 the process, he would be leading the process, he

23 would evaluate that. If there was financial

24 resource implications beyond what they could do,

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1 that would come to us, but the administrative

2 director and myself. Similarly if there is changes

3 of technology, that would also come up that way.

4 From time to time, it's in every area of the

5 laboratory there are quality issues, these issues

6 are addressed usually internally with reporting

7 through a quality group which we have, which, in

8 fact, has representation from all of the areas and

9 has a fulltime coordinator, but there may be a

10 resource issue or there may be a sensitivity issue

11 that there's a problem needs to be addressed in a

12 very timely fashion and at that point we would

13 become aware of it.

14 COFFEY, Q.C.:

15 Q. Now, I'm going to come back to the quality group and

16 ask you how that kind of fits into the overall

17 scheme of things.

18 DR. PRITZKER:

19 A. Okay.

20 COFFEY, Q.C.:

21 Q. But in terms of Ms. Wegrynowski, she reports to whom

22 in that scheme?

23 DR. PRITZKER:

24 A. She reports to the charge technologist for

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1 histology, a person by the name of Cindy Dunn.

2 COFFEY, Q.C.:

3 Q. Okay. And Ms. Dunn reports to?

4 DR. PRITZKER:

5 A. The administrative director.

6 COFFEY, Q.C.:

7 Q. Who reports -

8 DR. PRITZKER:

9 A. Who is Mr. Vince D'Mello.

10 COFFEY, Q.C.:

11 Q. And reports, her reports -

12 DR. PRITZKER:

13 A. And Mr. Vince D'mello works with me.

14 COFFEY, Q.C.:

15 Q. Ultimately?

16 DR. PRITZKER:

17 A. Yeah.

18 COFFEY, Q.C.:

19 Q. Okay, so that's--you were aware that that kind of

20 lines of authority in a flow chart sense would meet?

21 DR. PRITZKER:

22 A. That's correct.

23 COFFEY, Q.C.:

24 Q. Okay.

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1 DR. PRITZKER:

2 A. And those are delineated in our organizational

3 charts.

4 COFFEY, Q.C.:

5 Q. Doctor, the quality group you referred to, where do

6 they come--what relationship do they have to this?

7 DR. PRITZKER:

8 A. Well, they are not specifically related to

9 immunohistochemistry -

10 COFFEY, Q.C.:

11 Q. Yes, I appreciate that.

12 DR. PRITZKER:

13 A. They apply to all the processes in the laboratory.

14 And once again we have a physician, in our place

15 it's Dr. Bernard Fernandez, and we have quality

16 officer, Mr. Gaman Modi, who are responsible for

17 organizing the quality program. It's these folks

18 who organize and work with all of the other groups.

19 It's a large, it's a large and revolving exercise to

20 ensure that the standard operating protocols are in

21 place, that we have the quality--the proficiency

22 testing that we prepare and, for accreditation, that

23 we address any deficiencies that we find, this kind

24 of thing. It's not only internal, both these folks

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1 work externally, as well, in the hospital and
 2 elsewhere as part of their duties.
 3 COFFEY, Q.C.:
 4 Q. And I take it they're charged with, in one sense,
 5 kind of an oversight, make sure that -
 6 DR. PRITZKER:
 7 A. That's right.
 8 COFFEY, Q.C.:
 9 Q. - everybody is doing what is required -
 10 DR. PRITZKER:
 11 A. That's right.
 12 COFFEY, Q.C.:
 13 Q. In terms of quality, quality -
 14 DR. PRITZKER:
 15 A. It's not only that the pieces are in place, it's not
 16 only that you have a standard operating protocol,
 17 but actually, the standard operating protocols are
 18 used and used as stated.
 19 COFFEY, Q.C.:
 20 Q. And, Doctor, from your perspective, your vantage
 21 point, how much interaction is there, for example,
 22 between the IHC technologists and the pathologists
 23 who utilize that service and what sort of
 24 interaction occurs?

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1 DR. PRITZKER:
 2 A. Well, it's daily and it's active. So I've described
 3 partially the high-level interaction, but on a daily
 4 interaction the pathologists are responsible for all
 5 the work which comes from each pathologist, because
 6 they use that as the basis to render their opinion
 7 and their judgment. So if there is an issue, and
 8 there often is, with a particular set of materials,
 9 it's common to go to the immunohistochemistry
 10 laboratory and discuss this with the technologist,
 11 to ask for a repeat, if necessary, this kind of
 12 thing. So this is not always done by a walk
 13 through, sometimes it's done by a phone call or
 14 other means, but there's a steady parade of
 15 physicians interacting with the technologists in the
 16 immunohistochemistry laboratory each day. When I'm
 17 on service, I do my turn there, too.
 18 COFFEY, Q.C.:
 19 Q. And, Doctor, we have, Commissioner has heard not a
 20 lot yet and she will hear a lot more, I anticipate,
 21 about this sort of matter, but--and, for example,
 22 when Dr. O'Malley was here this morning and she made
 23 reference in passing to, more than in passing, in
 24 fact, a fixation, fixation as being a concern at

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1 times. And just from her comments I understood that
 2 the fixation process begins really with excision of
 3 the tissue and that would be in the OR, in the main?
 4 DR. PRITZKER:
 5 A. That's correct.
 6 COFFEY, Q.C.:
 7 Q. And what, if any, is the relationship between, like,
 8 the laboratory people, you on the bench, as it were,
 9 at times, because you say you take your turn looking
 10 at slides even today, and ensuring that fixation
 11 protocols exist and are actually followed in the OR,
 12 who takes care of that and what liaison, if any, is
 13 there, or oversight?
 14 DR. PRITZKER:
 15 A. Right. We do, we provide the fixative and we
 16 provide the protocols for the fixation conditions.
 17 COFFEY, Q.C.:
 18 Q. And that's "we" in this context is?
 19 DR. PRITZKER:
 20 A. We, being the department.
 21 COFFEY, Q.C.:
 22 Q. Department, your department?
 23 DR. PRITZKER:
 24 A. Not myself personally.

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1 COFFEY, Q.C.:
 2 Q. Your department?
 3 DR. PRITZKER:
 4 A. Yeah, our department.
 5 COFFEY, Q.C.:
 6 Q. Okay.
 7 DR. PRITZKER:
 8 A. And our department would work with the nurses,
 9 predominantly, who are in the operating room who
 10 are--the nursing administration in the operating
 11 room to ensure that the materials are delivered,
 12 that the materials are appropriate and so on, the
 13 fixative is appropriate and so on.
 14 COFFEY, Q.C.:
 15 Q. The fixative is appropriate and I take it in terms
 16 of then it has to be moved from the OR, the tissue
 17 sample, to the laboratory to be processed?
 18 DR. PRITZKER:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. And that would be moved, I take it, by porters or
 22 the equivalent?
 23 DR. PRITZKER:
 24 A. That's correct.

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1 COFFEY, Q.C.:

2 Q. And so in terms of just making sure that the whole

3 process works in a timely fashion, who's responsible

4 for that?

5 DR. PRITZKER:

6 A. Well, again, we have a list of what is being

7 operating on, what to expect. We have people whose

8 job title is pathologist assistant, these are

9 technologists who have a special interest in

10 receiving the materials and assessing the material

11 for sampling. And we try to make sure that

12 everything that we expect to get is received and is

13 received in a timely fashion. I should say that the

14 routine is to place something in the fixative

15 immediately after excision unless there is special

16 direction to forward it to the lab immediately for

17 examination.

18 COFFEY, Q.C.:

19 Q. And now, you referred just now to pathology

20 assistants?

21 DR. PRITZKER:

22 A. Um-hm.

23 COFFEY, Q.C.:

24 Q. How long have they existed at Mount Sinai?

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1 DR. PRITZKER:

2 A. Oh, I think we started over ten years ago, somewhere

3 in that neighbourhood.

4 COFFEY, Q.C.:

5 Q. And you indicated that at least back in 1980s, I

6 believe, you were the president of the Canadian

7 Association of Pathologists at one point in your

8 career?

9 DR. PRITZKER:

10 A. That's correct.

11 COFFEY, Q.C.:

12 Q. And I take it since then, though, you have routine

13 contacts with your colleagues across the country?

14 DR. PRITZKER:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. And elsewhere?

18 DR. PRITZKER:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. What, if anything, is your understanding about

22 pathology assistants and I got--you said Mount Sinai

23 began it about a decade or more ago. How about

24 elsewhere in the country and how has it progressed?

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1 DR. PRITZKER:

2 A. Well, the pathology assistants have been a topic for

3 at least 30 years, but over the last ten years it's

4 become very necessary to have these individuals as

5 the workload has gone up. This is something very

6 similar to other kinds of professionals who've

7 developed assist positions, and the most important

8 aspect about this is their formal training and

9 ultimately their accreditation. So what has

10 happened is that in the past it was quite a loose

11 group of people in the sense, or quite a varied

12 group of people in the sense that they came from

13 many different kinds of backgrounds in the

14 hospitals. We deliberately chose to have medical

15 laboratory technologists because they have an

16 independent professional status, though they don't

17 have a college of their own, and because these

18 individuals have a basic background which enables

19 the training. I'm very pleased to say that the

20 Canadian Association of Pathologists has fostered

21 the concept of pathologists assistants that a year

22 ago--actually, it was two years ago here in

23 Newfoundland they established a section of

24 pathologists assistants. And that the group in the

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1 Toronto area, Ontario, is self organizing and

2 they've had two annual meetings so far attracting

3 over 80 people. So actually, the group itself is

4 ahead of the educational bodies and the regulatory

5 bodies in terms of getting itself together, and

6 that's quite a good thing.

7 COFFEY, Q.C.:

8 Q. And within, again, the laboratory at Mount Sinai

9 ultimately, I take it, the pathologists assistants

10 report in that structure, organizational structure

11 eventually to you?

12 DR. PRITZKER:

13 A. That's correct, that's correct.

14 COFFEY, Q.C.:

15 Q. And, Doctor, I'm going to ask you about how Mount

16 Sinai became to be involved in the activities that

17 have ended up with you sitting here. If I could,

18 please, Registrar, Exhibit P-0543? Now, Doctor,

19 this is an office copy of a letter dated, it's from

20 Dr. Donald Cook dated August 2nd, 2005 to yourself

21 in your professional capacity at Mount Sinai. And

22 he just writes, "As discussed in our telephone

23 conversation, I am currently putting a hold on the

24 reporting of all estrogen and progesterone receptors

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1 from our laboratory medicine program in St. John's
 2 hospitals, Eastern Health for all virgin and newly
 3 diagnosed patients with breast cancer. I certainly
 4 appreciate your laboratory's assistance in
 5 performing immunohistochemical staining along with
 6 interpretative results on these cases. I anticipate
 7 we may be dealing with anywhere from 30 to 40 cases
 8 per month, possibly over a three-month period. We
 9 will correlate Mount Sinai's results with our own to
 10 further help us validate our Ventana automated
 11 system. I will be in contact with Maria Mandes at
 12 your laboratory regarding this. We will, of course,
 13 reimburse Mount Sinai for all costs incurred. Thank
 14 you for your help at this difficult time." Before I
 15 go on, Maria Mandes is whom?
 16 DR. PRITZKER:
 17 A. Maria Mandes is our manager of research services in
 18 our laboratory. These are services which we perform
 19 for the pharmaceutical and device industries and we
 20 keep this separate from our routine services for a
 21 number of reasons, one is that the--these services
 22 have their own rhythm, they tend to be custom. They
 23 are extremely high quality in the sense that the
 24 documentation exceeds what would go on in a

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1 conventional hospital setting and the documentation
 2 and the practices meet a standard called Good
 3 Laboratory Practices, which is set up by the FDA and
 4 it's independently audited. Those practices
 5 essentially are ones which demand extraordinarily
 6 extensive documentation and, of course, adherence to
 7 the documentation in terms of the operation of the
 8 work that goes on there. So we asked Maria to do
 9 this because our laboratory was fully--our regular
 10 laboratory was fully occupied with work. Our
 11 research and innovation laboratory was fully
 12 occupied with work, but it was possible to be able
 13 to shift some of the work which we already had in
 14 order to do this work. It was also a review which
 15 we could do on a batch basis, which the research
 16 laboratory lended itself to do.
 17 COFFEY, Q.C.:
 18 Q. The idea of processing a lot of samples, kind of in
 19 bulk as it were.
 20 DR. PRITZKER:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. It's set up more for that, a particular type of
 24 sample?

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1 DR. PRITZKER:
 2 A. That's right, it could deal with things that are
 3 offline in a batch basis.
 4 COFFEY, Q.C.:
 5 Q. And now could you tell then, the Commissioner, what
 6 you recall about how you got yourself involved in
 7 this?
 8 DR. PRITZKER:
 9 A. Well, the documentation, the e-mails are in the
 10 exhibits, but essentially, first I received a phone
 11 call from Don Cook requesting assistance and we
 12 receive, from time to time, but quite often, a
 13 number of calls asking for assistance of one type or
 14 another and we try to accommodate, even though
 15 there's usually very little capacity in our system,
 16 and as you can see from the exhibit, the request was
 17 for a limited number of cases and for a limited time
 18 period. So we did offer our help and then we
 19 determined how we could get this done.
 20 COFFEY, Q.C.:
 21 Q. I take it this initially here is referring to maybe
 22 dealing with anywhere from 30 to 40 cases per month,
 23 possibly over a three-month period. I take it that
 24 refers to current cases, 30 to 40, about one a day?

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1 DR. PRITZKER:
 2 A. That's correct, and but we did expect to receive the
 3 material in batches of five or six at a time,
 4 something like this.
 5 COFFEY, Q.C.:
 6 Q. Now sir, what then happened?
 7 DR. PRITZKER:
 8 A. Well, this is 2005, as I recall, the actual work
 9 started somewhere in November of 2006, in terms of--
 10 not in terms of this, but in terms of the look back
 11 stuff. So for the period of 2005 to that period,
 12 the work was being performed and there was really no
 13 difficulty or strain on the part of our laboratory.
 14 COFFEY, Q.C.:
 15 Q. Just in terms of that, Doctor, I'm just going to ask
 16 you, because I understand, in fact, the look back
 17 started in '05 actually, in September. So this is
 18 August of--I think we just looked at August of '05.
 19 DR. PRITZKER:
 20 A. Right.
 21 COFFEY, Q.C.:
 22 Q. So you just said '06. I'm just wondering -
 23 DR. PRITZKER:
 24 A. Well, I believe it was '06 where the big work was

1 done, but -
 2 COFFEY, Q.C.:
 3 Q. Well, I'll take you then to some of the documents,
 4 Doctor.
 5 DR. PRITZKER:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Now just in terms of that, just so the Commissioner
 9 has some sense of what, you know, how much
 10 involvement you, yourself, would have in this, when
 11 you were first asked by Dr. Cook, like "can you
 12 help?" who if anyone internally did you check with
 13 first?
 14 DR. PRITZKER:
 15 A. Well, we were--this was a request to perform
 16 services because there was some question about
 17 whether the interpretation and whether the staining
 18 had been correct in the original place. So the first
 19 thing which we did was, in our discussions, was to
 20 determine what we would have to do to assure that
 21 our staining was completely at the leading edge of
 22 standards, and so we reviewed what we were doing.
 23 Those standards have changed and evolved over the
 24 years. Fortunate to have people such as Dr.

1 Donald Cook. The subject is ER and PR consultation,
 2 immunohistochemistry, and you said "Don, this is to
 3 ask your advice about billing for our services," and
 4 you go on to talk about that, and you say "you may
 5 be happy with this arrangement, however,
 6 particularly if you never see the dollars or the
 7 budget, however, this arrangement is not specific to
 8 pathology services, nor was it designed for 'look
 9 backs' such as the studies to be performed on ER or
 10 PR negative tissues. The alternative is for Mount
 11 Sinai Hospital to bill you directly, and one
 12 suggestion is to bill in usual way for active
 13 consultations and to bill you directly for the
 14 services associated with review of the negatives.
 15 Please advice. Thanks, Ken."
 16 So I take it that this was, of course, dealing
 17 with Dr. Cook to straighten out, well, somebody's
 18 got to pay--you know, in terms of how it will be
 19 billed for.
 20 DR. PRITZKER:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. Somebody has to pay for it, and you were suggesting
 24 here that for active consultations, I take it which

1 O'Malley and others who are experts in what
 2 standards should be present. So we did that. We
 3 reviewed our standard operating protocols. The next
 4 question was how were we going to get this work
 5 done, and so we had to line up both the technical
 6 work and the professional work involved, and we
 7 basically asked Maria, who's expert at organizing
 8 technical work, to lead that and to work with Cindy
 9 Dunn and Trish to ensure that the processes which we
 10 were doing were identical to those which would be
 11 going on in the routine laboratory.
 12 I did this with Dr. Mullen, who is my
 13 associate, as he is a very active, very experienced
 14 surgical pathologist, does participate in the breast
 15 pathology and is quite expert in processes, in terms
 16 of organizational processes to get work done. So
 17 those were the people we talked with, as well as
 18 with Frances O'Malley, of course.
 19 COFFEY, Q.C.:
 20 Q. And if we could, please, Exhibit P-1706? Now
 21 Doctor, these are two e-mails, one of August 10th--
 22 well, both of them are August 10th, 2005, one just
 23 internal to Eastern Health, but the one below, it's
 24 from yourself, August 10, 2005, 4:12 p.m. to Dr.

1 would be generally the current cases ongoing?
 2 DR. PRITZKER:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. You would bill through the usual OHIP/MCP whatever?
 6 DR. PRITZKER:
 7 A. That's correct. That is the means in place for
 8 interprovincial payments for direct patient
 9 services. It was never designed for laboratory
 10 services, but it's the way we've been doing things.
 11 COFFEY, Q.C.:
 12 Q. And in the alternate, and is also though to bill
 13 Eastern Health directly for the services associated
 14 with the review of the negatives, like the past
 15 cases?
 16 DR. PRITZKER:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. Okay, if we could, please, Exhibit P-0567? And
 20 Doctor, this is an e-mail from Donald Cook, Dr. Cook
 21 to yourself, Thursday, August 11th 2005. The
 22 subject is ER and PR consultations. He writes "Hi,
 23 Ken. Regards to billing, your suggestion is good.
 24 You can bill for active consultation and bill me

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1 directly for the services employed in the review of
 2 the negative ERS. I'm hoping to send our reviews
 3 for the years 2003 and 2002 as soon as we can
 4 compile these cases, hopefully by the end of next
 5 week. We will submit the other years following
 6 these. I will contact Maria when we are ready to
 7 send these cases for your help. Once again, thanks
 8 for all your help." Signed Don.
 9 And then to give yourself some sense of at
 10 least what the documentation that I'm going to be
 11 showing you suggests, if you'll look, please, at
 12 Exhibit P-1707? This is an e-mail, Doctor, from
 13 Nancy Good to Dr. Brendan Mullen. The subject is
 14 ER/PR list. It's sent September 13th, 2005 and Ms.
 15 Good writes "Hi, Dr. Mullen. Here is the list of
 16 all the patients we have received blocks from so
 17 far. The ones highlighted in blue have been
 18 stained," and I'm not going to take you through
 19 them, pages in the attachment, but there are ten
 20 pages listing patients, specimen numbers, I take it,
 21 prepared for Dr. Mullen as of September 13th.
 22 Doctor, who is Nancy Good?
 23 DR. PRITZKER:
 24 A. Nancy Good is a technologist, quite an experienced

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1 technologist, who was working in
 2 immunohistochemistry at the time.
 3 COFFEY, Q.C.:
 4 Q. And what was her involvement in this, do you know,
 5 your understanding?
 6 DR. PRITZKER:
 7 A. I don't know all the details actually. It looks,
 8 from the e-mails, that she was one of the people,
 9 maybe the main person, who was responsible for, on a
 10 technical side, keeping all things in order. She
 11 was--actually, Nancy is in the--was in the histology
 12 laboratory. She was so very experienced
 13 technologist, she was also working with Maria Mandes
 14 on the research things. So this hybrid aspect that
 15 we needed some of the resource from the main
 16 histology laboratory and we needed some of the
 17 resource from the research laboratory, which
 18 involved Nancy.
 19 COFFEY, Q.C.:
 20 Q. And just then when you say you wouldn't know all the
 21 details of this, and that was really a point I
 22 wanted to make with you is that it would be Dr.
 23 Mullen and Nancy Good and Maria Mandes who would, in
 24 fact, be, from your perspective, by that point in

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1 time -
 2 DR. PRITZKER:
 3 A. Absolutely.
 4 COFFEY, Q.C.:
 5 Q. - charged with actually getting it done?
 6 DR. PRITZKER:
 7 A. That kind of detail.
 8 COFFEY, Q.C.:
 9 Q. You having agreed, on behalf of the hospital, to
 10 have the hospital participate and do it and made the
 11 arrangements, it would be left to Dr. Mullen and
 12 company to -
 13 DR. PRITZKER:
 14 A. That's right. The set up of these spreadsheets and
 15 so on was something which I'm sure that Maria and
 16 Brendan did and as part of a way of keeping track of
 17 all this material.
 18 COFFEY, Q.C.:
 19 Q. If we could, please, Registrar, just again to give
 20 the Commissioner some sense of what stage the review
 21 retesting process was at various points in time,
 22 Exhibit P-1708, please? And Dr. Pritzker, this is
 23 an e-mail from Nancy Good, Thursday, October 20th,
 24 2005. It's to Dr. Cook, but it's copied to Dr.

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1 Mullen, Maria Mandes and yourself. The subject is
 2 ER/PR blocks, and the attachment is block
 3 discrepancies.xls. Ms. Good writes "Hi, Dr. Cook.
 4 Maria would like to know if we will be receiving any
 5 more blocks for retesting and if so, approximately
 6 how many more? Everything has been logged into our
 7 database (we have approximately 547 patients)
 8 although some don't have an RS number yet. Please
 9 find the attached list of block discrepancies and
 10 other notes. If you have any questions, please give
 11 me a call." So I take it you'd be copied on this,
 12 Doctor, at that point in time, just simply to keep
 13 you in the loop, as it were?
 14 DR. PRITZKER:
 15 A. That's right. That's our practice is to try to keep
 16 everybody involved by e-mail. RS stands for
 17 research service number.
 18 COFFEY, Q.C.:
 19 Q. Yes, and I take it by this--that suggested, I take
 20 it, that by that point in time, there were about 547
 21 retests in the queue as it were or some, I
 22 understand, had already been reported, but in total
 23 received up to then.
 24 If we could, please, Exhibit 1703? Doctor,

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1 this is a series of e-mails. The earliest in time
 2 is October 20th, 2005 at 2:38 p.m. It's from George
 3 Tilley to Dr. Robert Bell, and he refers, the
 4 contents of it, a conversation Mr. Tilley apparently
 5 had with Dr. Bell. Do you know Dr. Robert Bell?
 6 DR. PRITZKER:
 7 A. Very well.
 8 COFFEY, Q.C.:
 9 Q. Okay. Who is he?
 10 DR. PRITZKER:
 11 A. Robert Bell is currently the president and chief
 12 executive officer of the University Health Network,
 13 but before he had that--before he took on that
 14 position, he was head of surgical oncology and he
 15 was also the lead sarcoma surgeon in Toronto. So he
 16 was a--he's a colleague of mine, who we worked very
 17 closely together over many, many years, on the
 18 sarcoma service.
 19 COFFEY, Q.C.:
 20 Q. University Health Network, Doctor, could you tell
 21 the Commissioner what is that?
 22 DR. PRITZKER:
 23 A. University Health Network is a corporate entity
 24 which incorporates three hospitals, the Toronto

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1 General Hospital, the Toronto Western Hospital, and
 2 the Princess Margaret Hospital. They have three
 3 different functions, but they have one corporate
 4 governance and administration.
 5 COFFEY, Q.C.:
 6 Q. And here in this context, the bottom of the first
 7 page of the exhibit, there's a reference to "our
 8 laboratory clinical chief," that would be Don Cook,
 9 in this context, "will be contacting the two
 10 individuals you referenced to also see what insight
 11 they can offer in terms of national follow," and
 12 when we look up above there, sir, at October 23rd,
 13 2005, Dr. Bell has sent or sends an e-mail
 14 responding to Mr. Tilley and copies it to Bruce
 15 Youngson and Dr. Frances O'Malley, and the
 16 Commissioner met Dr. O'Malley this morning, but
 17 who's Dr. Bruce Youngson, do you know?
 18 DR. PRITZKER:
 19 A. Dr. Bruce Youngson is a breast pathologist at
 20 University Health Network and he's a professional
 21 colleague of Frances O'Malley's.
 22 COFFEY, Q.C.:
 23 Q. And this, I take it, on October 24th 2005, that
 24 October 23rd e-mail was forwarded by Dr. O'Malley to

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1 yourself for your information, I take it.
 2 DR. PRITZKER:
 3 A. Right.
 4 COFFEY, Q.C.:
 5 Q. With a view, I take it, because she was referenced
 6 in it.
 7 DR. PRITZKER:
 8 A. She was referenced and she was aware that it might
 9 have downstream implications for us, and that I
 10 should be alerted to that.
 11 COFFEY, Q.C.:
 12 Q. If we could, please, Exhibit P-1306? Now Dr.
 13 Pritzker, this is an e-mail from George Tilley,
 14 October 20th, 2005, to yourself. Subject is ER/PR
 15 testing. He writes "Hi, Ken. Just wanted to thank
 16 you again for talking with me this morning. I
 17 appreciated the opportunity to talk through this
 18 difficult issue with you and get your advice. There
 19 appears to be a growing body of evidence and opinion
 20 that there are many questions inherent with this
 21 ER/PR test. Even for me as a non-clinician, it
 22 raises eyebrows. As a member of the Board of
 23 Canadian Patient Safety Institute, I wanted to
 24 ensure that if there were"--I'm sorry, "if there are

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1 learnings from our experience, we will share it.
 2 Having said that, I understand that Ontario already
 3 has a comprehensive accreditation program in place
 4 for its labs. Our clinical"--I'm sorry, "our
 5 laboratory clinical chief will be contacting the
 6 Canadian Association of Pathologist and others that
 7 we may subsequently identify. It appears that there
 8 is a gap in terms of a national entity who can take
 9 the lead with this issue. So we are likely to have
 10 a shotgun approach"--I'm sorry, "to take a shotgun
 11 approach to the follow up and hope that there is
 12 someone who can keep it moving." Signed George. Do
 13 you recall speaking with Mr. Tilley?
 14 DR. PRITZKER:
 15 A. Yes, I do.
 16 COFFEY, Q.C.:
 17 Q. Could you tell the Commissioner, please, about that?
 18 DR. PRITZKER:
 19 A. Yes, well Mr. Tilley phoned me and outlined the
 20 problems as he saw it and actually informed me of
 21 the depth of the problems, at least, on a greater
 22 insight as to what we were dealing with that it was
 23 a much larger issue than we had appreciated before.
 24 And he did ask questions and inquired of whether I

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1 had suggestions for how to enhance quality in a
 2 system. The accreditation program that he refers to
 3 is the Ontario Laboratory Accreditation Program
 4 which was instituted about nine years ago as an
 5 outgrowth of how to, how to ensure quality in the
 6 laboratory settings and it was modelled after the
 7 College of American Pathologists Program, it has a
 8 slightly different emphasis, much more emphasis on
 9 the technical aspects than the College of American
 10 Pathologists Program. We participate in both of
 11 these, and he did ask about national activities and
 12 I'm sure I explained to him, which he already knew
 13 very well, that the--in Canada our health systems
 14 are operated as provincial systems, so all of the
 15 operations are provincially based, that the various
 16 kinds of national organizations and the Federal
 17 government have responsibilities for setting
 18 standards, but have no capacity for or have very
 19 limited capacity, I would say, for ensuring those
 20 standards, that responsibility is the responsibility
 21 of a Provincial governments and the societies and
 22 organizations and is done differently in each
 23 province.
 24 COFFEY, Q.C.:

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1 Q. And you did just, several minutes ago, refer to some
 2 initiative, I gather, that started in Newfoundland
 3 about, oh at least it was a meeting, I take it here
 4 in Newfoundland, several, two or three--two and a
 5 half years ago?
 6 DR. PRITZKER:
 7 A. The initiative that I referred to is the
 8 pathologist's assistant initiative.
 9 COFFEY, Q.C.:
 10 Q. Yes, okay.
 11 DR. PRITZKER:
 12 A. As would be an example of fostering a group of
 13 health professionals that--emerging group of health
 14 professionals that are needed for the kinds of
 15 things which we do. The Canadian Association of
 16 Pathologists has also been very active over the
 17 years in advocating standards for many things, one
 18 notably is the storage--guidelines for the storage
 19 of slides and blocks and reports, but many other
 20 kinds of guidelines over the years as well.
 21 COFFEY, Q.C.:
 22 Q. Now -
 23 THE COMMISSIONER:
 24 Q. Can I just interrupt for a second while this is in

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1 my mind?
 2 COFFEY, Q.C.:
 3 Q. Sure.
 4 THE COMMISSIONER:
 5 Q. The activities that the Canadian Association of
 6 Pathologists in, as you describe it, I think,
 7 promoting standards.
 8 DR. PRITZKER:
 9 A. Uh-hm.
 10 THE COMMISSIONER:
 11 Q. Then I'm assuming that's just what it is, it's just
 12 a group of people who are interested who will say
 13 "we suggest" and that's as far as the power goes?
 14 DR. PRITZKER:
 15 A. Yes, that is as far as the power goes, for example
 16 in the kinds of recommendations that they make, it's
 17 quite a persuasive power because it represents the
 18 consensus of the leadership of Canadian pathologists
 19 and it's usually developed reflecting the consensus
 20 of pathologists worldwide. So when these
 21 recommendations come along, they've got a very
 22 substantive basis, but the actual implementation of
 23 those recommendations are either at a provincial
 24 level or even at a local level if there's not a

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1 specific provincial directive and very seldom is
 2 there a provincial directive.
 3 THE COMMISSIONER:
 4 Q. When you say "provincial directive" you mean as in
 5 provincial government directive of some kind?
 6 DR. PRITZKER:
 7 A. That's correct.
 8 THE COMMISSIONER:
 9 Q. Thank you.
 10 COFFEY, Q.C.:
 11 Q. Exhibit P-0386 please? Now, Doctor, I'm just going
 12 to put this in context, that e-mail from Mr. Tilley
 13 of October 20th is at the bottom of the first page
 14 of this exhibit. On October 26th, 2005, you
 15 apparently forwarded that on to--that e-mail, to Dr.
 16 Brendan Mullen and Dr. Donald Cook, subject is
 17 "ER/PR testing" and you write, "Brendan and Don,
 18 there may be an opportunity here, pathologists
 19 advocacy and patient safety initiatives. May assist
 20 finding resources for pathology labs, even restoring
 21 the autopsy to prominence, worth thinking about.
 22 Signed KP." Doctor, in this context what does that
 23 e-mail refer to and what are you contemplating?
 24 DR. PRITZKER:

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1 A. Well I think no matter what the laboratory is in
 2 this country over the last, well maybe even for much
 3 longer than ten years, the resources have not kept
 4 pace with the needs and the demands that have been
 5 placed upon us. There is also whatever guidelines
 6 and reasonable advice we can provide on quality, I
 7 think virtually every laboratory has had to make
 8 choices because of budget constraints and we would
 9 try to make those choices as wisely as we can and to
 10 make sure that everything we do is safe and well
 11 done, but I think we're saying that you--that there
 12 is a resource issue, amongst other things, and that
 13 as professionals, we should be taking advantage of
 14 every opportunity when a problem has been identified
 15 to responsibly respond and use the difficulty to try
 16 to redress the problem and obtain the resources so
 17 that we can get solutions to put these kinds of
 18 problems in the past.

19 COFFEY, Q.C.:

20 Q. If we could, please, exhibit P-0682, Doctor, these
 21 are two e-mails of November 16th, 2005, the first of
 22 them at 3:32 p.m., it's from Dr. Cook to yourself
 23 and he writes, "Hi, Ken, I would like to thank you
 24 and your department for your ongoing efforts in

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1 helping us deal with this very difficult situation.
 2 We are getting a lot of pressure for faster
 3 reporting of the retro cases. In speaking to the
 4 'powers that be' I have repeated to them that Mount
 5 Sinai is operating at full capacity and that
 6 resources are limited. This appears to be the
 7 general state of laboratory medicine today in
 8 Canada. There is very little flexibility in the
 9 system, especially when it comes to our pathology
 10 manpower situation and the shortages we are
 11 experiencing. If there is any way Mount Sinai can
 12 speed up the process, I would certainly appreciate
 13 it. In the meantime the issue if 'national
 14 standards for immunohistochemistry testing' will be
 15 on the agenda for our next executive meeting of the
 16 Canadian Association of Pathologists in late
 17 November. There may be a good opportunity to make
 18 this a national issue to bring to the Federal
 19 Minister of Health, along with the need for
 20 additional human and financial resources for our
 21 labs. Issues surrounding patient safety and
 22 national standards for all aspects of laboratory
 23 medicine. I will keep you posted on any
 24 developments. Many thanks. Signed Don Cook." And

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1 then the same day you responded to Dr. Cook at 6:54
 2 p.m. saying, "Don, we have done 200 with 500 to go.
 3 As we were at capacity, we had just received a batch
 4 stainer which I'm told can go live next week, then
 5 the pressures will be on us for interpretation. We
 6 will try to get this stuff out as soon as we can. I
 7 had a good chat with Bev earlier in the afternoon.
 8 Cheers, Ken." So in mid November then, what was the
 9 state of affairs, Doctor?

10 DR. PRITZKER:

11 A. Okay, so it is 2:05, I appreciate being reminded.
 12 At this time we were undergoing a consideration of
 13 upgrading the technology in the immunohistochemistry
 14 laboratory and we were undergoing an expansion of
 15 our research services laboratory, and we were under
 16 a great deal of strain because not only were we at
 17 full capacity in our regular laboratory, we were
 18 close to full capacity in our research laboratory
 19 and we were trying to make efforts to expand both.
 20 So that was the scene. The batch stainer for
 21 immunohistochemistry works exactly the same way,
 22 it's actually manufactured, I believe, by the same
 23 company, as the other automated stainer, the ones in
 24 the routine laboratory are designed to have each

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1 slide stained with a different immunohistochemical
 2 stain; the batch stainer is designed so that you can
 3 put through many slides for the same stain.

4 COFFEY, Q.C.:

5 Q. If we could, please, exhibit P-1710?

6 DR. PRITZKER:

7 A. So Judith John is our--was, she just left, our
 8 communications and marketing individual and Jeannine
 9 Banack is the vice-president at the time who related
 10 to the laboratory and obviously when there are--when
 11 there is news that affects us, it's important to
 12 communicate that to the administrative folks in our
 13 environment, so that's what this letter is about.

14 COFFEY, Q.C.:

15 Q. And that says as of December 4th, 2005.

16 DR. PRITZKER:

17 A. Yeah.

18 COFFEY, Q.C.:

19 Q. It's an internal e-mail. And just one or two points
 20 in it I wanted to refer you to, the second last
 21 paragraph reads, "The amount of work involved"--and
 22 that's the work, the current cases for Newfoundland
 23 and the retesting--"the amount of work involved is
 24 very large and is a great burden for us, as we were

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1 pushing capacity with our existing work; however, we
 2 agreed to take this on as it was important to
 3 Newfoundland to have confidence in the repeated
 4 results and for Mount Sinai Hospital, this was a
 5 national service to assist patient care. Naturally
 6 the patients and the politicians in Newfoundland are
 7 anxious to have these studies completed as soon as
 8 possible. We are too, but realistically this will
 9 take a few months until everything is completed.
 10 Our peers in Newfoundland understand this well and
 11 are appreciative; however the pressures from the
 12 press and public continue. Signed Ken." So,
 13 Doctor, as of the beginning of December, 2005, I
 14 take it your earlier e-mail referred to this batch
 15 stainer and Mount Sinai had gathered, like the
 16 machinery resource that it needed to increase its
 17 capacity and I take it it was a matter of getting
 18 it, bringing that on line, getting slides produced
 19 and then allowing Dr. Mullen the opportunity to
 20 actually review the many, many slides?
 21 DR. PRITZKER:
 22 A. Yes, and we'd like you to take note of the date,
 23 it's December 4th, so that within two weeks,
 24 somewhere December 15th, the laboratory ordinarily

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1 starts to ramp down for two weeks to give people a
 2 break, but in this particular case we kept this
 3 process going through the entire season and I must
 4 say, at a personal cost of our folks who had to work
 5 through that period, but it was done.
 6 COFFEY, Q.C.:
 7 Q. If we could, please, exhibit P-1342? Doctor, this
 8 is two e-mails, but the one at the top of the page
 9 here from yourself, December 20th, 2005, 5 p.m. to
 10 Dr. Cook, copied to Dr. Mullen, Maria Mandes and Dr.
 11 Williams, you write and it's an update on ER/PR,
 12 "Don, as of today everything is tracking towards a
 13 successful completion at end of January, 2006. All
 14 the best for the holidays and the New Year. Signed
 15 Ken."
 16 DR. PRITZKER:
 17 A. Uh-hm.
 18 COFFEY, Q.C.:
 19 Q. So that is consistent with your memory that this was
 20 going on through -
 21 DR. PRITZKER:
 22 A. That's right and that's what was happening.
 23 COFFEY, Q.C.:
 24 Q. If we could please, exhibit P-1075? Again, there

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1 are a couple of e-mails here of January 9th, 2006,
 2 we're into. The first is from Dr. Cook to Brendan
 3 Mullen, effectively asking on behalf of the vice-
 4 president of Medical Services here in St. John's as
 5 to when they might expect to receive further results
 6 and Dr. Mullen, on January 9th, at 4:30 p.m.,
 7 responded to Dr. Cook, but also copied you, saying
 8 "Yes, they will all be reported by the end of
 9 January. When do you plan to re-institute the
 10 ER/PR, HER2 assessment for the current cases?
 11 Signed Brendan Mullen." So I take it by that point
 12 and we'll hear more from Dr. Mullen on this, but it
 13 was anticipated, I take it at that point in time
 14 that Dr. Mullen would finish up his review of the
 15 retests by the end of January.
 16 DR. PRITZKER:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. And there was at least thought being given by him
 20 and Mount Sinai at large that St. John's might be or
 21 asking when St. John's would be in a position to
 22 take on their own current work again.
 23 DR. PRITZKER:
 24 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. And in that context, Doctor, well I'll ask you this,
 3 does Mount Sinai have enough work to do without
 4 doing Newfoundland's work?
 5 DR. PRITZKER:
 6 A. Well our challenge is on a continuing basis is to
 7 meet the demands of the work that's thrust upon us
 8 and we tend to be a place that gets asked to do
 9 things when other people can't cope or don't have
 10 the resources, and if we can't do it, there isn't
 11 another place where it's easy to get it done, so we
 12 try to accommodate what we can do and we try to grow
 13 our operation so we can sustain these kind of
 14 things, but it's a continuing exercise, I must tell
 15 you.
 16 COFFEY, Q.C.:
 17 Q. If we could, please, exhibit P-1711? Doctor, this
 18 is an e-mail from Brendan Mullen, Dr. Mullen of
 19 January 20th, 2006, it's to Dr. Cook but it's copied
 20 to yourself and others and Dr. Mullen writes,
 21 "Attached please find the ER/PR results for the
 22 Newfoundland and Labrador retrospective review. The
 23 initial report of the ER/PR results has been revised
 24 for seven cases due to restaining of the material

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1 when the initial specimen was negative and the
 2 internal controls were either negative or absent."
 3 And he names--he identifies those cases by number
 4 and continues "When you have the opportunity to
 5 review the results, I would like to discuss some of
 6 the technical difficulties we encounter with
 7 processing and staining of specimens. Some of the
 8 same issues are present in the current Newfoundland
 9 and Labrador material." And I'll be asking Dr.
 10 Mullen about that latter statement, but I take it
 11 then by the January 20th, 2006 from Mount Sinai's
 12 perspective, the end was in sight in terms of the
 13 retesting?
 14 DR. PRITZKER:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. And this is your advice. Doctor, there is an
 18 exhibit I would like to refer you to, it's P-1713.
 19 I appreciate this is--it's an e-mail of May 16th,
 20 2007 from yourself to Joseph Mapa?
 21 DR. PRITZKER:
 22 A. Yes, Joseph Mapa is the president of Mount Sinai,
 23 probably the most informed CEO about laboratories in
 24 the country because he and I had been working

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1 together on this for a very long time and again,
 2 that was--and Mr. Stationwala is the current VP who
 3 relates to laboratories.
 4 COFFEY, Q.C.:
 5 Q. And here, the text reads, "Breast cancer
 6 diagnostics, the media, TV, radio and newspapers
 7 have been discussing Newfoundland problem of
 8 unreliable results for breast cancer diagnostics
 9 with adverse patient consequences. Lab is blamed
 10 but it is also clear that lab was severely under
 11 resourced, consequences of 'picking on labs' for
 12 cost savings happens everywhere in Canada. A race
 13 to the bottom in cost without understanding patient
 14 care consequences. For this stuff, PLM was
 15 referenced lab to compare with original Newfoundland
 16 results. So far Mount Sinai hospital has received
 17 good press. Signed Ken." Now this, Doctor, would
 18 be just after this broke in the media nationally on
 19 May 15th.
 20 DR. PRITZKER:
 21 A. Uh-hm.
 22 COFFEY, Q.C.:
 23 Q. You were writing, I take it, to let your president
 24 know internally that if Mount Sinai's name came up,

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1 as it were, in the context it did, to give him at
 2 least a heads up this was doing on. You do, though,
 3 refer here to--and you've got it in quotes "picking
 4 on labs for cost savings". Doctor, you've got a
 5 long career and what did you observe over the years
 6 in terms of that?
 7 DR. PRITZKER:
 8 A. The laboratories are obviously a vital and central
 9 portion of health care, but they're also one which
 10 is one step removed from the patients, so whenever
 11 they--whenever there is pressures on a health care
 12 system, the word goes out that it should be clinical
 13 care that should be preserved and that everything
 14 else should be truncated. And unfortunately the
 15 laboratory--it becomes interpreted that the
 16 laboratories should be one of those areas for "cost
 17 savings". There is also in Canada a private
 18 laboratory industry which, by and large, works in
 19 ambulatory care, not in hospital care, which has a
 20 whole different rhythm to it. They, naturally,
 21 proclaim that they're great and that the hospital
 22 laboratories are extraordinarily expensive, but in
 23 fact that's not the case, the hospital laboratories
 24 are doing different things under very different

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1 conditions, even if they're doing some of the same
 2 tests, they're doing it under very different
 3 conditions. It's one thing to provide a test on a
 4 batch basis, it's another thing to provide a test in
 5 five minutes, this type of thing. So where this is
 6 a private e-mail, perhaps, as part of my efforts to
 7 share information and view points with the
 8 administrative leadership of Mount Sinai, but I
 9 would stand by the statement.
 10 COFFEY, Q.C.:
 11 Q. Yes, and that's why, in fact, I gathered, that's why
 12 I raised it because at exhibit P-1714 please? This
 13 is an e-mail, Dr. Pritzker from yourself, May 19th,
 14 2007 to the same individuals. I'm not going to take
 15 you through it, it's just, I gather it's more, the
 16 same sentiment, just more elaborated upon.
 17 DR. PRITZKER:
 18 A. That's correct and I haven't seen the details beyond
 19 the screen there, haven't looked at that for some
 20 time, but I can say that the efforts by our staff
 21 were no less than extraordinary, it was really quite
 22 complex, there was a very, very large amount of work
 23 and it was done as best we could and I think as far
 24 as I could see, it was a model of its type and I

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1 really would--wasn't aware of where else there was a
 2 precedent at that time.
 3 COFFEY, Q.C.:
 4 Q. And if we could, please, exhibit P-0978? Doctor,
 5 this is a letter of July 19th, 2007, it's from a
 6 Robert Thompson, the Deputy Minister of Health in
 7 Newfoundland at the time, addressed to yourself and
 8 he writes, "I'm writing in follow up to your
 9 conversation on Tuesday, July 17th with Mr. Don
 10 MacDonald of the Newfoundland and Labrador Centre
 11 for Health Information. As Mr. MacDonald noted, the
 12 Department of Health and Community Services is
 13 carrying out a review of events surrounding ER/PR
 14 testing of breast cancer patients in Newfoundland
 15 and Labrador." And he goes on at some length and
 16 concluding with "Specifically I am requesting the
 17 following data fields for the period of January 1,
 18 '97 to December 31, 2005." And he has fifteen
 19 different types of data specified, so he's looking
 20 for, I take it, information at that point. If we
 21 can look, please, at exhibit P-0990? And this is a
 22 letter on Mount Sinai Hospital letterhead, Pathology
 23 and Laboratory Medicine. It's August 3rd, 2007, to
 24 Mr. Thompson, it's from yourself and it--you write,

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1 "Dear Mr. Thompson, thank you for your letter of
 2 July 19th, 2007 enclosed. Mount Sinai Hospital will
 3 be pleased to provide the information requested in
 4 database format to the Government of Newfoundland
 5 and Labrador in the very near future." So I take it
 6 that even after the retesting was all done, when the
 7 government approached Mount Sinai in the summer of
 8 '07, you undertook to provide the data requested?
 9 DR. PRITZKER:
 10 A. Yes, I want to comment on this.
 11 COFFEY, Q.C.:
 12 Q. Yes.
 13 DR. PRITZKER:
 14 A. The request was for extremely sensitive data which
 15 is very patient specific and so what we did was we
 16 actually validated all of the people who were asking
 17 this were the people who were supposed to be asking
 18 for this, that the data would be kept confidential,
 19 that the--and that no patient specific data would be
 20 revealed and we received those assurances, we
 21 validated those assurances and we then undertook to
 22 transmit the data in the most confidential way that
 23 we were advised could be done.
 24 COFFEY, Q.C.:

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1 Q. And in terms of that, and I did skip over a couple
 2 of lines, in exhibit P-0990? Page 3, in fact,
 3 that's the letter from Mr. Thompson of--if I could,
 4 Doctor, of July 19th, 2007. He concluded by saying,
 5 "I assure you that any data provided by Mount Sinai
 6 Hospital to the Centre for Health Information on
 7 behalf of the Department of Health will be held in
 8 the strictest confidence and will only be used by
 9 the Department of Health in carrying out the
 10 aforementioned review." So there was certainly that
 11 assurance given.
 12 THE COMMISSIONER:
 13 Q. Mr. Coffey, when you find a convenient place, we'll
 14 take the afternoon break.
 15 COFFEY, Q.C.:
 16 Q. Doctor, one question I did have in the exhibit we
 17 looked at just several minutes ago, you did refer to
 18 the idea that the problem in Newfoundland is perhaps
 19 due to or at least the laboratory in Newfoundland
 20 was perhaps under resourced. What was your source
 21 of that knowledge? What led you to believe that?
 22 DR. PRITZKER:
 23 A. The source of that knowledge was, I guess, periodic
 24 discussions which I had had with Don Cook and with

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1 probably others that were more informal, of what the
 2 resources were like compared to resources enjoyed by
 3 other hospitals which we knew.
 4 COFFEY, Q.C.:
 5 Q. And had you met Dr. Cook before this particular
 6 matter?
 7 DR. PRITZKER:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. How long have you known Dr. Cook?
 11 DR. PRITZKER:
 12 A. It goes back some way.
 13 COFFEY, Q.C.:
 14 Q. Okay.
 15 DR. PRITZKER:
 16 A. I know him as a professional colleague at national
 17 meetings and this kind of thing.
 18 COFFEY, Q.C.:
 19 Q. If we could break, Commissioner, thank you.
 20 THE COMMISSIONER:
 21 Q. Take the afternoon break.
 22 (RECESS)
 23 THE COMMISSIONER:
 24 Q. Please be seated. Mr. Coffey.

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1 COFFEY, Q.C.:

2 Q. Thank you, Commissioner. Doctor, one final

3 question, national--for example, national standards

4 for laboratory medicine, or standards applied

5 nationally, what sorts of organization or

6 organizations would be required to be engaged in

7 order to formulate such standards?

8 DR. PRITZKER:

9 A. Well, it starts with the professional societies, not

10 just the physicians but the other professional

11 societies. There are regulatory groups, such as the

12 Royal College of Physicians and Surgeons of Canada,

13 but really that's a regulatory group for examination

14 standards and continuing education standards. In

15 order to have standards that are implementable, both

16 provincial advocacy groups, provincial medical

17 societies, technology organizations and provincial

18 regulatory groups, such as the, in Ontario it would

19 be the College of Physicians and Surgeons of

20 Ontario, might need to be involved. In Ontario, in

21 a lab field, there are two organizations, one is the

22 Ontario Laboratory Accreditation, which is mandatory

23 and is really run as a joint effort by the Ontario

24 Medical Association and the Ministry of Health and

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1 Long-term Care and also the sort of long-standing

2 program, the Quality Management Laboratory Services,

3 which involves proficiency testing and other kinds

4 of audits. So it's actually quite a large set of

5 groupings to promote standards. I would say though

6 that it's not--we're not looking at national

7 standards. It should be the same standard wherever

8 these procedures are done, in whatever country it's

9 done, whatever jurisdiction it's done, and we need

10 to not invent our own wheel with respect to the

11 standards, but to work together to be part of really

12 it's an international effort and increasingly, that

13 seemed to be so.

14 COFFEY, Q.C.:

15 Q. And where laboratory medicine is concerned, and in

16 particular, immunohistochemistry, IHC, I take it,

17 are they almost there or just beginning?

18 DR. PRITZKER:

19 A. Well, in all of the technological developments, it's

20 rare you get to the end. It's a continuing

21 evolution. It turns out that staining itself,

22 specific staining, is an art form that's been very

23 useful and it's been a substrate part of our

24 infrastructure for about 150 years, and it's

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1 gradually becoming a science or the science is

2 gradually becoming incorporated into it and it's

3 gradually going from a qualitative science to a

4 quantitative science, and we're just really at the

5 beginning of the quantitative aspects of it.

6 COFFEY, Q.C.:

7 Q. I take it that translates into we still have -

8 DR. PRITZKER:

9 A. We have a long way -

10 COFFEY, Q.C.:

11 Q. - you're never ultimately -

12 DR. PRITZKER:

13 A. We have a way to go. We have a way to go here, but

14 it's compounded by the fact that it's not something

15 that's totally new. It's something that's been with

16 us for some time and those processes, to remodel

17 those processes and to move those processes forward

18 is actually more work than something which would

19 come about as a brand new advance.

20 COFFEY, Q.C.:

21 Q. Thank you, Commissioner, they're the questions I

22 have. Other counsel might have some questions for

23 you, Doctor. Thank you.

24 THE COMMISSIONER:

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1 Q. Mr. Pritchard?

2 MR. PRITCHARD:

3 Q. Commissioner, I have no questions for this witness.

4 Thank you, Dr. Pritzker.

5 THE COMMISSIONER:

6 Q. Mr. Simmons?

7 DR. KENNETH PRITZKER, EXAMINATION BY MR. DANIEL SIMMONS

8 MR. SIMMONS:

9 Q. Thank you, Commissioner. Good afternoon, Dr.

10 Pritzker. I'm Dan Simmons. I'm the counsel for

11 Eastern Health. Thank you very much for making the

12 trip to share your knowledge on this subject with

13 us. You, I understand, have been involved in

14 pathology laboratory medicine since before

15 immunohistochemistry was a regular and standard part

16 of the testing processes, I believe?

17 DR. PRITZKER:

18 A. That's correct.

19 MR. SIMMONS:

20 Q. Can you give us maybe some overview of how

21 immunohistochemistry has grown over the time that

22 you've been involved in laboratory medicine, and

23 some appreciation maybe of whether the complexity of

24 the tests have increased and what maybe the

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1 significant changes or challenges have been with IHC
 2 testing, as you've seen it over the years? Big
 3 question.
 4 DR. PRITZKER:
 5 A. Sure. Well, when I began pathology, and that's
 6 close to 40 years ago, there were antibodies that
 7 were used to stain tissues to determine the presence
 8 of particular substances. They were florescent and
 9 there were very few of them, maybe three or four
 10 that were in common use. The change to a method
 11 which could use a bright field microscope, an
 12 ordinary microscope, started to occur in the mid
 13 1970s and I recall was initially one stain, and it
 14 was a stain that could be used to assist the
 15 pathologist to provide some information about what
 16 type of tissue, what type of cells was there, but
 17 was not related in any way to a therapy that was
 18 being offered.
 19 Somewhere in the early 1980s or around 1980,
 20 there was the beginning of automation and year by
 21 year, the numbers of these tests increased, and by
 22 the 1990s, the automation was quite extensive and
 23 there was conversion of methods that had been
 24 previously done by chemistry techniques, such as the

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1 ligand assay for the estrogen receptor and
 2 progesterone receptor to immunohistochemical
 3 techniques. So it was growing and growing.
 4 I can say that at the present time, in our
 5 laboratory, we have about 150 antibodies, which
 6 estrogen receptor and progesterone receptor are only
 7 two. That our volumes are increasing
 8 disproportionate to the number of specimens and to
 9 the growth in other work in our laboratory. So it's
 10 a very, very substantial thing and growing and
 11 continuing to grow. It's also, with--perhaps it's
 12 about five to seven years that there's been
 13 attention to trying to determine these assays with
 14 some increasing quantitation. I believe that Dr.
 15 O'Malley explained to you that the current standard
 16 is zero or one plus, two plus, three plus. Those
 17 are reasonable ways of dividing off the results.
 18 They compare reasonably well whether you put some
 19 numbers on the one plus, two plus or three plus or
 20 whether this is done by the subjective judgment of a
 21 pathologist or qualified delegate, but it's not good
 22 enough--well, it's not optimal, because there's
 23 still a greater range of prognosis within each of
 24 those categories than might be warranted if we had

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1 better ways of quantitation. There's a great deal
 2 of effort going on, in our place, but also in other
 3 places around the world, to try to achieve this.
 4 MR. SIMMONS:
 5 Q. So in relation to the ER/PR test specifically, which
 6 you're speaking of now, I understand, although the
 7 test is, I think, quite useful, I understand to be
 8 quite useful as it's currently applied, I gather
 9 you'd be suggesting that there's still much room for
 10 improvement in how you quantify the results of the
 11 test and use it in the clinical environment?
 12 DR. PRITZKER:
 13 A. That's correct. In many different kinds of
 14 processes in medicine, there are things which we
 15 would like to be able to do and which people are
 16 working to try to achieve.
 17 MR. SIMMONS:
 18 Q. You mentioned earlier some of your observations
 19 regarding when times are tight in health care and
 20 resources are scarce, it's the direct patient care
 21 that gets the emphasis and services like laboratory
 22 are often put in the second rank, where resources
 23 are applied. I'm paraphrasing. You expressed it
 24 much more eloquently. Am I right in recalling that

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1 it was during the 1990s, the late 1990s, that health
 2 care in Canada went through a period of restraint,
 3 starting with the Federal Government and restraint
 4 in the money that the Federal Government was putting
 5 into health care, transferring to the provinces for
 6 that purpose. Recall that as being around that time
 7 period?
 8 DR. PRITZKER:
 9 A. I certainly did.
 10 MR. SIMMONS:
 11 Q. Does that coincide reasonably well with some of this
 12 period in the growth of complexity and numbers of
 13 tests and the demands on the immunohistochemistry
 14 services in Canada?
 15 DR. PRITZKER:
 16 A. First, I would like to say that the pathology lab
 17 medicine services are direct patient care.
 18 MR. SIMMONS:
 19 Q. Yes.
 20 DR. PRITZKER:
 21 A. They're not always recognized that way, but they are
 22 direct patient care, and I would like to emphasize
 23 that to you and to others. There was a constraint
 24 that started in probably the late 80s, early 90s,

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1 that related to patient care in a very--that
 2 resulted in a very substantial squeeze on laboratory
 3 services, which that was never really the subject of
 4 largesse. So we were always marginal. So we had
 5 the squeeze at the same time as where we've
 6 experienced throughout my career, a continuing
 7 growth in terms of the advocacy and demand for
 8 laboratory services and this growth is accelerating
 9 actually. Laboratory services are becoming more
 10 relevant to health care than ever and so it's a
 11 greater challenge for us to obtain the resources to
 12 get this work done well.

13 MR. SIMMONS:
 14 Q. I expect you'd agree with me that Mount Sinai is
 15 regarded as a leader in Canada in areas such a
 16 immunohistochemical testing and laboratory services.

17 DR. PRITZKER:
 18 A. We try.

19 MR. SIMMONS:
 20 Q. Through those time periods where resources have been
 21 scarce and demands have been growing, how has Mount
 22 Sinai coped with those pressures and maintained its
 23 quality of service in the immunohistochemistry area?
 24 DR. PRITZKER:

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1 A. Well, we have had some special opportunity and the
 2 special opportunity for us came about that
 3 independently of the services which we provided for
 4 patients, we've been providing services for
 5 industry, same kinds of services. So it's basically
 6 been a process of mixing and matching those
 7 resources that have enabled us to be able to cope
 8 with this.

9 MR. SIMMONS:
 10 Q. So the services provided through your research
 11 laboratory then, if I understand correctly, may have
 12 provided some financial supplement to the services
 13 that you provided to your clinical lab and from what
 14 Dr. O'Malley has told us, also meant that you had to
 15 apply very stringent standards in the research lab
 16 performance of this testing.

17 DR. PRITZKER:
 18 A. That's correct. That is one of the key factors.
 19 The other is that we deliberately set out to recruit
 20 individuals who would be leaders in their fields.
 21 They develop their own research and they also
 22 develop their own connectivity to other leaders in
 23 the field. So we basically have early warning, if
 24 you will, certainly knowledge of what's out there,

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1 what's coming down the pipe and so on.

2 MR. SIMMONS:
 3 Q. We've heard quite a bit in the media, certainly
 4 here, and I think somewhat nationally in recent
 5 months about a national shortage of pathologists,
 6 difficulties recruiting and here in Newfoundland
 7 certainly in retaining. What has your experience
 8 been at your institution with recruitment and
 9 retention of pathologists and finding enough
 10 qualified people to meet the requirements that you
 11 have?

12 DR. PRITZKER:
 13 A. Well, it's exceptional. We have--first, there was a
 14 time in the mid 90s where they virtually cut off the
 15 training of laboratory physicians, and making it
 16 very difficult for anybody to recruit, because the
 17 supply had been cut off. That was a unwise
 18 decision, but that was the health planners'
 19 decision. It wasn't ours. At Mount Sinai, we have
 20 to recruit not only people who are competent, but
 21 people who have got a special interest in a subject
 22 and people who are interested in the academic side,
 23 the research and teaching. So it's a very
 24 specialized pool. To do so, basically we've had to

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1 do long range planning and we've managed that
 2 reasonably successfully. I think our faculty is
 3 quite good and knowledge of it is quite good. But
 4 it takes some time to recruit folks. We've been
 5 fortunate in our place, with all the difficulties,
 6 to provide an environment to retain these folks and
 7 the folks that have moved on from us have actually
 8 moved to positions where we couldn't hold them
 9 because they were going to a senior leadership
 10 position somewhere or something like this.

11 MR. SIMMONS:
 12 Q. Are there any particular advantages to being able to
 13 retain pathologists in your service for a longer
 14 period of time, versus having them move on and be
 15 replaced by others?

16 DR. PRITZKER:
 17 A. Yes, there's huge advantages, not only for
 18 pathologists, but for other staff. Also, just while
 19 my mind's on it, say that the shortage is beyond
 20 pathologists. It's also technologists.

21 MR. SIMMONS:
 22 Q. Yes.

23 DR. PRITZKER:
 24 A. And you should be aware of that. The advantage is

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1 that it takes time to build and operate a culture
 2 where people are talking together and understanding
 3 each other and so continuity within the department,
 4 continuity between the professionals on the lab side
 5 and the clinical people is extremely important in
 6 building quality of care.

7 MR. SIMMONS:
 8 Q. Okay. How do these things, your Mount Sinai's
 9 ability to cope with financial pressures in the IHC
 10 lab, the recruitment and retention of pathologists
 11 and technologists, in your observations, how do
 12 those compare with what you've seen in other
 13 institutions in Ontario or in Canada and their
 14 ability to cope with those kinds of pressures?

15 DR. PRITZKER:
 16 A. Well, it's fair to say that we've done better in
 17 terms of coping than our peer institutions, but
 18 we're also the only laboratory that was not subject
 19 to any mergers, amalgamations, or other kinds of
 20 disruptions over that period. We're the only--I
 21 wouldn't call it survivors, but the only people who
 22 managed to emerge from this without any interruption
 23 to our programs.

24 MR. SIMMONS:

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1 Q. And I gather you perceive that as having been an
 2 advantage not to have had to participate in mergers
 3 and amalgamations?

4 DR. PRITZKER:
 5 A. Yes, it was actually quite difficult to achieve, but
 6 it was a very major advantage.

7 MR. SIMMONS:
 8 Q. Right, and what are your observations about what
 9 disadvantages there may have been to others who had
 10 to go through mergers and amalgamations in this
 11 period?

12 DR. PRITZKER:
 13 A. Well, there was inevitable discontinuity of
 14 organization.

15 MR. SIMMONS:
 16 Q. Um-hm.

17 DR. PRITZKER:
 18 A. I can't speak to specific situations because I
 19 wasn't inside them, but I can--we can see from the
 20 Ontario experience where they had a wholesale change
 21 of services about circa year 2000 that there was a
 22 period of time, two or three or four years where
 23 there were a lot of difficulties in just obvious
 24 communication because people either had just arrived

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1 or they were just departing or they weren't there,
 2 and that was reflected in the kinds of work that was
 3 referred to us, for example. But I can also say
 4 that as those organizations rebuilt themselves, so
 5 the last couple of years, for example, they're
 6 becoming stronger and stronger and it's going--but
 7 there is an opportunity cost, there has been an
 8 opportunity cost related to the quality, related to
 9 all of the various kinds of mergers and
 10 reorganizations. And unfortunately, there hasn't
 11 been very much in the way of achievement in what was
 12 set out to be done, which was cost savings, if one
 13 looks very hard at this. That's not to say that
 14 reorganization shouldn't ever happen but they have
 15 to done with care.

16 MR. SIMMONS:
 17 Q. You've mentioned that in Ontario there is a program
 18 for laboratory, I think it's accreditation, that's
 19 the QMPLS program?

20 DR. PRITZKER:
 21 A. That's more proficiency testing. The accreditation
 22 is a separate body.

23 MR. SIMMONS:
 24 Q. Okay. So there is accreditation for laboratory

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1 services in Ontario?

2 DR. PRITZKER:
 3 A. That's correct.

4 MR. SIMMONS:
 5 Q. And that's a provincial accreditation?

6 DR. PRITZKER:
 7 A. That's correct.

8 MR. SIMMONS:
 9 Q. Are you familiar with the, I'm sure you are, with
 10 the Canadian Council on Health Services
 11 Accreditation, CCHSA?

12 DR. PRITZKER:
 13 A. That's right, they're now Accreditation Canada, I
 14 believe.

15 MR. SIMMONS:
 16 Q. Oh, okay.

17 DR. PRITZKER:
 18 A. They've changed the name once again.

19 MR. SIMMONS:
 20 Q. Okay. Can you tell me, if you can, what kind of
 21 role the accreditation services provided by CCHSA
 22 plays in looking at laboratory services if, in fact,
 23 it does at all?

24 DR. PRITZKER:

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1 A. Sure. That's evolving. In the past they would
 2 accredit hospitals on a periodic basis, usually
 3 every, at one point it was every four years, but say
 4 every three years, and it was a comprehensive
 5 accreditation of which the laboratories were a very
 6 small part.
 7 MR. SIMMONS:
 8 Q. Um-hm.
 9 DR. PRITZKER:
 10 A. And what they were looking for in the past was that
 11 the standards were there. They were looking to see
 12 that the standards were actually implemented on the
 13 ground.
 14 MR. SIMMONS:
 15 Q. Um-hm.
 16 DR. PRITZKER:
 17 A. That's all changed. And in the current, past two
 18 years, they've become, that particular organization
 19 has changed its philosophy completely, and as I
 20 understand it, the accreditation process now is one
 21 which involves tracers of activity. So the auditors
 22 would come in and they would say, well, I want to
 23 look at this, and then they would go up and down
 24 that process to see that it was being done as it was

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1 said to be done.
 2 MR. SIMMONS:
 3 Q. Um-hm.
 4 DR. PRITZKER:
 5 A. That's a much more hands-on, real-time exercise and
 6 one which is, in my view, much more beneficial for
 7 quality processes. It's also a process which is
 8 similar to the good laboratory practices process
 9 which we have been experiencing in our place for
 10 many years.
 11 MR. SIMMONS:
 12 Q. Right, okay. You've told us that in your laboratory
 13 you have, I guess what we could call dedicated
 14 people whose job it is to promote quality
 15 initiatives within your laboratory services. And
 16 how long have you had that, those positions in
 17 place, that program?
 18 DR. PRITZKER:
 19 A. We put this in place at the time of the crunch of
 20 services where we--in 1993. So we had to shrink the
 21 laboratory, it was mandated that we do this, and we
 22 decided that if we were going to do this, we were
 23 going to, within the budget that was remaining, put
 24 in sufficient funding to have high quality and to

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1 have a quality program and then we had a few other
 2 things which we wanted to do, and we did all that.
 3 MR. SIMMONS:
 4 Q. At that time when you were shrinking the laboratory
 5 program, was there any consideration given to
 6 putting the responsibility for quality initiatives
 7 on those people who were managing the daily
 8 activities of the lab versus creating the separate
 9 positions?
 10 DR. PRITZKER:
 11 A. Well, it's both.
 12 MR. SIMMONS:
 13 Q. Yes.
 14 DR. PRITZKER:
 15 A. The individual was, the best way to describe it is a
 16 coach.
 17 MR. SIMMONS:
 18 Q. Yes.
 19 DR. PRITZKER:
 20 A. Okay. And the quality is part of the responsibility
 21 of all of the folks in the laboratory irrespective
 22 of their qualifications. And our desire at that
 23 time was to standardize protocols across sections of
 24 the laboratory to ensure that the operations were

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1 according to the protocols and there were two ideas
 2 behind it, one idea, of course, was to raise the
 3 quality and partly as it differentiated and partly
 4 because that's what should be done, and also if we
 5 could put a system of quality across the entire
 6 laboratory and do it in a uniform way, our overheads
 7 would be, would decrease. Ultimately once you
 8 achieve quality, that's the cheapest way to go.
 9 MR. SIMMONS:
 10 Q. Okay. You were asked, I think, if you are aware of
 11 any other situation analogous to what happened here
 12 in Newfoundland where the hospital here asked your
 13 institution to do a retest for a seven-year period,
 14 a look back. I believe I understood you to say that
 15 you weren't aware of anything like that having been
 16 done previously?
 17 DR. PRITZKER:
 18 A. That's correct.
 19 MR. SIMMONS:
 20 Q. So to your--had you been asked back in--maybe you
 21 were, back in 2005 by anyone from Newfoundland is
 22 there anyone we can go to whose got some experience
 23 with this to give us some help as to how to handle
 24 this large retesting issue, would you have been

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1 aware of anyone who had had any kind of experience
 2 like that?
 3 DR. PRITZKER:
 4 A. Well, certainly if had been or we had thought of it,
 5 we would have mentioned those folks, it was--we want
 6 to try and have the work done, any work done in the
 7 place where it's most appropriate.
 8 MR. SIMMONS:
 9 Q. Yes.
 10 DR. PRITZKER:
 11 A. Yeah.
 12 MR. SIMMONS:
 13 Q. I was thinking more in lines of advice about how to
 14 manage the issue, someone who would give them
 15 something like that for -
 16 DR. PRITZKER:
 17 A. Again, again if there is any--if we had thought of
 18 it or we could have thought of where to go, we would
 19 have asked for the advice ourselves.
 20 MR. SIMMONS:
 21 Q. Oh, yes, I'm sorry, I misunderstood.
 22 DR. PRITZKER:
 23 A. Or we would have directed the folks in Newfoundland
 24 to those people.

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1 MR. SIMMONS:
 2 Q. So there was no where you knew to refer?
 3 DR. PRITZKER:
 4 A. No. We did, we did discuss this, as well, we did do
 5 a small literature search to see whether there had
 6 been case studies that could be helpful to us, but
 7 we didn't find very much.
 8 MR. SIMMONS:
 9 Q. Um-hm, okay. And finally, I wonder if you want,
 10 it's up to you, I'm interested in knowing if you
 11 have any views on where the delivery of complex lab
 12 services is going or should be going in Canada,
 13 because the complexity has been increasing, the
 14 demands have been increasing, is there a direction
 15 that you foresee that's a preferable way to manage
 16 these issues in the country in the future?
 17 DR. PRITZKER:
 18 A. Well, this a question which, of course, we could
 19 spend a lot of time on and which we've had a lot of
 20 thought about and talked over the years about. The
 21 lab services are complex services, no question about
 22 that. And part of the complexity involves the
 23 intimate interaction with both the clinical folks
 24 and the support folks, so that it's not possible to

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1 have one large regional laboratory, sort of one
 2 restaurant in town.
 3 MR. SIMMONS:
 4 Q. Um-hm.
 5 DR. PRITZKER:
 6 A. Because if you do this, then the interaction with--
 7 it's very difficult to maintain the interaction on
 8 the clinical side. It's also not possible to do
 9 every test in every laboratory.
 10 MR. SIMMONS:
 11 Q. Um-hm.
 12 DR. PRITZKER:
 13 A. And the traditional--the traditional way of
 14 operating regional labs and in Canada the historical
 15 way was to have one, in the small provinces, one
 16 laboratory in each province which would do high-end
 17 tests and the small laboratories would refer to
 18 that. It was basically a mountain and a plane
 19 model. The--we can't do, it's not a sustainable
 20 model because we need to have the expertise
 21 everywhere, so we need to migrate to a networked
 22 model. We need to be able to have a model in which
 23 the centres such as ours engage in peer review just
 24 as other laboratories do for all our services. And

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1 this creates some difficulties because if you're the
 2 only place in the province or the only place in the
 3 country, where do you get that peer review? Well,
 4 the answer is you get that peer review from a peer
 5 laboratory anywhere else in the world that was
 6 willing to work with you. And in our case we've
 7 done this with a few laboratories. The--strongly,
 8 I'm strongly in favour of this model of essentially
 9 capacitating the groups in the field, okay, that are
 10 out in the regions because it is important to be
 11 able to have local presence of the expertise that
 12 can work with the clinical peers, but that expertise
 13 has to be supported and supported on a peer basis by
 14 access to resources and assistants and interaction
 15 with more academic centres is the traditional term
 16 for it. We're now in a position--we weren't in a
 17 position that this could be done easily a decade
 18 ago, but we are in a position now that this could be
 19 done because we have the means of communication.
 20 This process today is being watched, I don't know
 21 how far away, but it's certainly available anywhere
 22 in the world, right now.
 23 MR. SIMMONS:
 24 Q. Um-hm.

1 DR. PRITZKER:
 2 A. And so is any of our expertise. So we need to learn
 3 how to exchange expertise amongst ourselves in new
 4 ways and I think this is imminently feasible.
 5 MR. SIMMONS:
 6 Q. Thank you, very much, Dr. Pritzker. I don't have
 7 any other questions for you.
 8 COMMISSIONER:
 9 Q. Thank you, Mr. Simmons. Mr. Browne?
 10 DR. KENNETH PRITZKER, EXAMINATION BY MR. PETER BROWNE
 11 MR. BROWNE:
 12 Q. Thank you, Commissioner. Good afternoon, Dr.
 13 Pritzker. I did mention to you over the break that
 14 I may be introducing some articles. I think you
 15 have copies, you've just been given copies by the
 16 Registrar. But before I refer to them, I just want
 17 to follow up on a--there's two areas that I actually
 18 wanted to sort of canvas with you, Doctor, and the
 19 first relates to a question by my colleague, Mr.
 20 Simmons, concerning, I guess, the financial crisis
 21 facing labs in the early 1990s, and you explained
 22 how your institution dealt with that. And just to
 23 sort of tie that in with the whole evolution, the
 24 Romanov report dealt with, I guess, some of the

1 EXHIBIT P-1727 ENTERED INTO EVIDENCE.
 2 EXHIBIT P-1767 ENTERED INTO EVIDENCE.
 3 MR. BROWNE:
 4 Q. Thank you. Doctor, this is, and this sort of
 5 follows on the last question you were asked by Mr.
 6 Coffey about--and you commented there's a need for
 7 international standardization in the area of
 8 immunohistochemistry. Did I understand that
 9 correctly?
 10 DR. PRITZKER:
 11 A. Yes.
 12 MR. BROWNE:
 13 Q. And, in fact, the article that I have here and
 14 hopefully will just walk through it in a minute, is
 15 from the Applied, or the Applied
 16 Immunohistochemistry and Morphology, the June, 2007
 17 article. The individuals that are listed here,
 18 would you consider these leaders, I guess, in the
 19 field of immunohistochemistry, this Dr. Goldstein,
 20 Dr. Taylor among several individuals?
 21 DR. PRITZKER:
 22 A. Yes, I certainly know Doctors Taylor, Hewitt,
 23 Goldstein and they are, yes.
 24 MR. BROWNE:

1 problems that developed with the under funding of
 2 the health care system as a result of that time
 3 period. And am I correct in understanding that the
 4 Canadian Association of Pathologists, in fact, made
 5 a submission to the Romanov Report with regard to
 6 the effect of, I guess, these financial constraints
 7 on the lab system, and if so, are you aware of that?
 8 DR. PRITZKER:
 9 A. I believe they did, but I don't recall the details
 10 of what was said.
 11 MR. BROWNE:
 12 Q. Are you aware whether, in fact, it made its way into
 13 the Romanov Report in any consideration?
 14 DR. PRITZKER:
 15 A. I'm not aware of that detail and I'm not aware of
 16 either the status of either the Romanov Report or
 17 the Kirby Report on the impact of health care in
 18 this country.
 19 MR. BROWNE:
 20 Q. Thank you. The second area and I'll refer to those
 21 now, Registrar, if we could have entered, please,
 22 Exhibit 1727, Commissioner, please, and 1767?
 23 COMMISSIONER:
 24 Q. Entered.

1 Q. And this article is entitled "Recommendations for
 2 Improved Standardization of Immunohistochemistry" and
 3 is coming out in June of 2007.
 4 CROSBIE, Q.C.:
 5 Q. Can we see it?
 6 MR. BROWNE:
 7 Q. Sorry.
 8 REGISTRAR:
 9 Q. Which number is that?
 10 MR. BROWNE:
 11 Q. Oh, I'm -
 12 THE COMMISSIONER:
 13 Q. On my list is 1767.
 14 MR. BROWNE:
 15 Q. 1767, I don't have that. I apologize. Okay, sorry.
 16 And if we could just follow down here back to--we'll
 17 just see now, that's--it came out in June of 2007
 18 and as you've acknowledged, several of these
 19 individuals--as a matter of fact, they're members of
 20 the ad hoc committee on immunohistochemistry
 21 standardization. Is this a committee--we've heard
 22 several committees from the United States referenced
 23 by Dr. O'Malley this morning, is this CAP or another
 24 committee?

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1 DR. PRITZKER:
 2 A. I'm not sure who this particular committee reports.
 3 It says, in fact, it's an ad hoc committee. So, my
 4 guess is that it's a group of leaders in the
 5 immunohistochemistry field and I'm not sure of the
 6 journal, but I suspect that the journal is supported
 7 by this particular interest group in terms of -
 8 MR. BROWNE:
 9 Q. In effect -
 10 DR. PRITZKER:
 11 A. - (unintelligible) article, things like this.
 12 MR. BROWNE:
 13 Q. If we jump ahead to the end, Doctor, which is a good
 14 observation, you'll see and that's at page 130,
 15 acknowledgments that the ad hoc committee--sorry,
 16 let's go back here -
 17 DR. PRITZKER:
 18 A. It's the DAKO Corporation.
 19 MR. BROWNE:
 20 Q. The DAKO Corporation, correct.
 21 DR. PRITZKER:
 22 A. DAKO is one of the larger suppliers around the world
 23 of immunohistochemical reagents. It's reasonably
 24 standard practice for large corporations to provide

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1 grants in aid to professional groups to try to work
 2 towards developing standards.
 3 MR. BROWNE:
 4 Q. Okay. And in fact, if we look at what's in that
 5 acknowledgment section for a moment, it says that
 6 this meeting was held in, these recommendations in
 7 the body of this article flow from a meeting in
 8 August of 2006 in Santa Barbara which seems to
 9 suggest that this was the first ever international
 10 course on immunohistochemistry molecular morphology
 11 DR. PRITZKER:
 12 A. Well, it would not be the first course on
 13 immunohistochemistry, far from it, right, or it
 14 would be--these individuals together or separately
 15 have, I know Dr. Taylor for sure, has provided
 16 courses in other venues that would relate to how to
 17 do immunohistochemistry towards standardization.
 18 What this represented was a group of experts meeting
 19 perhaps for the first time in this context to try to
 20 address the issue of standardization. And what they
 21 appear to have done or what they have done and I
 22 have read this article before, was they collated the
 23 literature and put in order many of the
 24 considerations that are required, that they feel are

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1 required for quality immunohistochemistry. All of
 2 this is dependent on the current state of
 3 immunohistochemistry reagents.
 4 MR. BROWNE:
 5 Q. Right.
 6 DR. PRITZKER:
 7 A. That's a very important statement. As the reagents
 8 improve, then the kinds of things that would have to
 9 do, the numbers of checks and balances, the quality,
 10 all kinds of things like this might change as the
 11 reagents become more robust.
 12 MR. BROWNE:
 13 Q. Okay.
 14 DR. PRITZKER:
 15 A. The reagents are quite robust now, but as you can
 16 see from this ten pages or so, there's a large
 17 number of very specialized conditions that are
 18 required to achieve an excellent result. The object
 19 of the exercise would be to achieve the
 20 standardization and also to reduce the number of
 21 preconditions in order to achieve that quality.
 22 MR. BROWNE:
 23 Q. And if we could, if we look at the first page,
 24 Doctor, you'll see the first paragraph, third line

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1 there says, "recognized over a decade ago that IHC
 2 assay standardization was vital for reproducible and
 3 reliable results". Do you see that sentence? If
 4 you drop down, it says in the second paragraph on
 5 the right hand column there, it says, "despite the
 6 improvements of reagents automation", excuse me,
 7 "authors of the years have consistently noted
 8 inconsistent quality of IHC assays". So, I guess
 9 what the authors are saying is that even in 2007,
 10 there's still inconsistency noted despite all these
 11 articles and -
 12 DR. PRITZKER:
 13 A. That's correct and where it says that prior
 14 consensus conferences identified the likely
 15 causative factors, that was actually published and
 16 it was published in year 2000, that's reference 14.
 17 MR. BROWNE:
 18 Q. But despite that, these authors recognizes there's
 19 still -
 20 DR. PRITZKER:
 21 A. Still problems.
 22 MR. BROWNE:
 23 Q. - problems. And, in fact, just to go over to the
 24 next page, if we could, page 125, you'll see, the

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1 right hand column again, the first full paragraph
 2 beginning with, and I'll just--just bear with me.
 3 Okay, I'm on the right page and I'll put my cursor
 4 there. You'll see, actually, I have the cursor
 5 there, "given the increasing role IHC assays play as
 6 a predictive marker of oncology therapeutic agent
 7 response, faster turnaround time and laboratory
 8 costs containment should not be prioritized as goals
 9 ahead of the laboratory procedures required for
 10 reliable, accurate and reproduced by IHC assays".
 11 So, this again comes back to the point, I think
 12 you've been making throughout your testimony here
 13 today, that there has to be recognition that these
 14 things do, cost containment measures and so on will
 15 have an effect on the end product.
 16 DR. PRITZKER:
 17 A. Yes, the costs, whatever they are, are very small
 18 fraction of the costs for patient care that result.
 19 And if the patient care proceeds without the quality
 20 laboratory result, essentially it's an appropriate
 21 utilization of services. And with the predictive
 22 markers, these are ones which, on the basis of the
 23 task, a therapeutic decision is made, the potential
 24 for cost savings and the potential for decreased

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1 patient risk by high quality laboratory testing is
 2 extreme. We're talking about yes or no to therapy
 3 which is potentially in the tens of thousands of
 4 dollars per patient and has, and therapy, which has
 5 its risks which--so, the therapy shouldn't be
 6 offered to patients that have a small chance or no
 7 chance of benefitting from that therapy.
 8 So, all of this is relatively new, the
 9 realization of this is relatively new. Even though
 10 the HER2/neu marker has been around for some time,
 11 the realization that it does have this kind of cost
 12 benefit impact is new and the idea that the test
 13 must be done at recognized high quality is
 14 relatively new.
 15 MR. BROWNE:
 16 Q. We heard from Doctor O'Malley this morning, Doctor,
 17 that in fact, sort of the whole role out has been
 18 turned on its head, for instance. HER2/neu has come
 19 out and there are standards in place as it is coming
 20 out, whereas that wasn't the case for IHC and ER/PR,
 21 these standards are now only starting to become
 22 developed, isn't that the case?
 23 DR. PRITZKER:
 24 A. Yes, there's the evolution of this is quite

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1 interesting. The estrogen receptor, progesterone
 2 receptor story is one that evolved over 40 years.
 3 The Her2/neu story is one that has evolved over
 4 somewhere about 15 to 20 years, actually, since the
 5 beginning of it. I'm now involved in the next one,
 6 which is K-ras testing, which has evolved over six
 7 months. So the pace of pressure on us to evolved
 8 testing is increasing very dramatically and it's
 9 actually happening faster than any part of the
 10 system can absorb at the moment, but it is there and
 11 from a patient standpoint it's a very good thing.
 12 We're now having more and more powerful diagnostics
 13 which affect therapeutics. This trend is going to
 14 increase and the rate of ascent of this trend is
 15 going to increase for the foreseeable future.
 16 MR. BROWNE:
 17 Q. Doctor, just moving ahead on this article, as a
 18 matter of fact, what I've attached, as well, is an
 19 interview which came out as a result. Now, Doctor,
 20 just on that point, to go back to your answer, while
 21 I might find this, is any of this sort of change in
 22 approach due to cause and effect given what has
 23 happened with ER/PR that it's recognized that we now
 24 need to come at this in a different perspective and

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1 develop these standards much more early on in the
 2 process?
 3 DR. PRITZKER:
 4 A. Absolutely.
 5 MR. BROWNE:
 6 Q. Okay.
 7 DR. PRITZKER:
 8 A. You know, traditionally the way the testing goes
 9 from the research laboratory to the service
 10 laboratory is to adopt and refine a research-based
 11 test. Increasingly that's not the case. What's
 12 happening in most recent times is that a test is
 13 offered on a service basis or would be offered on a
 14 service basis after the reagent has been perfected
 15 and validated sufficient for national regulatory
 16 authorities such as Health Canada and the FDA in the
 17 United States. And increasingly it would be a
 18 standard analyte specific reagent, the standard
 19 reagent for the test that was manufactured would be
 20 very consistent rather than in the remote past where
 21 some of these things would be made in a adjacent
 22 research laboratory.
 23 MR. BROWNE:
 24 Q. Now, Doctor, what I have on the screen here now, is

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1 at 1767, page 11, is, in fact, a question and answer
 2 session with the same authors. And I just want to
 3 sort of go over a couple of points, the first, and
 4 it's in relation to the recommendations that these
 5 authors made. And you just note here in bold type
 6 that the authors seem to suggest that right now
 7 we're stuck with formaldehyde, that's the best
 8 alternative we have for fixation and there's--it's
 9 because especially in relation to
 10 immunohistochemistry it's the most proven fixative
 11 in terms of the assay results. Do you agree with
 12 the authors in respect to that observation?
 13 DR. PRITZKER:
 14 A. Well, I would say the statement in bold is a
 15 provocative statement. The, I guess it's at the
 16 back here, so I can actually read it. It's a
 17 provocative statement in that, in fact, formalin is
 18 quite safe used in appropriate ways. It's a natural
 19 product that is present in our environment.
 20 Obviously if it is used in an uncontrolled setting,
 21 it does cause irritation and so on, but we have
 22 occupational standards which are applied that ensure
 23 that in Canada, at least, that the environment is
 24 quite safe. We actually monitor formalin in our

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1 laboratories. So it is, well, so it is safe and it
 2 is a--it is cheap and it is effective. And there
 3 are, from time to time, novel ways of trying to fix,
 4 fix tissues. And what we're trying to say is, when
 5 we say fix tissues, is preserve the capacity to
 6 identify the molecules, in the case of
 7 immunohistochemistry, that's what we're trying to
 8 do. So there are ways of doing it, methods such as
 9 freezing, which has its own difficulties,
 10 microwaving is another technology. So I do expect
 11 the technologists to change and to evolve, but I
 12 don't see replacement of formalin fixation in the
 13 very near future.
 14 MR. BROWNE:
 15 Q. And if we just carry on further down, there's
 16 another comment there you'll see in the centre of
 17 the page, "So far no one has enforced any rule about
 18 fixation and no one has really tried." So I guess
 19 is there, again, another provocative statement, from
 20 your perspective?
 21 DR. PRITZKER:
 22 A. I think so, I think it is provocative. Most
 23 laboratories are very well aware of the properties
 24 of formalin and other fixatives, particularly

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1 alcohol fixatives and we are aware that the capacity
 2 to fix tissues decreases, for example, with time as
 3 they--as the materials become exposed to air. We're
 4 aware of, we're aware of some of the other
 5 difficulties that you need certain volumes of
 6 fixative to the amount of tissue that the, cutting
 7 the tissue in thin enough slices to get penetration
 8 in fixation is important and all that kind of thing.
 9 That's wide--that's in textbooks that histology
 10 technologists know and pathologists know and most
 11 laboratories apply that knowledge with care.
 12 MR. BROWNE:
 13 Q. Okay. Now, further on down, and maybe these are all
 14 provocative statements, Doctor, you'll see in the
 15 left-hand corner, at least on my screen, a question
 16 with regard to quality assurance standards and
 17 referenced by several--answers by several of the
 18 pathologists. And there's a reference by--or an
 19 answer by Dr. Yaziji, "The best quality control
 20 method standardizing IHC are across the Atlantic and
 21 north of the border. There is ample data to suggest
 22 that CAP proficiency testing doesn't come close to
 23 the European and Canadian systems." Are you able to
 24 comment on that statement?

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1 DR. PRITZKER:
 2 A. Well, okay. So remember, this is -
 3 MR. BROWNE:
 4 Q. This sounds like an open mic session with these -
 5 DR. PRITZKER:
 6 A. This is an open mic session in a non-peer review
 7 publication that's trying to generate interest in
 8 the standardization of immunohistochemistry, and I
 9 think it has to be taken in that context. The
 10 quality control methods and quality assurance
 11 methods that are used by the College of American
 12 Pathologists are used by our laboratory and other
 13 laboratories which has CAP inspections and has had
 14 inspections locally and by--we participate in some
 15 European groups, as well. They all have different
 16 flavours, but the quality of--and they're already
 17 useful or we wouldn't be participating in them. But
 18 none of them assure the quality in the laboratory by
 19 themselves. The assurance of quality in
 20 laboratories is the implementation of quality in the
 21 laboratory and so what is needed then is the
 22 capacity to have a really a peer review sampling of
 23 what is actually going on in the laboratory, a peer
 24 review first within the laboratory so that there's

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1 transparency of the quality processes within the
 2 laboratory by folks who are both involved in a
 3 particular process and the folks who are distanced
 4 from a particular process but are involved in
 5 quality. And second, peer review from these other
 6 kinds of exercises and a variety of them. I think
 7 blanket statements are unwarranted, they are very
 8 good laboratories in many different countries,
 9 including the United States, including Europe and
 10 including Asia and I've visited many of those
 11 laboratories on the ground and I know what they do
 12 and I've learned from them and so have my
 13 colleagues. So it's not a simple thing and it's not
 14 a matter of "policing", there's too many things to
 15 do and in terms of what needs to be done to ensure
 16 quality, so it's really a culmination of a mindset
 17 and a mindset that ensures that what we say we are
 18 doing with quality is actually done.
 19 MR. BROWNE:
 20 Q. Now, Doctor, I think within the body of either this
 21 article or the previous one, there is some
 22 suggestion by these authors that while that is the
 23 case, it is involved on an individual lab basis and
 24 hence the problem and the need, I guess, for

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1 standardizing and more importantly sharing this
 2 information among the colleagues. You'll see in the
 3 last comment there, I'm just pointing out with the
 4 cursor about the question to each of the panel
 5 members about the fact that significant changes have
 6 happened over the years at a very fast pace and I
 7 think it's up at the top here as well, sorry, "there
 8 are major developments going on in the field and it
 9 is impossible to keep up with all aspects of
 10 scientific and technological developments" and
 11 that's Doctor Badve and then you'll see Doctor
 12 Taylor who says here, it requires a coordinated and
 13 global response, which I think you've mentioned as
 14 well earlier I think in answer to Mr. Simmons'
 15 question. So I think despite all the controversy
 16 around these statements, would you agree with the
 17 last sort of observation of the pathologists?
 18 DR. PRITZKER:
 19 A. Well certainly we do need to have ongoing continuing
 20 efforts towards both modularization and
 21 standardization of health care, including laboratory
 22 services, including the technical aspects of the lab
 23 services and including, really essentially including
 24 immunohistochemistry. It's, the state of health

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1 care that these efforts which, while they may in
 2 some places be locally based, provincially based or
 3 nationally based, are in fact international. They
 4 are occurring in many aspects of health care at the
 5 moment, not just the laboratories, as you're aware,
 6 and they are a very good thing, and most of us or I
 7 would say many, many people have--are participating
 8 in various initiatives and learning the principles
 9 of how you develop this kind of consensus. I also
 10 have to say that developing consensus and
 11 standardization is not a simple thing.
 12 MR. BROWNE:
 13 Q. Right.
 14 DR. PRITZKER:
 15 A. It really isn't.
 16 MR. BROWNE:
 17 Q. Could you explain that to the Commissioner, how that
 18 sort of approach developed, please?
 19 DR. PRITZKER:
 20 A. Sure. Well it's obviously needed because you have
 21 to have one standard--it's desirable to have one
 22 standard of communication and you have to have a
 23 best practice environment. It has to be in such a
 24 way that it's not so rigid that everyone is doing

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1 exactly the same thing because everybody could be
 2 lemmings over the cliff type of approach. And what
 3 happens at the beginning of these processes and I
 4 have been involved in these processes is that people
 5 come with very different protocols, each one
 6 thinking that theirs is the best, and absolutely
 7 convinced. And first there's a discussion as to
 8 what are we looking for anyway, right, and then
 9 there's a discussion of how--what are the options to
 10 achieve it and a review of how each of the different
 11 protocols has achieved it. The next step after that
 12 is to devise a standard which can be adhered to by
 13 most competent organizations who are doing the
 14 process. If one has a process that can only be done
 15 in lab A and no place else in the world, it's not a
 16 standard because lab A can't do all the work. So
 17 these or clinic A can't do all work if it's a
 18 clinical standard, so it is--there is a evolution of
 19 these processes and typically from a first meeting
 20 to the first set of standards is somewhere between
 21 two and four years. You might be able to shrink
 22 that a bit, but that's the conversation time that it
 23 requires to evolve these standards.
 24 MR. BROWNE:

1 Q. That's all the questions I have. Thank you very
 2 much, Doctor. Thank you, Commissioner.
 3 THE COMMISSIONER:
 4 Q. Thank you, Mr. Browne. Mr. Pritchard?
 5 MR. PRITCHARD:
 6 Q. No questions, Commissioner.
 7 THE COMMISSIONER:
 8 Q. Ms. Newbury?
 9 MS. NEWBURY:
 10 Q. I just have a couple.
 11 DR. KENNETH PRITZKER, EXAMINATION BY MS. JENNIFER NEWBURY
 12 MS. NEWBURY:
 13 Q. Good afternoon, Dr. Pritzker, Jennifer Newbury for
 14 the Canadian Cancer Society, Newfoundland and
 15 Labrador Division. I just want to ask you a couple
 16 of questions. First of all, you mentioned that
 17 there were some capacity issues I guess it was
 18 straining the limits of the capacity for Mount Sinai
 19 in assisting Newfoundland in the retesting, as well
 20 as the current testing. And I'm just wondering in
 21 light of that, do you know why your lab would be
 22 chosen given those concerns that you had regarding
 23 capacity?
 24 DR. PRITZKER:

1 situations.
 2 MS. NEWBURY:
 3 Q. Okay, and you weren't able to find anything--I just
 4 want to understand -
 5 DR. PRITZKER:
 6 A. No, we didn't, it wasn't relevant to what we chose
 7 to do.
 8 MS. NEWBURY:
 9 Q. So does that mean that retrospective reviews don't
 10 take place or they don't take place with regard to
 11 ER/PR testing or is it something about the magnitude
 12 of the review, the number of years, the number of
 13 patients?
 14 DR. PRITZKER:
 15 A. It was certainly not common to have a large scale
 16 review of any type of testing, it's been a common
 17 and we've had experience in our own lab to do
 18 retrospective peer review of certain testing because
 19 there were questions asked and we wanted to satisfy
 20 folks that things were done as well as they could
 21 have been.
 22 MS. NEWBURY:
 23 Q. Okay, so retrospective reviews are done, but they're
 24 not of the same scope? I'm just trying to

1 A. Well I understand from conversations other labs were
 2 asked as well, they--I think our lab was asked
 3 because we have a reputation for trying to help
 4 other labs, that's probably why we were asked.
 5 MS. NEWBURY:
 6 Q. Okay, so there were other labs that could have done
 7 it from an experience, I guess, or reputation point
 8 of view, but were these other labs also experiencing
 9 capacity issues?
 10 DR. PRITZKER:
 11 A. I can't comment on that, I would doubt that there
 12 would be any laboratory in Canada that would have
 13 had spare capacity.
 14 MS. NEWBURY:
 15 Q. Okay. And you were also asked a bit about the look
 16 back, I guess, or the retrospective review and the
 17 fact that you weren't able to find any research
 18 regarding a retrospective study, did I understand
 19 your evidence correctly on that, you were looking
 20 how press correspond -
 21 DR. PRITZKER:
 22 A. We did look, I can't say we looked extensively, we
 23 looked at what was easily available to us or what we
 24 thought was easily available to us for similar

1 understand -
 2 DR. PRITZKER:
 3 A. Yes, so it's quite typically they're--for
 4 subspecialized testing, and this commonly goes on in
 5 laboratories around the world, there may be a
 6 question that, okay, so there's been a change in
 7 what you've been doing and is this change a result
 8 of the patient population or is it a result of your
 9 intrinsic quality in something you don't recognize
 10 and so the idea would be to take out a sample and to
 11 do this, to compare the sample with a peer
 12 laboratory, and most of the time it's a local
 13 laboratory but sometimes it's, in our case it's been
 14 international and it goes both ways, we don't do it
 15 just, send our samples to X, it's Y sends their
 16 samples to us as well. It's symmetrical.
 17 MS. NEWBURY:
 18 Q. And are there any procedures or protocols in place
 19 once you become aware of a potential issue in terms
 20 of how or whether you're required to conduct a
 21 retrospective review?
 22 DR. PRITZKER:
 23 A. No, the decision to do these things is the choice of
 24 the--at the present time is a choice of the

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1 laboratory director and this is done on the
 2 recommendation of staff and the various other kinds
 3 of pressures. You must be aware that retrospective
 4 reviews incur a very substantial sort of cost and in
 5 a typical laboratory setting, those costs would have
 6 to be absorbed by the operating budget of the
 7 laboratory, so for the most part we emphasize that
 8 we use these, you know, in a limited way and as a
 9 tool, find out what we have to find out and then
 10 spend most of our resource improving the system or
 11 moving on to the next demand for the resource I
 12 would say.

13 MS. NEWBURY:
 14 Q. Okay, so cost then would be a factor weighing
 15 against a retrospective review or perhaps the size
 16 of the retrospective review -

17 DR. PRITZKER:
 18 A. Well it's also my experience that in the, for the
 19 average set of problems which we have done these
 20 small reviews, essentially we can affirm what we
 21 already know and we're just providing some
 22 additional reassurance to folks that things were
 23 done well. So the idea, there isn't enough resource
 24 to do all these things, to have very extensive

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1 retrospective reviews all the time and I don't feel
 2 it's a cost-effective resource unless there's a
 3 particular problem has been identified. It's much
 4 better to use the scarce resources to develop
 5 quality on an ongoing basis and develop the new
 6 things which we are asked to do.

7 MS. NEWBURY:
 8 Q. Uh-hm. Would the possible advantages to patients be
 9 a factor in deciding whether or not to conduct a
 10 retrospective review when you feel there might be a
 11 potential problem?

12 DR. PRITZKER:
 13 A. Well that's what provokes the question of whether
 14 you should do a review or what action you should
 15 take is that some results, whether they're a small
 16 number or a moderate number, are discordant with
 17 what someone's perception of what the results should
 18 be.

19 MS. NEWBURY:
 20 Q. Uh-hm.

21 DR. PRITZKER:
 22 A. And further, when we look back on all of the
 23 materials that we have that state what we did and
 24 what quality and so on, we could not find the source

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1 of error that would give rise to this, so then the
 2 question is do we have it right or don't we have it
 3 right, and the way of doing that is to compare it
 4 further with another group and the reason why we do
 5 it reciprocally is because, you know, you have to be
 6 sure, you have to have some mechanism to ensure that
 7 the other group has got it right too, okay, so it's
 8 a question of sending things out to a consultant,
 9 how many consultants do you--to send the things out
 10 to. You need an objective way of assessing the
 11 advice that you are given and the materials you are
 12 given.

13 MS. NEWBURY:
 14 Q. Okay, so then are retrospective reviews conducted in
 15 situations, not just when there might be a problem
 16 but just for random purposes, I guess, for quality -

17 DR. PRITZKER:
 18 A. No, it's not random, it's usually on a--it's usually
 19 when a problem is perceived and where the source of
 20 the problem is not perceived, and it turns out that
 21 more often than not there is variation in--there may
 22 be variation in patient results, but there may and
 23 there have been in our experience variations in
 24 reagent manufacture which were not discovered by the

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1 company themselves.

2 MS. NEWBURY:
 3 Q. Uh-hm.

4 DR. PRITZKER:
 5 A. And they're very appreciative when that's found and
 6 with all of the, you know, we do somewhere in the
 7 order of 2500 different kinds of tests, so the
 8 chances of something happening somewhere along the
 9 line with something is pretty frequent, and so we
 10 do--we are aware of these things and we are trying
 11 to find ways of identifying the problem and solving
 12 the problems.

13 MS. NEWBURY:
 14 Q. Okay, and would your standard quality procedures
 15 that you have in a lab, would that be a way of
 16 perhaps minimizing the need to conduct a
 17 retrospective study in the future? Is that how you
 18 would possibly pick up -

19 DR. PRITZKER:
 20 A. That's where we go first, of course, and one of the
 21 things which we're always on the look out for are
 22 ways in which we can retrospectively and
 23 prospectively survey our material so that we can
 24 better identify deviations from quality. That's a

1 work in progress, I would say the quality in most
 2 laboratories is very high and uses industry standard
 3 processes, but I would also say that the volume of
 4 testing, the sheer volume of testing and the
 5 emerging capacity to understand the deviations from
 6 the quality by computational techniques, has
 7 promised to improve quality still further.
 8 MS. NEWBURY:
 9 Q. Thank you, those are all the questions I have.
 10 THE COMMISSIONER:
 11 Q. Mr. Crosbie, do you have any questions for this
 12 witness?
 13 CROSBIE, Q.C.:
 14 Q. I do.
 15 THE COMMISSIONER:
 16 Q. Now we're nearing the end of the day, so can I--but
 17 I understand our witness has a flight to catch, so
 18 I'm going to ask the indulgence of counsel and
 19 suggest we press on.
 20 CROSBIE, Q.C.:
 21 Q. I'm hoping this is only five minutes worth.
 22 THE COMMISSIONER:
 23 Q. All right. If that's the case, then why don't we do
 24 it now. I was going to propose if you were going to

1 numbers and we started to scope out what was
 2 required to get it done.
 3 CROSBIE, Q.C.:
 4 Q. Did you actually give them an estimate about how
 5 long it was going to take?
 6 DR. PRITZKER:
 7 A. Yes, we did.
 8 CROSBIE, Q.C.:
 9 Q. And can you tell us when that was and whether it was
 10 in writing?
 11 DR. PRITZKER:
 12 A. Well, I do know that I was informed--I believe I was
 13 informed of what it was going to take somewhere in
 14 early November, it may have been before, and I
 15 recall this because it would be a very substantial--
 16 it was a very substantial issue for us to do this in
 17 finite time. We had to reorganize a lot of
 18 resources to get this done. So I remember the scale
 19 of the problem was large. I don't remember
 20 communicating myself in writing to Newfoundland
 21 about the exact detail, but I do believe the detail
 22 was communicated by Dr. Mullen and Ms. Mandes.
 23 CROSBIE, Q.C.:
 24 Q. By, I'm sorry?

1 be any length of time, we take a short break, but if
 2 we're talking five minutes, let's press on.
 3 DR. KENNETH, PRITZKER, EXAMINATION BY CHESLEY CROSBIE, Q.C.
 4 CROSBIE, Q.C.:
 5 Q. That's, I think, all it is. In the materials we've
 6 had, we've heard that Eastern Health, and seen in
 7 documentation, had the idea that the look back was
 8 going to take maybe four weeks, six weeks originally
 9 back in the early fall period of 2005. Where would
 10 they get that idea from? Did that come from you?
 11 DR. PRITZKER:
 12 A. No, it didn't. The first materials, as you can see
 13 from the exhibit that was presented here, was 30 to
 14 40 cases a week for three months.
 15 CROSBIE, Q.C.:
 16 Q. That wasn't a look back though.
 17 DR. PRITZKER:
 18 A. No.
 19 CROSBIE, Q.C.:
 20 Q. That was the ongoing -
 21 DR. PRITZKER:
 22 A. That was the ongoing one, and so the first that we
 23 had an idea that this was a larger exercise was
 24 somewhere in mid fall when they actually gave us the

1 DR. PRITZKER:
 2 A. By Maria Mandes, who would be the coordinator of
 3 that project.
 4 CROSBIE, Q.C.:
 5 Q. Okay. Would six or eight weeks, once the scope and
 6 number of the specimens to be reviewed was known,
 7 ever be a reasonable estimate for your lab to make?
 8 DR. PRITZKER:
 9 A. I'm sorry, I don't understand the question.
 10 CROSBIE, Q.C.:
 11 Q. Would you ever have thought that this was going to
 12 take six to eight weeks once you knew the number of
 13 slides you were going to have to reexamine?
 14 DR. PRITZKER:
 15 A. Well, once we knew what we had to examine, we knew
 16 what time it was going to take us, and we -
 17 CROSBIE, Q.C.:
 18 Q. But was that six to eight weeks, when you knew that?
 19 DR. PRITZKER:
 20 A. That the work itself would take six to eight weeks?
 21 CROSBIE, Q.C.:
 22 Q. Yes.
 23 DR. PRITZKER:
 24 A. I believe that the original estimate was much longer

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1 than that, and we tried to truncate it to whatever
 2 time we could. We're now talking to--we're now
 3 somewhere in November, I believe, early November
 4 perhaps, of '05 and they wanted it before the
 5 holiday. Newfoundland wanted it before the holiday.
 6 We couldn't provide that and we felt it was going to
 7 go--I can remember conversations, it would go into
 8 March or whatever, and we tried to figure out ways
 9 in which we could supply this work faster and by the
 10 end of July--end of January, I'm sorry, end of
 11 January, we had completed the work. The memo was
 12 dated January the 20th and the work was
 13 substantially complete.
 14 CROSBIE, Q.C.:
 15 Q. Do I have the idea you had people working overtime
 16 on this outside normal working hours?
 17 DR. PRITZKER:
 18 A. That's correct.
 19 CROSBIE, Q.C.:
 20 Q. Weekends and evenings?
 21 DR. PRITZKER:
 22 A. That's correct, over the Christmas holidays.
 23 CROSBIE, Q.C.:
 24 Q. And over the Christmas holidays. Can you tell us

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1 what the unit price per, however you describe this,
 2 slide I suppose ended up being?
 3 DR. PRITZKER:
 4 A. Actually, I can't. I don't have that immediately
 5 available to me, but that information is available,
 6 but I don't have it at the top of my head.
 7 CROSBIE, Q.C.:
 8 Q. Presumably Eastern Health knows that too.
 9 DR. PRITZKER:
 10 A. Yes.
 11 CROSBIE, Q.C.:
 12 Q. Can you tell us what the gross cost to Eastern
 13 Health was?
 14 DR. PRITZKER:
 15 A. I can't tell you that either off the top of my head.
 16 CROSBIE, Q.C.:
 17 Q. It was billed -
 18 DR. PRITZKER:
 19 A. There was a costing and there was a billing, but I
 20 would have to ask for that information.
 21 CROSBIE, Q.C.:
 22 Q. This was billed directly to the Health Care
 23 Corporation here, was it?
 24 DR. PRITZKER:

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1 A. Yes.
 2 CROSBIE, Q.C.:
 3 Q. Not to the Government?
 4 DR. PRITZKER:
 5 A. The retrospective stuff was billed to the Health
 6 Care Corporation.
 7 CROSBIE, Q.C.:
 8 Q. Okay. Have you spent all the money already?
 9 DR. PRITZKER:
 10 A. As you know, we're continuing to do testing. The
 11 testing was--the services were performed at that
 12 time we did them and they were billed appropriately
 13 and what we did was to ensure that the costing and
 14 the billing was on a formula that favoured the
 15 health care system, which is quite a bit lower than
 16 our usual and customary price for this.
 17 CROSBIE, Q.C.:
 18 Q. Lower than your price for -
 19 DR. PRITZKER:
 20 A. Pharma.
 21 CROSBIE, Q.C.:
 22 Q. Pardon?
 23 DR. PRITZKER:
 24 A. Lower than our price to the pharmaceutical companies

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1 and this kind of thing.
 2 CROSBIE, Q.C.:
 3 Q. Lower than your price for the ongoing work, not the
 4 look back work, but the work you were picking up
 5 over a few months?
 6 DR. PRITZKER:
 7 A. I can't compare it. The work that was done on the
 8 look back was done on a, here's a whole group of
 9 things, and a whole group of results, rather than on
 10 a here's a case coming in here, here and here. So
 11 that those are two different kinds of conditions.
 12 CROSBIE, Q.C.:
 13 Q. Was the look back price established by negotiation,
 14 bid or a combination or how?
 15 DR. PRITZKER:
 16 A. It was basically done by--it was done by
 17 negotiation, but we offered them a price. We
 18 offered Newfoundland, the health authority a price
 19 and they accepted it.
 20 CROSBIE, Q.C.:
 21 Q. Do you know if there were any competitors for the
 22 work?
 23 DR. PRITZKER:
 24 A. I wasn't aware of anything else at the time. We

1 were not bidding on a competitive basis. We were
 2 offering to do the work because we were asked to and
 3 it was urgent and I wasn't aware--I wasn't even
 4 aware until a few weeks ago that they had approached
 5 other and had been turned down, and I wasn't aware
 6 that this was a competitive, industrial bid. I
 7 don't think we would have approached it in a way had
 8 we known that. This work produced great strain in
 9 our laboratory and we did this because we felt that
 10 it was very important for patient care, and that we
 11 recognized that there were few other places in our
 12 country, at least, that could even attempt to do
 13 this work.

14 CROSBIE, Q.C.:

15 Q. That leaves my last question. There would be labs
 16 one could find in the United States who, for the
 17 right price, would do this as well.

18 DR. PRITZKER:

19 A. That's correct, presumably.

20 CROSBIE, Q.C.:

21 Q. Reputable labs?

22 DR. PRITZKER:

23 A. Yes.

24 CROSBIE, Q.C.:

1 consistently noted the inconsistent quality of IHC
 2 assays," and then the footnote 6 through 11, and you
 3 can take your time and have a look at those if you
 4 like, they are and cover everything from Seidal et
 5 al's article, 2001, Interpretation and
 6 Quantification of Immunostains; Wick's, O'Leary,
 7 Maxwell, footnote 9, DeLellis and Taylor, C.R.
 8 Taylor, footnote 11. Okay?

9 DR. PRITZKER:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. And then he goes on to write, the authors go on to
 13 say, "unlike previous IHC epochs, most of the
 14 causative responsibility lies with the individual
 15 laboratory performing the IHC and specifically the
 16 lack of standardization and attention to quality
 17 assurance programs" and there, at footnotes 12 and
 18 13, which is the study in 2004 by Varma et al and
 19 Rhodes. Well, Rhodes publishes a number of papers,
 20 but this is a paper in particular in 2003, Quality
 21 Assurance in Immunohistochemistry.

22 And then he goes on to say "prior consensus
 23 conferences identified the likely causative factors"
 24 and they are at Table 1, which is if you turn the

1 Q. Thank you.

2 THE COMMISSIONER:

3 Q. Mr. Pike?

4 MR. PIKE:

5 Q. No questions, thank you.

6 THE COMMISSIONER:

7 Q. Mr. Clements?

8 MR. CLEMENTS:

9 Q. No, thank you.

10 THE COMMISSIONER:

11 Q. Mr. Coffey, anything arising?

12 DR. KENNETH PRITZKER, RE-EXAMINATION BY BERNARD COFFEY, Q.C.

13 COFFEY, Q.C.:

14 Q. I just have one point, Commissioner, thank you. If
 15 we could, please, Exhibit P-1676? I'm sorry, 1767,
 16 I apologize, 1767. This is that article that Mr.
 17 Browne referred you to, Doctor. Just on the first
 18 page of the exhibit, the right-hand side, first full
 19 paragraph. I think he read you the first sentence
 20 or so, but I just want to refer you to a couple of
 21 lines from it and ask for your views on what's
 22 stated here.

23 It reads "despite the improvements or reagents
 24 and automation, authors over the years have

1 page you'll see those, Table 1 on the next page,
 2 footnote 14, which is again a paper by Taylor in
 3 2000 entitled The Total Test Approach to
 4 Standardization of Immunohistochemistry, and then
 5 finally "recent studies suggest that these problems
 6 are widespread and not insignificant," and that's
 7 footnotes 15 through 17. The footnote 15 is Perez
 8 et al's study published in 2006, and then a Rhodes
 9 paper in 2001 at footnote 16 and a Rhodes paper at
 10 footnote 17 in 2000.

11 The point being, Doctor, that--and finally,
 12 toward the end of that first paragraph or full
 13 paragraph, it reads "unfortunately, laboratories
 14 often do not appreciate the negative impact on their
 15 specimens and the validity of IHC performed on them
 16 created by diverging away from these
 17 recommendations," and they have this list of
 18 recommendations.

19 And what I wanted to ask you about in relation
 20 to this, Doctor, was this: really, effectively,
 21 I'll ask you about the second sentence, "unlike
 22 previous IHC epochs, most of the causative
 23 responsibility rests with the individual laboratory
 24 performing the IHC and specifically the lack of

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1 standardization and attention to quality assurance
 2 programs." So if one takes their starting premise,
 3 which is there's a problem or problems do exist in
 4 various places concerning IHC tests, these authors
 5 do posit that, at least in their views, most of the
 6 causative responsibility rests with the individual
 7 lab performing the test. Would that be--if there
 8 are problems, ultimately -
 9 DR. PRITZKER:
 10 A. Well, the responsibility for performing all tests is
 11 that of the individual laboratories. That's a true
 12 statement, and that's a statement that is true
 13 irrespective of how many standards there are and of
 14 how many regulations there are. It relates to the
 15 implementation of the standards.
 16 Why hasn't there been a standardization? I
 17 mean, that's a question that hasn't been addressed
 18 today or this afternoon, but I think you can see
 19 that in the Table 1. There are close to 20
 20 different areas where the tests could vary, and
 21 within that, there are a number of different choices
 22 as well. So that reflects the complexity of the
 23 immunohistochemistry technology, which all of us
 24 would like to have much simpler, but that's--it

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1 reflects that technology. And then over the past
 2 decade, especially, there have been two things.
 3 One, there have been advances in the technology, not
 4 only more assays and development of the platforms
 5 and more sensitivity, but also a greater realization
 6 of what the difficulties actually are in doing this
 7 technique. So it's a greater recognition by those
 8 who are in the field and doing this, and so it was
 9 the state of the art. We're now talking about a
 10 paper that's only a year ago. It was state of the
 11 art is one which standardization isn't there yet,
 12 where there is a cry to have the field move towards
 13 standardization. This is only one of several papers
 14 that have said this kind of thing in this time
 15 range, and I think this reflects the state of the
 16 art of immunohistochemistry at that time.
 17 One can discuss the details, whether it should
 18 be this way or that way, but in fact, each of the
 19 technical details will evolve as we learn more and
 20 learn how to take all these variables and make them
 21 less variable.
 22 COFFEY, Q.C.:
 23 Q. And I take it ultimately, and if you disagree,
 24 please say so, ultimately the responsibility rests

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1 with the individual laboratory?
 2 DR. PRITZKER:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. From your perspective. Thank you. Those are the
 6 questions I have, Commissioner. Thank you.
 7 THE COMMISSIONER:
 8 Q. Thank you very much. Dr. Pritzker, I very much
 9 appreciate your having come from Ontario to assist
 10 us in the process of trying to learn more and more
 11 about this interesting subject of yours and
 12 hopefully along the way that learning process will
 13 take place. I'll keep trying.
 14 DR. PRITZKER:
 15 A. Thank you.
 16 THE COMMISSIONER:
 17 Q. Counsel, please do not turn off your computers. I'm
 18 advised by the administrative office that there will
 19 be someone arriving shortly with new exhibits and
 20 updates for you. Thank you once again. We'll meet
 21 in the morning at 9:30.

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1
 2 CERTIFICATE
 3
 4
 5 I, Judy Moss, hereby certify that the foregoing is a true
 6 and correct transcript in the matter of the Commission of
 7 Inquiry on Hormone Receptor Testing, heard on the 23rd day
 8 of June, A.D., 2008 before the Honourable Justice Margaret
 9 A. Cameron, Commissioner, at the Commission of Inquiry,
 10 St. John's, Newfoundland and Labrador and was transcribed
 11 by me to the best of my ability by means of a sound
 12 apparatus.
 13
 14 Dated at St. John's, Newfoundland and Labrador
 15 this 23rd day of June, A.D., 2008
 16
 17
 18
 19 Judy Moss

<p>-\$-</p> <p>\$45,000.00 [1] 187:22</p> <p>.-.</p> <p>'-M-a-l-l-e-y [1] 5:1</p> <p>'05 [3] 220:17,18 309:4</p> <p>'06 [2] 220:22,24</p> <p>'07 [1] 250:8</p> <p>'80s [1] 12:20</p> <p>'93 [1] 71:10</p> <p>'97 [1] 249:18</p> <p>'98 [3] 71:6,8,10</p> <p>'look [1] 223:8</p> <p>'national [1] 238:13</p> <p>'picking [1] 246:11</p> <p>'powers [1] 238:4</p> <p>-0-</p> <p>0 [1] 61:12</p> <p>0067 [1] 165:20</p> <p>-1-</p> <p>1 [8] 47:4 48:17 66:16 67:4 249:17 315:24 316:1 317:19</p> <p>10 [7] 15:9,23 48:19 50:22 66:16 81:9 222:24</p> <p>100 [3] 48:19 173:2 203:1</p> <p>109 [1] 198:23</p> <p>10fmol/mg [1] 13:14</p> <p>10th [2] 222:21,22</p> <p>11 [3] 289:1 315:2,8</p> <p>11th [1] 224:21</p> <p>12 [1] 315:17</p> <p>125 [1] 284:24</p> <p>126 [2] 2:4,5</p> <p>1294 [1] 48:13</p> <p>13 [1] 315:18</p> <p>130 [1] 281:14</p> <p>13th [3] 80:17 225:14,21</p> <p>14 [2] 284:16 316:2</p> <p>145 [2] 2:5,6</p> <p>14th [2] 78:17 80:13</p> <p>15 [7] 15:9,24 75:22 81:10 287:4 316:7,7</p> <p>150 [2] 254:24 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