

<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;">July 30, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C. 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>Darlene Russell. 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>David Eaton Q.C./ Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p> <p>William Clark Counsel for Dr. Banerjee</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-2430 THROUGH P-2435 Pg. 5</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. DIPONKAR BANERJEE - AFFIRMED</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 4 - 266 Examination by Daniel Simmons Pgs. 266 - 280 Examination by Jennifer Newbury Pgs.281 - 301 Examination by Madam Commissioner Pgs. 301 - 311</p> <p>Certificate</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 THE COMMISSIONER: 2 Q. Mr. Coffey. 3 COFFEY, Q.C.: 4 Q. Commissioner, the next witness is Dr. 5 Banerjee. 6 DR. DIPONKAR BANERJEE, AFFIRMED, EXAMINATION BY BERNARD 7 COFFEY, Q.C. 8 REGISTRAR: 9 Q. Would you please state and spell your complete 10 name for the Commission? 11 DR. BANERJEE: 12 A. My name is Diponkar Banerjee, D-I-P-O-N-K-A-R 13 B-A-N-E-R-J-E-E. 14 REGISTRAR: 15 Q. Thank you. 16 THE COMMISSIONER: 17 Q. Mr. Coffey, we have a new solicitor with us 18 this morning. 19 COFFEY, Q.C.: 20 Q. Yes, we do. 21 MR. CLARK: 22 Q. Yes, Commissioner, I'm William Clark. I'm 23 here as counsel for Dr. Banerjee. 24 THE COMMISSIONER: 25 Q. Welcome, Mr. Clark.</p>

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1 COFFEY, Q.C.:

2 Q. Commissioner, I have some new exhibits,

3 please, I'd ask that be entered. They are P-

4 2430 through P-2435 inclusive.

5 THE COMMISSIONER:

6 Q. Entered.

7 EXHIBITS ENTERED AND MARKED P-2430 THROUGH P-2435

8 COFFEY, Q.C.:

9 Q. Thank you, Commissioner. Registrar, could we

10 bring up Exhibit P-2435, please? Doctor, is

11 this the first page of your curriculum vitae,

12 Doctor?

13 DR. BANERJEE:

14 A. It is.

15 COFFEY, Q.C.:

16 Q. Doctor, I'm not going to take you through it

17 in detail. I'm looking at the last page here

18 on the paper copy I have, it's page 30, so

19 we'd be here for quite a while going through

20 it. I'm going to ask you, please, Doctor, to

21 outline for the Commissioner your educational

22 and professional background?

23 DR. BANERJEE:

24 A. Certainly. So my undergraduate training and

25 medicine, surgery was at Makerere Medical

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1 School in Uganda. Following that post

2 graduate medical education in pathology and

3 laboratory medicine starting at the University

4 of Minnesota and then I moved to Ottawa and

5 finished my training there, and as you can

6 see, the -

7 COFFEY, Q.C.:

8 Q. It's actually at page 30.

9 DR. BANERJEE:

10 A. Sorry?

11 COFFEY, Q.C.:

12 Q. You're actually on page 30 of the -

13 DR. BANERJEE:

14 A. Yes, I am.

15 COFFEY, Q.C.:

16 Q. - CV, and you go right ahead, Doctor. You go

17 right ahead.

18 DR. BANERJEE:

19 A. And so I finished my residency training in

20 Ottawa. I did my Royal College Fellowship,

21 and at the same time, I did a PhD program at

22 the University of Ottawa. So that's the

23 extent of my professional education.

24 COFFEY, Q.C.:

25 Q. So you would have finished up in Ottawa in

Page 7

1 1975/76?

2 DR. BANERJEE:

3 A. That's correct.

4 COFFEY, Q.C.:

5 Q. Where did you go from there, Doctor?

6 DR. BANERJEE:

7 A. My first faculty appointment was at the

8 University of Western Ontario as an assistant

9 professor, starting in, I believe, 1978, and I

10 was there for several years and then moved to

11 the University of Toronto, where I was full

12 professor, and then at that time, I was also

13 the head of cancer pathology at Princess

14 Margaret Hospital and the Ontario Cancer

15 Institute, and then I moved to British

16 Columbia, where I was head of pathology

17 department at the B.C. Cancer Agency and

18 professor at the University of British

19 Columbia, and the last 16 months, I've been

20 the Executive Medical Director for the

21 Provincial Health Services Authority

22 Laboratories, that includes the Cancer Agency,

23 Children's Hospital, Women's Hospital, Centre

24 for Disease Control and Riverview Hospital in

25 Vancouver.

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1 COFFEY, Q.C.:

2 Q. And just in terms of the years involved, if we

3 could look to page two, please, that's the

4 years of your actual professional life after

5 your education. Page two, I take it, Doctor,

6 we pick it up then, your career in 1979, there

7 towards the top of the page, '79 to '87, you

8 were the Director of the Immunopathology

9 laboratory, University Hospital, London,

10 Ontario. '87 to '91, the chief of pathology

11 at St. Joseph's Health Centre in London. '87

12 to '91, the Chairman of Cell Biology Division

13 of Lawson Research Institute, and then from

14 '91 through '97, the chief of oncologic

15 pathology and Medical Director of

16 Laboratories, Princess Margaret. So I'm

17 trying to give the Commissioner some sense of

18 the years because you referred to Princess

19 Margaret.

20 DR. BANERJEE:

21 A. Yes.

22 COFFEY, Q.C.:

23 Q. You were, in effect, at Princess Margaret

24 throughout the 1990s?

25 DR. BANERJEE:

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1 A. That's correct.
 2 COFFEY, Q.C.:
 3 Q. Toward the end. At the same time, we go back
 4 to the page before, if I could, I'm just going
 5 to--page one, at the bottom of the page, you
 6 had moved then by 1994 to 1998, were involved
 7 with the Department of Pathology at the
 8 University of Toronto and then from '95 to
 9 '99, the Canadian Reference Centre for Cancer
 10 Pathology, the Eastern Division, the Director
 11 and overlapping with that, '97 to 2000, the
 12 Medical Director Immunology and
 13 Immunopathology, the Department of Laboratory
 14 Medicine and Pathobiology at the University
 15 Health Network in Toronto, and from there, I
 16 gather, Doctor, you finished up in Toronto in
 17 2000, just looking at this, and moved then, in
 18 2000, out to Vancouver where you described
 19 where you are.
 20 DR. BANERJEE:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. Doctor, I take it then, Doctor, just looking
 24 at your CV, that you've been involved in
 25 immunopathology really since the end of the

Page 10

1 1970s, in one form or another?
 2 DR. BANERJEE:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. Doctor, could you give the Commissioner,
 6 again, I appreciate it'll be just an overview,
 7 but an overview of your experience with
 8 immunopathology in your working lifetime, as
 9 to how it's evolved over time?
 10 DR. BANERJEE:
 11 A. Certainly. So immunopathology evolved over a
 12 long period of time. At the time I was
 13 undergoing training, immunopathology was
 14 confined to studying auto immune diseases and
 15 kidney diseases and the methodology was
 16 limited to using frozen tissue and
 17 fluorescence labelled antibodies to visualize
 18 particular proteins in a tissue. However, in
 19 the late '60s and early '70s, certainly in
 20 research labs, people published methods that
 21 would allow proteins to be identified in
 22 routinely fixed, i.e. formalin fixed tissue,
 23 which until that point was not possible, using
 24 very sensitive methods which were non-
 25 fluorescence based methods. So what we call

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1 Brightfield microscopy methods. That is, you
 2 can use a regular microscope to actually
 3 visualize where the antibodies bind to tissues
 4 by using a coloured product at the end of the
 5 reaction. So it would be a brown or red or
 6 blue product.
 7 COFFEY, Q.C.:
 8 Q. This would have come in -
 9 DR. BANERJEE:
 10 A. This would be, in terms of general usage,
 11 would have happened during the late '70s. So
 12 just after I finished my training as a
 13 pathologist, the early papers began to be
 14 published about the use of this method and
 15 looking at cancer markers, the earliest being
 16 CEA or carcino-embryonic antigen, and that
 17 became very interesting to me because until
 18 that point, cancer pathology was largely based
 19 on microscopic analysis of routinely stained
 20 sections, by which I mean hematoxylin eosin or
 21 H&E stained sections, and all of cancer
 22 classification is based on morphological
 23 appearance of cancers under the microscope and
 24 to this day, that's still a correct statement.
 25 However, because of the improvement in

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1 immunopathology methods, of the
 2 immunoperoxidase method, as it was called in
 3 those days, and now immunohistochemistry as a
 4 general term, it became possible to look at
 5 specific proteins that are known to be
 6 associated with specific cancer types or cell
 7 types.
 8 So over the early '80s, the whole concept
 9 of using H&E as the sole method for
 10 classifying cancer changed into H&E plus
 11 immunohistochemistry which refined our ability
 12 to separate out cancers which were relatively
 13 poorly differentiated. The well
 14 differentiated cancers are not difficult to
 15 identify, but when they're poorly
 16 differentiated, they lose their appearance
 17 that would allow us to identify the cell type
 18 and they all start to look very similar, even
 19 though they're entirely different cancers, and
 20 immunohistochemistry allowed us to actually
 21 clearly identify different types of cancer and
 22 that's been a huge improvement in the tools
 23 available to pathologists.
 24 So in immunohistochemistry, the
 25 predominant application is to help us identify

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1 the cell type in a different--in different
 2 kinds of cancers, so that you can classify the
 3 cancer more accurately. At the same time, it
 4 became possible to look at certain proteins
 5 which are important in terms of oncologists
 6 making a decision about what treatment to use
 7 in a given cancer and one of the earlier--the
 8 earliest examples of that is the hormone
 9 receptors in breast cancer. There are many
 10 other proteins which are not important as
 11 targeted therapies become a standard of care.
 12 So Herceptin therapy and, in the case of
 13 breast cancer, is targeted to one protein,
 14 which is HER2/neu as it's called, and the
 15 therapy only works if the protein is over
 16 expressed. So these kinds of tests are now
 17 called predictive tests. So they actually
 18 tell you whether or not a patient is eligible
 19 for a particular type of treatment.
 20 The degree of accuracy and optimization
 21 of the methods becomes more critical as you
 22 use these tests to actually determine not
 23 whether a patient has cancer or not, but what
 24 kind of treatment is the patient eligible for,
 25 and it becomes very critical to get that

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1 right. I'll give you examples of why that is
 2 so.
 3 I'll start with Herceptin therapy as the
 4 example. That's the prototype for targeted
 5 therapy and there are many more targeted
 6 therapies being introduced. So it's important
 7 to understand this point. The drug itself is
 8 expensive, so it costs--I forget the exact
 9 cost now, but it's something like \$43,000 per
 10 patient. It will only work if the target is
 11 expressed in the patient's tumour cells and
 12 therefore if you have a method which has a
 13 high false negative or false positive rate, it
 14 creates a huge dilemma. Number one, let's
 15 take a patient who has been tested and was a
 16 false positive. The oncologist wouldn't know
 17 that. The oncologists depend on the labs to
 18 tell them whether something is positive or
 19 not. If the lab hasn't optimized the method
 20 and validated it, then the potential for false
 21 positive staining is very high in this
 22 particular situation. What that will do is
 23 that the patient will then be offered
 24 Herceptin therapy, even though it's not going
 25 to work, because the patient's tumour is

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1 actually negative. Now, you'll say well, it's
 2 just waste of money, but it's not just the
 3 cost, because the Herceptin drug is not a
 4 benign drug. It does have side effects,
 5 particularly cardiotoxic side effects. So
 6 it's not just the cost, but you can actually
 7 harm the patient with no actual clinical
 8 benefit. Take the other side of that coin and
 9 say if it's a false negative test, what
 10 happens? Then you're denying that patient
 11 therapy that she would have been eligible for
 12 and could have benefitted from. So that's an
 13 example of why testing has to be of high
 14 quality.
 15 Take estrogen receptors, which has been
 16 around much longer in terms of our knowledge
 17 of estrogen receptors and the efficacy of
 18 estrogen receptor blocking agents such as
 19 Tamoxifen. So there again, if the receptor is
 20 expressed in the tumour cells, then there's a
 21 higher chance of that patient responding to
 22 Tamoxifen. I must point out that this is not
 23 a 100 percent relationship because there are
 24 patients who are estrogen receptor positive
 25 who may not benefit from Tamoxifen, for

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1 reasons that are not fully understood. One of
 2 the reasons is we have over simplified the
 3 whole issue of estrogen receptors and
 4 Tamoxifen therapy because there are many,
 5 actually several estrogen receptor types.
 6 It's not just one. And most of the antibodies
 7 we use currently in labs across the world tend
 8 to focus on one type, which is the estrogen
 9 receptor alpha molecule.
 10 COFFEY, Q.C.:
 11 Q. As opposed to the beta? In contra distinction
 12 to the beta?
 13 DR. BANERJEE:
 14 A. That's right, and there's the beta and the
 15 gamma. There's very little known about gamma,
 16 but certainly some knowledge on beta. And it
 17 turns out that Tamoxifen is not a
 18 straightforward drug because depending on
 19 where the estrogen receptor is expressed, it
 20 has different effects. If it's in the breast,
 21 it blocks it. If it's in the uterus, it
 22 actually stimulates the estrogen receptor. It
 23 turns out that the estrogen receptor alpha
 24 molecule actually when you add Tamoxifen to
 25 the tumour cells, there's a dual effect. One

Page 17

1 is blocking the receptor, so the estrogen will
 2 not have an effect. The other is actually
 3 stimulating the receptor, because Tamoxifen
 4 can do both. So in an individual patient, one
 5 could say that the estrogen receptor response
 6 to Tamoxifen could be a combination of
 7 inhibition and stimulation and it could vary
 8 with the individual.
 9 Estrogen receptor beta, on the other
 10 hand, is a somewhat different receptor because
 11 Tamoxifen always blocks it. There is a small
 12 subset of patients who are estrogen receptor
 13 alpha negative, but estrogen receptor beta
 14 positive and in most labs, we are not testing
 15 for beta, so there is going to be a small
 16 subset of patients whose ER test may be called
 17 negative, but actually will benefit from
 18 Tamoxifen because they have the beta subtype
 19 being expressed. So that's something that has
 20 to evolve into standard of practice and hasn't
 21 happened yet.
 22 COFFEY, Q.C.:
 23 Q. And I take it that that is still in a state of
 24 development or flux?
 25 DR. BANERJEE:

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1 A. That's right, yes. So now back to the issue
 2 of how well done the immunohistochemistry test
 3 has to be for oncologists to be confident in
 4 the result, and the story of estrogen
 5 receptors is quite a long one because
 6 initially, it started out as a biochemical
 7 test, which you've all heard about.
 8 COFFEY, Q.C.:
 9 Q. So Doctor, I take it when you started your
 10 training, in particular your residency, was it
 11 still estrogen receptor progesterone receptor
 12 testing still done by the biochemical assay?
 13 DR. BANERJEE:
 14 A. That's correct.
 15 COFFEY, Q.C.:
 16 Q. When you started out in your residency?
 17 DR. BANERJEE:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Perhaps then if you could take us then through
 21 that?
 22 DR. BANERJEE:
 23 A. So the biochemical test was a dextran and
 24 charcoal coated test which was a radioimmuno
 25 assay. Well, it's not radioimmuno assay.

Page 19

1 It's a radio ligand banding assay which looked
 2 at radio labels estrogen and how it bound to
 3 the receptors in breast tissue and that was
 4 done in biochemistry labs because it was a
 5 biochemical method and it required frozen
 6 tissue from the operating room. So the
 7 pathologist would do a quick section to see
 8 whether or not there was cancer in the tissue
 9 removed by the surgeon, and if there was a
 10 cancer, they would then take a part of it,
 11 freeze it, and send it to the biochemistry lab
 12 which would then do the test, and it was a
 13 quantitative test, so actual concentration of
 14 the receptor molecule would be actually
 15 reported, and by correlating with response to
 16 Tamoxifen thresholds of positivity that were
 17 clinically significant were established, and
 18 that was used for several years and the test
 19 tended to be centralized in one particular lab
 20 in a particular region. There was quality
 21 assurance program where labs would compare
 22 their results with one another.
 23 COFFEY, Q.C.:
 24 Q. Doctor, just so the Commissioner can get some
 25 background on this, why was it -- at the time

Page 20

1 what was your understanding about why the
 2 biochemical assay process tended to be
 3 centralized?
 4 DR. BANERJEE:
 5 A. I'm not sure exactly what led to the
 6 centralization policy, but virtually every
 7 province went that route, and this is based on
 8 recommendations from the biochemist community
 9 that would have made that recommendation,
 10 largely to ensure that the expertise required
 11 for that test was available, and if you have
 12 the test done by multiple labs, I think it
 13 would have been very expensive. The reagent
 14 is very expensive. These are radioactive
 15 molecules, not easy to handle, etc. So there
 16 were several reasons for centralization.
 17 COFFEY, Q.C.:
 18 Q. And they were centralized and there was
 19 quality assurance, quality control measures?
 20 DR. BANERJEE:
 21 A. Yes, and labs had voluntarily compared their
 22 results with one another to keep the quality
 23 assurance going. So that test evolved. So to
 24 try and move away from radioactive materials,
 25 when the first monoclonal antibodies were

Page 21

1 developed against the estrogen receptor and
 2 progesterone receptor proteins, many of the
 3 biochemical labs switched their methods to
 4 immuno enzyme assay, which essentially used
 5 the antibodies to detect the estrogen receptor
 6 protein in the cells. They're still using
 7 frozen tissue and solubilizing the estrogen
 8 receptor protein and using immuno assay to
 9 actually detect protein concentration. It's
 10 still a quantitative assay.

11 COFFEY, Q.C.:
 12 Q. And these are still biochemist?
 13 DR. BANERJEE:
 14 A. It was still done by a biochemist because they
 15 would do other immuno enzyme assays for other
 16 disease categories. What people realized --
 17 the oncologists realized that there was a
 18 subset of patients who would not respond to
 19 Tamoxifen in the expected manner, and we began
 20 to wonder whether part of the problem was when
 21 you have frozen tissue and you grind it up to
 22 do the biochemical test or the immuno enzyme
 23 test, and realizing that not all tumour tissue
 24 is pure tumour, there's always normal tissue
 25 around, including normal breast epithelium,

Page 22

1 that perhaps some of the biochemical results
 2 were based on the presence of normal
 3 epithelium which would be positive for
 4 estrogen receptors, and, therefore, some of
 5 these women where actually the tumour is
 6 negative for estrogen receptors, but the test
 7 was coming out positive because of the
 8 inclusion of normal tissue in the material
 9 that was being analyzed. So people began to
 10 wonder whether they could actually visualize
 11 where the tumour cells were and the normal
 12 cells were by using tissue sections and using
 13 immuno-fluorescence methodology. So the
 14 initial tissue based issues in receptor assays
 15 were immuno-fluorescence assays, they kept
 16 antibodies available from various vendors and
 17 these then became the standard in the early
 18 80s because you could not visualize where the
 19 tumour cells were and where the normal cells
 20 were, and you could look specifically at the
 21 tumour cells and determine whether they were
 22 positive. Further evolution happened because
 23 as screening mammography became standard
 24 screening system, the women with breast cancer
 25 were being diagnosed earlier and earlier. So

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1 as a result, the tumour size and initial
 2 diagnosis was getting smaller and smaller to
 3 the point that some tumours are not actually
 4 palpable any more, so you can't actually feel
 5 a lump, you can only see an abnormal
 6 mammogram, and the surgeon would then have to
 7 use the mammogram appearance to decide what
 8 kind of procedure they're going to go through
 9 because there was no obvious lump that could
 10 be biopsied. So pathologists then had to deal
 11 with these kinds of cases where the location
 12 of the tumour was uncertain other than the
 13 mammographic abnormality, and that meant that
 14 you couldn't just freeze some breast tissue
 15 and set it for the biochemical test or do a
 16 frozen section estrogen receptor assay because
 17 frozen section morphology is not as good as
 18 formalin fixed tissue morphology. It's harder
 19 to interpret. So then people started to think
 20 about using those antibodies to actually
 21 detect the protein in formalin fixed paraffin
 22 embedded tissue, and the earliest papers that
 23 were successful in demonstrating the protein
 24 were published in the late 80s and the early
 25 90s, but the -- and although the correlation

Page 24

1 with the biochemical test was pretty good,
 2 there was clearly a subset of cases that did
 3 not correlate. So there may be cases that
 4 would be biochemically positive, but by
 5 immunohistochemistry negative, and it was not
 6 always because of the presence or absence of
 7 normal tissue, and people began to suspect
 8 that the sensitivity of their method wasn't
 9 sufficient for immunohistochemistry to be
 10 completely reliable. So additional steps were
 11 introduced. By then people realized that
 12 formalin fixation tends to stabilize proteins
 13 in a particular way by cross linking different
 14 parts of the protein cell. The morphology was
 15 good, but the antibody binding sites of the
 16 antigens would be distorted, and since
 17 antibodies bind to proteins by recognizing
 18 shape, if you alter the shape of the protein,
 19 antibody may not bind any more. So they tried
 20 to figure out some ways of reversing that
 21 cross linking effect of formalin. Initially
 22 what they used were various enzymes that tend
 23 to break proteins into smaller pieces, with
 24 the hope that as you get the fragmentation of
 25 the proteins, that some of those hidden

Page 25

1 antigens where the antibody needs to bind to
 2 would be exposed and that was successful.
 3 However, the --
 4 COFFEY, Q.C.:
 5 Q. Is this the process we've heard of, this
 6 antigen retrieval?
 7 DR. BANERJEE:
 8 A. This is one of the early methods of antigen
 9 retrieval using enzymes.
 10 COFFEY, Q.C.:
 11 Q. Using enzymes, okay.
 12 DR. BANERJEE:
 13 A. But it was soon realized that because the
 14 enzyme preparations were not consistent from
 15 batch to batch, that there was variation, they
 16 could never have a perfectly reproducible
 17 method. Then somebody discovered the antigen
 18 retrieval method using heat, so initially
 19 using steam and now microwaving or even
 20 pressure cooking the sections that are already
 21 cut and placed on glass slides, and that
 22 seemed to work very well, and that's become
 23 the most commonly used antigen retrieval
 24 system now. Even in the automated systems
 25 like the Ventana System, that's the basic

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1 antigen retrieval method used. It's not
 2 perfect for all types of proteins. In many
 3 labs, there are certain antigens that they
 4 know would require enzymatic treatment and
 5 others would be okay with just the heat
 6 treatment. Estrogen receptor proteins are
 7 detectable after heat treatment quite well and
 8 it's quite reproducible.
 9 COFFEY, Q.C.:
 10 Q. And when would heat treatment have started to
 11 come into usage, Doctor, approximately?
 12 DR. BANERJEE:
 13 A. Probably about the mid 90s that this started
 14 to become widely known, and certainly in the
 15 late 90s and early 2000, it was just pretty
 16 standard. What helped is the
 17 immunohistochemistry reagent vendors and the
 18 manufacturers of automated staining systems
 19 introduced these as standard methodology to
 20 improve the consistency of the results in
 21 different labs. So the commercial industry
 22 side of this whole system drove that, and for
 23 good reasons, and improved their
 24 reproducibility from lab to lab. Having said
 25 that, one has to say that if you look at

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1 inter-lab variability in immunohistochemistry,
 2 particularly with the hormone receptors and
 3 HER2/neu, there is still variability even
 4 though the methods have been pretty much
 5 standardized now across the world. Then if
 6 you consider why there is that variability, it
 7 probably boils down to two major steps in the
 8 process. One is the quality of fixation. So
 9 if the tissue is not fully fixed because the
 10 formalin did not penetrate into the centre of
 11 the -- into the tumour mass, then the
 12 possibility of the estrogen receptor being
 13 lost through diffusion is actually quite
 14 significant. So tissue has to be adequately
 15 fixed. Over fixation doesn't seem to make
 16 much of a difference, but under fixation
 17 definitely has an effect on the quality of the
 18 morphology and the immunohistochemistry
 19 results. So that's one thing. The second
 20 thing is variability in the antigen retrieval
 21 method. Even though the method is the same,
 22 the conditions under which the method is used
 23 may vary from lab to lab. For instance, some
 24 people still use steam, some people use
 25 microwaving, some people use pressure cookers.

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1 All those introduce variability. The buffer
 2 medium that you're immersing the slides in
 3 also has an effect. So these are some of the
 4 remaining reasons for inter-lab variability.
 5 It's interesting that the biggest quality
 6 assurance program, which is the United Kingdom
 7 program, has published some data on their
 8 various proficiency testing programs, and
 9 looked at variability, and I don't know
 10 whether this particular paper has been
 11 discussed earlier in the Commission inquiry,
 12 but one of the conclusions was that the
 13 biggest reason for variability was the antigen
 14 retrieval methodology. When you read through
 15 that paper, there's a little section in the
 16 materials and methods that say that cases
 17 where fixation wasn't optimized and internal
 18 controls which are the benign breast epithelia
 19 cells were not present or did not stain were
 20 excluded from that study. I suspect that if
 21 you looked at the true variability, it would
 22 be greater than was what was reported in that
 23 paper.
 24 COFFEY, Q.C.:
 25 Q. Than even was reported, and that paper was --

Page 29

1 do you recall the approximate year, Doctor?
 2 DR. BANERJEE:
 3 A. Sorry?
 4 COFFEY, Q.C.:
 5 Q. The year of the paper?
 6 DR. BANERJEE:
 7 A. I'd say it was probably in '95 or '96,
 8 something like that.
 9 COFFEY, Q.C.:
 10 Q. Okay, so it was in the mid 90s. This is before
 11 Rhodes, is it?
 12 DR. BANERJEE:
 13 A. Sorry?
 14 COFFEY, Q.C.:
 15 Q. We've heard references to and seen references
 16 to a Dr. Rhodes in the UK. He published a
 17 paper around 2000 -- a series of papers
 18 beginning around 2000. Would this be before
 19 that?
 20 DR. BANERJEE:
 21 A. I think this was probably one of the first
 22 papers from that group, yeah.
 23 COFFEY, Q.C.:
 24 Q. And you've noted that cases that might have
 25 been, for the reasons you've indicated, cases

Page 30

1 that had apparent problems with fixation?
 2 DR. BANERJEE:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. Or internal controls might be an issue?
 6 DR. BANERJEE:
 7 A. Right.
 8 COFFEY, Q.C.:
 9 Q. They were excluded from the study?
 10 DR. BANERJEE:
 11 A. They were excluded from the analysis of --
 12 that was reported in the paper, but it didn't
 13 actually specify how many cases have that
 14 problem. So it would have been interesting to
 15 find out.
 16 COFFEY, Q.C.:
 17 Q. And even then there was inter-lab variability?
 18 DR. BANERJEE:
 19 A. Correct.
 20 COFFEY, Q.C.:
 21 Q. But they -- in that context, identifying the
 22 retrieval method, antigen retrieval method, as
 23 being the primary factor?
 24 DR. BANERJEE:
 25 A. That's right.

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1 COFFEY, Q.C.:
 2 Q. Causing potentially the variability.
 3 DR. BANERJEE:
 4 A. Right. So --
 5 COFFEY, Q.C.:
 6 Q. I take it -- so, Doctor, in that regard then,
 7 are you suggesting that in so identifying
 8 antigen retrieval as the culprit, as it were -
 9 -
 10 DR. BANERJEE:
 11 A. Uh-hm.
 12 COFFEY, Q.C.:
 13 Q. They, at least at that point, may have been
 14 excluding considering fixation problems?
 15 DR. BANERJEE:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. And the utilization of internal controls?
 19 DR. BANERJEE:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. As a potential problem.
 23 DR. BANERJEE:
 24 A. Right.
 25 COFFEY, Q.C.:

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1 Q. Okay.
 2 DR. BANERJEE:
 3 A. I think the point they were trying to make and
 4 emphasize was that the false negative rates
 5 were seen mainly in the cases where the
 6 estrogen receptor concentration was very low,
 7 and that's where the main problems lie. So if
 8 it's a very high concentration, then I think
 9 most labs would call those positive even if
 10 the methods weren't optimized. So that was a
 11 good observation, but I think they lost an
 12 opportunity to address the fixation issues and
 13 the internal control issues.
 14 COFFEY, Q.C.:
 15 Q. Doctor, in your own experience and the
 16 institutions you worked in, when did you first
 17 encounter ER and PR analysis using the IHC
 18 method yourself?
 19 DR. BANERJEE:
 20 A. If I remember correctly, it would have been in
 21 the mid 80s that we were doing it by the
 22 frozen section method.
 23 COFFEY, Q.C.:
 24 Q. Frozen section.
 25 DR. BANERJEE:

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1 A. And then by the early 90s, we had switched to
 2 -- it would have been around '95/'96 that we
 3 switched to the formalin fixed paraffin
 4 section method. In fact, in my own research,
 5 I had been trying to do that, at the time
 6 frozen sections was the standard because we
 7 realized that you can't always identify the
 8 tumour in fresh tissue for reasons I've
 9 explained before; tumour size is very small
 10 these days. It was a tough thing to do.
 11 Until the whole methodology evolved and
 12 antigen retrieval became possible and so on,
 13 it was very difficult to do that.

14 COFFEY, Q.C.:

15 Q. This was back in the days of frozen sections?

16 DR. BANERJEE:

17 A. That's right, so methods evolved and one thing
 18 I have to emphasize, this is a never-ending
 19 issues, methods will continue to improve, get
 20 better, new methods are introduced, there's
 21 new targeted therapies are introduced, all of
 22 that means that labs have to introduce new
 23 assays for a patient selection and it's
 24 critical for us to have, I'll use the word
 25 robust, quality assurance systems across the

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1 country to make sure that we don't have
 2 problems like this again.

3 COFFEY, Q.C.:

4 Q. Now, Doctor, just in relation to that because
 5 you had referred to the biochemists and
 6 regionalized centres for conducting the
 7 biochemical assay and they had, your
 8 understanding was they had quality assurance
 9 measures in place.

10 DR. BANERJEE:

11 A. Uh-hm.

12 COFFEY, Q.C.:

13 Q. Who recognized, I gather, across the country
 14 and perhaps throughout North America.

15 DR. BANERJEE:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. What happened when the ER/PR testing moved
 19 from the biochemists to the pathologists in
 20 relation to quality assurance and kind of
 21 generalized standards, as it were, what
 22 happened? What was your -

23 DR. BANERJEE:

24 A. Well initially it remains centralized because
 25 immunohistochemistry was still relatively

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1 under-utilized technique and it was used
 2 mostly large teaching hospitals because we had
 3 to do it all manually, there were no automated
 4 machinery at the time. So there were
 5 dedicated technologists and usually dedicated
 6 pathologists with oversight of the lab and I
 7 was one of the directors of immunopathology
 8 very early on in my career. And everything
 9 had to be basically developed from scratch
 10 because there were no staining kits available,
 11 you had primary antibody and immunodetection
 12 systems all separately sold by the vendors and
 13 you had to put it all together in the right
 14 sequence and right concentrations and had to
 15 figure out what was optimal. Then as the
 16 industry grew so there were many vendors for
 17 antibodies and then the automated staining
 18 machines began to be introduced. The market
 19 for the vendors had to expand because the
 20 money was to be made on selling reagents and
 21 there was a much bigger menu of tests that
 22 could be done, et cetera. And with
 23 automation, it became possible for smaller
 24 hospitals to start to do these tests and so
 25 the centralization of immunohistochemistry

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1 soon changed to decentralized model across
 2 North America, and so hospitals that had very
 3 few cases to stain in a given week would be
 4 doing immunohistochemistry. And in my various
 5 positions, tended to be in mostly cancer
 6 centres, because of central review policies of
 7 cancer agencies I've worked with, we would see
 8 the results of these immunohistochemistry
 9 preparations from several different hospitals
 10 as part of our review process. And there was
 11 clearly quite a lot of variability in quality
 12 of fixation, quality of staining, et cetera.
 13 So in some ways by making it easy for labs to
 14 do this procedure, we lost the rigor of
 15 quality assurance and it's very easy to lump
 16 immunohistochemistry with other special stains
 17 that are normally done in pathology labs, but
 18 it's really oversimplification because
 19 immunohistochemistry is a very complex
 20 reaction between antibody and protein and each
 21 protein has its own characteristics in whether
 22 it responds to formalin in a particular way or
 23 responds to heat antigen retrieval in a
 24 particular way, all that has to be worked out
 25 very carefully and it's often difficult to

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1 have one protocol for everything. And smaller
 2 labs may not have the time or the expertise to
 3 figure that out, so they go by what the
 4 manufacturer says and in experienced labs, we
 5 use the manufacturer's data sheet as just a
 6 starting point, that's not the protocol we
 7 would use because, as I said, those proteins
 8 are very sensitive to fixation conditions and
 9 fixation is quite variable from lab to lab.
 10 Tissue processing itself is quite variable,
 11 even the morphology would look variable for
 12 the same reasons and therefore, it is not
 13 appropriate for any lab to just to take the
 14 manufacturer's protocols and say this is what
 15 they say you should use and expect it to work
 16 because it will not.

17 COFFEY, Q.C.:
 18 Q. I take it there's an outside chance it might,
 19 but generally it would not.

20 DR. BANERJEE:
 21 A. Right.

22 COFFEY, Q.C.:
 23 Q. You would have to tweak it in some way.

24 DR. BANERJEE:
 25 A. Yeah, you'd have to set up the protocol for

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1 your own lab, which is not difficult, it's
 2 time consuming.

3 COFFEY, Q.C.:
 4 Q. Doctor, could I have you repeat that?

5 DR. BANERJEE:
 6 A. It's not difficult, it's time consuming, so
 7 the effort required is quite significant and I
 8 guess over the years most labs have not kept
 9 up with their workload, so in terms of
 10 staffing and all of that because of financial
 11 constraints in the system, so the amount of
 12 time available for people to work up a method
 13 is limited. So that's a big challenge for all
 14 of us, but to go back to that whole issue of
 15 not simplifying the complexity of
 16 immunohistochemistry, I think the vendors have
 17 unfortunately created a false sense of
 18 confidence amongst all clinical labs saying if
 19 you buy our machine, buy our reagents, it's
 20 going to work. And in general, it's true,
 21 however if you haven't optimized your, the
 22 initial steps that you go through in terms of
 23 fixation, processing and so on, no matter how
 24 good your immunohistochemistry technique is,
 25 there's going to be a subset of patients where

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1 there's been so much degradation of the
 2 protein that you cannot demonstrate it. So,
 3 that remains a problem and I think if you look
 4 at the recent literature on things like, you
 5 know, central lab results versus referring lab
 6 results and different cancer bio-markers. A
 7 good study came out, I can't remember the
 8 year, I think it was 2005 in the journal of
 9 the National Cancer Institute which showed
 10 that if labs only did a few cancer cases a
 11 month and this was the HER2/neu protein assay
 12 for Herceptin therapy, that their error rate
 13 was quite significant compared to the large
 14 central labs, which did several hundred cases
 15 a month, so that tells you that, you know, you
 16 have to see enough cases to be able to
 17 actually judge whether or not your technique
 18 is working properly. If you don't see a lot,
 19 then you don't see those patterns, you don't
 20 observe their trends or drifts. Sometimes
 21 from batch to batch, reagents don't work as
 22 well and you have to correct for that, so
 23 those are the nuances of immunohistochemistry
 24 that only very experienced technologists fully
 25 understand and the supervising pathologist

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1 fully understands. Beyond the technique,
 2 there's the interpretation bias, inter-
 3 observer variability in how we interpret
 4 results. So that interaction between the
 5 pathologist and the technologist is critical
 6 in this area. For every protein, you're
 7 looking for used controls, so you could use
 8 external controls and internal controls.
 9 External controls are tissues from a different
 10 patient which have been fixed differently and
 11 processed differently in a different time, et
 12 cetera.

13 COFFEY, Q.C.:
 14 Q. Than the patient's tissue?

15 DR. BANERJEE:
 16 A. That's right, so internal controls are good in
 17 terms of making sure your staining is working,
 18 but it doesn't necessarily tell you whether a
 19 negative result in a patient is a true
 20 negative result.

21 COFFEY, Q.C.:
 22 Q. That is external controls don't necessarily do
 23 that.

24 DR. BANERJEE:
 25 A. That's right because the two tissues have been

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1 processed from different days and perhaps the
 2 fixation was not identical, et cetera.
 3 COFFEY, Q.C.:
 4 Q. So they would have been fixed at, obviously,
 5 different times.
 6 DR. BANERJEE:
 7 A. That's right.
 8 COFFEY, Q.C.:
 9 Q. The external control, the patient whose tissue
 10 ended up as the external control was probably
 11 dealt with, fixed a year, six months, maybe
 12 years ago.
 13 DR. BANERJEE:
 14 A. Could be a much older case.
 15 COFFEY, Q.C.:
 16 Q. And it was fixed and then it went through
 17 tissue processing at a different time.
 18 DR. BANERJEE:
 19 A. Yes, and in general labs will pick external
 20 controls from a case that stained beautifully,
 21 right, so lots of protein in that tissue and
 22 then you're comparing it with another
 23 patient's biopsy which might have a lower
 24 protein concentration and if your method is
 25 not optimized, you could have a false negative

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1 and even know about it.
 2 COFFEY, Q.C.:
 3 Q. So you're saying then external controls then
 4 has its usage, but beyond external controls,
 5 is it important to -
 6 DR. BANERJEE:
 7 A. So the other control I would look for is an
 8 internal control, so certain proteins
 9 expressed in normal cells, they're not unique
 10 to cancer cells, so you'd look for those
 11 normal cells and make sure they're staining
 12 appropriately, so estrogen receptor is a good
 13 example, which is expressed by normal breast
 14 epithelium, so it should always be positive.
 15 The intensity may be different from the tumour
 16 cells because some tumour cells actually make
 17 more of the protein than normal cells;
 18 however, if the internal controls are there,
 19 so normal breast epithelium was there in the
 20 section and it is negative, then if the tumour
 21 is negative, there's no way of concluding that
 22 this is a true negative because there may be
 23 other reasons why the stain was negative. So
 24 the situation like that, we would have to look
 25 for a different block which had maybe better

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1 fixed tissue or if there was no normal
 2 epithelium in the tumour section we were
 3 staining, then we would seek another block
 4 which had some normal tissue from the same
 5 patient, so you could then compare the
 6 internal controls with the tumour. There are
 7 situations where there is no normal tissue to
 8 look at because it's a small biopsy, like core
 9 biopsies, whatever, and in that situation if
 10 the test is negative, one has to be cautious
 11 about calling it a true negative, so we would
 12 normally report it as not interpretable
 13 because of the lack of internal controls, or
 14 of the internal control is negative, we would
 15 simply look at other blocks to try and get a
 16 better fixed example from the same patient.
 17 If that fails, we would then have to question
 18 how the tissue was processed and in our
 19 organization since we are a reference lab for
 20 many other hospitals, we see that fairly
 21 frequently, fixation related problems in
 22 immunohistochemistry and so on. Our staining
 23 protocols are optimized for other people's
 24 blocks. If you optimize it just on our own
 25 processed tissue, we would probably have a lot

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1 of false negatives, so we have to tweak the
 2 system to make it more sensitive to deal with
 3 blocks that come from other hospitals.
 4 COFFEY, Q.C.:
 5 Q. That may--that are not as well fixed as the
 6 blocks that would come from internally.
 7 DR. BANERJEE:
 8 A. Or if the fixation is fine, there's something
 9 different about their tissue processing
 10 protocol, I would have situations where blocks
 11 from one particular hospital would never work
 12 for a particular test until I started to ask
 13 questions about, so why the morphology is
 14 great, fixation looks okay, why is it not
 15 working? And it turned out that in the tissue
 16 processor they were using a slightly different
 17 set of chemicals from the standard that was
 18 used elsewhere. So these are things that good
 19 technologists have to figure out as a
 20 troubleshooting exercise.
 21 COFFEY, Q.C.:
 22 Q. I take it that requires them to have a
 23 significant level of knowledge about the
 24 theory of what they're doing?
 25 DR. BANERJEE:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And that would require the time that they
 4 could devote to that.
 5 DR. BANERJEE:
 6 A. Yes, and they would have to invest in the
 7 education of those people, have reference
 8 books, good workshops and so on, compare their
 9 slides with other labs and so on.
 10 COFFEY, Q.C.:
 11 Q. Doctor, the idea of utilizing internal
 12 controls for estrogen receptors and I take it
 13 that is equally true for progesterone
 14 receptors as well, you'd utilize internal
 15 controls.
 16 DR. BANERJEE:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. Utilizing the IHC method, by what point in
 20 time would you have been aware that that was
 21 important, to utilize internal controls if
 22 you're doing an ER/PR by IHC?
 23 DR. BANERJEE:
 24 A. I think basically when we first set up the
 25 methodology even with the frozen sections,

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1 that would be the standard.
 2 COFFEY, Q.C.:
 3 Q. That would be back in the frozen section days.
 4 DR. BANERJEE:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. And certainly by the time paraffin blocks came
 8 along.
 9 DR. BANERJEE:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Now, Doctor, you have indicated that, just in
 13 passing you said that you've, of course, been
 14 associated with certain universities, medical
 15 programs which suggest to me that throughout
 16 your career you have taught residents?
 17 DR. BANERJEE:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. The utilization of internal controls for the
 21 purposes you've just described, is that the
 22 sort of thing that you would teach a resident
 23 who was on your rotation?
 24 DR. BANERJEE:
 25 A. Yes, so the way we teach residents is we sign

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1 out cases together, to use a double head
 2 microscope, we'd be looking at the same slides
 3 simultaneously. So, if you're looking at the
 4 immunohistochemistry preparation, then I would
 5 talk about, particular junior residents who
 6 are seeing it for the first time, how do you
 7 approach analysing this? What do you look
 8 for? How do you troubleshoot something that
 9 didn't work or if there's too much non-
 10 specific staining background, how do you
 11 recognize that? And how do you correct it by
 12 discussion with the technologists?
 13 So, internal controls, it's a general
 14 rule because almost every tumour marker we
 15 look for in cancer is not unique to the
 16 tumour. It's a marker of the cell of origin.
 17 So, normal cells for which these cancers
 18 develop, become malignant, will also express
 19 this protein, not necessarily at the same
 20 concentration, but any particular marker
 21 you're looking for, there's bound to be some
 22 normal counterpart in that tissue that should
 23 be positive. So, you look for that because
 24 that's the best indicator that the test
 25 actually worked.

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1 COFFEY, Q.C.
 2 Q. The process you're using.
 3 DR. BANERJEE:
 4 A. That's right. The other thing you look for is
 5 cells that should not be expressing their
 6 protein in normal cells. If they are
 7 positive, then you'd question the specificity
 8 of your test. So, those are some of the clues
 9 we look for in any slide that we're looking
 10 at. So, if there's excessive background
 11 staining, something could look positive, just
 12 because of non-specific staining and I've seen
 13 examples of that from many labs, where they're
 14 not paying attention to that particular issue
 15 and that leads to the false positive test.
 16 False negative tests are again not just
 17 estrogen receptors, but any particular tumour
 18 bio-marker we're looking for, if the normal
 19 counterpart of the tumour cell is not
 20 expressing the protein then your method is not
 21 sensitive enough.
 22 COFFEY, Q.C.
 23 Q. Not expressing it in the sense of the slide
 24 that you're looking at, it's not apparent in
 25 that normal tissue.

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1 DR. BANERJEE:
 2 A. That's correct. And then you immediately
 3 question the sensitivity of the method. And
 4 it can be optimized. I would teach residents
 5 you can make anything look positive with
 6 immunohistochemistry and it can all be
 7 completely non-specific if your conditions are
 8 not right.
 9 COFFEY, Q.C.
 10 Q. But that would be not appropriate, I take it,
 11 you're saying you can do it, but, of course,
 12 it's not appropriate.
 13 DR. BANERJEE:
 14 A. Yes, so you have to recognize where the
 15 positivity should be -
 16 COFFEY, Q.C.
 17 Q. And where it should not be.
 18 DR. BANERJEE:
 19 A. - and where it should not be.
 20 COFFEY, Q.C.
 21 Q. And adjust your approach in the methods
 22 accordingly.
 23 DR. BANERJEE:
 24 A. That's right. So, that's why I was
 25 emphasizing the external controls are good in

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1 terms of making sure every run is appropriate,
 2 but it's not sufficient. You have to look at
 3 the internal controls.
 4 COFFEY, Q.C.
 5 Q. And Doctor, your understanding of that would
 6 go back to, well, what era, in terms of
 7 decade? Would it be '80s, '90s?
 8 DR. BANERJEE:
 9 A. Yes, well in a way because my research
 10 involved these technologies that, you know, I
 11 had to do all the work myself in my research
 12 lab anyways, it's a great way to learn about
 13 each of these proteins. So, in some ways I
 14 was perhaps more attuned to that with those
 15 kinds of problems than the average
 16 pathologist.
 17 COFFEY, Q.C.
 18 Q. Throughout the profession of pathology, the
 19 realization of the potential significance of
 20 internal controls, for example, in ER and PR
 21 testing, and from you perspective, and I
 22 appreciate you've worked in Ontario for quite
 23 a period of time in the '90s and then in
 24 British Columbia, what's your understanding or
 25 sense of when there was, kind of, generally,

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1 or would have generally been amongst your
 2 colleagues, an understanding of the importance
 3 of internal controls?
 4 DR. BANERJEE:
 5 A. It's hard to pinpoint that. I think -
 6 COFFEY, Q.C.
 7 Q. And I appreciate because in your world you're
 8 very--that is your world, in particular. I
 9 just ask you to reflect upon, for example,
 10 your dealing with regional hospitals because
 11 you've worked in reference hospitals,
 12 reference centres. The idea of encountering
 13 pathologists who were not familiar with were
 14 apparently alert to the utilization of
 15 internal controls. How far back would you
 16 have to go?
 17 DR. BANERJEE:
 18 A. I would say that the problem still exists. It
 19 all depends on the experience of the
 20 individual and whether or not the lab is set
 21 up so that there is oversight by a single
 22 individual and dedicated technologists. So,
 23 all of those variables play a role here. If
 24 you're in a situation where you've a practice
 25 where no pathologist has responsibility for

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1 the immunohistochemistry lab, then the risk of
 2 these things not being paid attention to,
 3 attention to detail is very high because in a
 4 busy practice you're trying to get your work
 5 done as fast as possible. So, you may tend to
 6 gloss over details like that, whereas if you
 7 were responsible for that service, the
 8 professional overseeing that particular
 9 section of the lab, then it would be your job
 10 to make sure that each slide that goes out was
 11 of high quality.
 12 COFFEY, Q.C.
 13 Q. And I take that if they were being interpreted
 14 by other pathologists, that those pathologists
 15 were aware of what they should be doing -
 16 DR. BANERJEE:
 17 A. Right, so I would have to say when we first
 18 got started in the whole business of
 19 immunohistochemistry and I was the--in 1979 I
 20 was the Director of Immunopathology for
 21 University Hospital. It was very clear that
 22 very few pathologists actually fully
 23 understood how to interpret those slides. And
 24 so the policy that I would look at every slide
 25 that went out of that lab to make sure things

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1 were okay. And over time, you know, because
 2 we had always discussed cases, rounds and have
 3 seminars for the residents, the other
 4 pathologists would be there and over time
 5 everybody sort of came up to speed on how to
 6 interpret these things and know what to look
 7 for and so on and so forth. It was also very
 8 clear that in those early days there was a lot
 9 of scepticism from pathologists about
 10 immunohistochemistry because they were so used
 11 to just looking at H&Es and making a
 12 diagnosis.
 13 COFFEY, Q.C.
 14 Q. So, this would be back through, as we go
 15 through the '80s?
 16 DR. BANERJEE:
 17 A. Yes. So, worldwide there was, actually, a lot
 18 of resistance to this technology being
 19 introduced. And people eventually realized
 20 that the H&E stain was not adequate for cancer
 21 diagnosis, particularly poorly differentiated
 22 tumours and some of the British publications
 23 in the early days, '70s, from I think David
 24 Mason and his group published a wonderful
 25 paper that went and looked at a hundred cases

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1 of poorly differentiated tumours which had
 2 been classified as poorly differentiated
 3 carcinomas, melanomas and lymphomas, et cetera
 4 and used immunohistochemistry to re-classify
 5 then and found a huge error rate in H&E based
 6 diagnosis, 40 - 60 percent being completely
 7 wrong.
 8 COFFEY, Q.C.
 9 Q. And this would be back approximately what time
 10 frame?
 11 DR. BANERJEE:
 12 A. Well, those were retrospective cases -
 13 COFFEY, Q.C.
 14 Q. Yes, but his paper would have been published
 15 approximately when?
 16 DR. BANERJEE:
 17 A. Probably the late '70s.
 18 COFFEY, Q.C.
 19 Q. Okay. So, and this is, Doctor, in terms of
 20 your accounting for the Commissioner, your own
 21 kind of experience as you went from the
 22 beginning of your career and progressed, being
 23 responsible for immunohistochemistry in your
 24 particular location.
 25 DR. BANERJEE:

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1 A. Yes.
 2 COFFEY, Q.C.
 3 Q. Dealing with your contemporaries or more the
 4 point, people who are senior to you in terms
 5 of, as a pathologist.
 6 DR. BANERJEE:
 7 A. Yes.
 8 COFFEY, Q.C.
 9 Q. They'd been trained in earlier days.
 10 DR. BANERJEE:
 11 A. One of my senior colleagues called it immuno-
 12 mythology.
 13 COFFEY, Q.C.
 14 Q. Mythology, okay.
 15 DR. BANERJEE:
 16 A. Because he didn't believe it; things have
 17 changed.
 18 COFFEY, Q.C.
 19 Q. Doctor, I point out, even today, I take it,
 20 that you would understand that there would be
 21 pathologists that you might encounter or
 22 pathologists work that you might encounter
 23 where it was apparent that they did not fully
 24 appreciate, for example, the importance of
 25 internal controls for certain of these IHC

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1 processes.
 2 DR. BANERJEE:
 3 A. Yes.
 4 COFFEY, Q.C.
 5 Q. And Doctor, I take it then a pathologist who
 6 is being trained today, for example, in your
 7 institution, you would expect to be exposed to
 8 that.
 9 DR. BANERJEE:
 10 A. Yes.
 11 COFFEY, Q.C.
 12 Q. But were there any particular pathologists who
 13 graduated years ago was exposed to, it would
 14 be function of their actual training and/or
 15 their curiosity in terms of looking at the
 16 literature.
 17 DR. BANERJEE:
 18 A. Right, it's a combination of the two. So,
 19 you're training program would train you what
 20 the standard of the day was, but as you
 21 practice as a professional, you have to keep
 22 up with what goes on in the field and that
 23 keeps changing.
 24 COFFEY, Q.C.
 25 Q. And, in particular I take it, in relation to

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<p>1 immunohistochemistry, it has changed 2 significantly over the past two decades. 3 DR. BANERJEE: 4 A. In terms of the spectrum of molecules you can 5 detect by the method, it's enormous, grown 6 hugely. 7 COFFEY, Q.C. 8 Q. And Doctor, I'm going to return, I hope, to 9 that whole subject a little bit later, but I 10 understand that in the past you'd been 11 involved with the Canadian Association of 12 Pathologists. 13 DR. BANERJEE: 14 A. Yes. 15 COFFEY, Q.C. 16 Q. And you have been involved with the executive 17 and, in fact, had served as the president. 18 DR. BANERJEE: 19 A. That's correct. 20 COFFEY, Q.C. 21 Q. As well I understand that you had met a 22 gentleman named Dr. Donald Cook. 23 DR. BANERJEE: 24 A. Yes. 25 COFFEY, Q.C.</p>	<p>1 the technology of the day. Use a variety of 2 controls and good idea to correlate with Mount 3 Sinai". And he's noted here, "Ventana 4 provides standardization and reproducibility". 5 I appreciate, Doctor, these are just simply 6 some handwritten notes and I just bring them 7 to your attention because it is, as far as I 8 can tell, I believe the first note of a 9 contact with yourself, August 2. 10 DR. BANERJEE: 11 A. Right. 12 COFFEY, Q.C. 13 Q. Doctor, what do you recall about your initial 14 contact with Dr. Cook which ended up in you 15 coming to St. John's? 16 DR. BANERJEE: 17 A. So, what I recall was clearly he was concerned 18 about the conversion rates between the old 19 technique and the Ventana based method. And 20 my initial thought was there was something 21 wrong with the Ventana method optimization 22 because Ventana instruments were being 23 purchased by several hospitals during that 24 time and had seen the results of their 25 immunohistochemistry procedures. And</p>
<p>1 Q. How did you know Dr. Cook? 2 DR. BANERJEE: 3 A. I think probably when I joined the executive I 4 got to know him. I'd known about him before 5 because he was a member of the association. 6 COFFEY, Q.C. 7 Q. And if we could bring up, please, Exhibit P- 8 1992. Now, Doctor, these are handwritten 9 notes of Dr. Cook and here he notes that, on 10 Tuesday, August 2nd, 2005 at about 5:30, that 11 would be local St. John's time, I take it, 12 he's contacted you, I gather, by phone. He 13 writes, "given range of our figure Diponkar 14 feels we are in the range, may have a problem 15 with the Ventana being too sensitive; may not 16 have a problem with the old methodology, 17 stressed the need for quality assurance and 18 proficiency testing program. And a good idea 19 to correlate with Mount Sinai and set up 20 proficiency testing program with them. A bit 21 concerned about us reporting negatives". 22 Something "when negative internal controls and 23 may suggest test invalid". He says, "don't 24 admit to"--he notes you as saying, "don't 25 admit to error with the old system as it was</p>	<p>1 initially if you just went with whatever the 2 manufacturer tells you to use because this is 3 almost a fully automated system where the re- 4 agents are already pre-diluted. So, there's 5 very little modification required by the 6 technologists. But in general, I was noting a 7 lot more background staining with that system 8 because of the detection methodology was 9 different from the DAKO methods. And so my 10 initial thought was that possibly seeing a lot 11 of cytoplasmic staining and calling that 12 positives, something like - 13 COFFEY, Q.C. 14 Q. In the Ventana. 15 DR. BANERJEE: 16 A. That's right. So, that was my first immediate 17 reaction, that maybe it hasn't been optimized. 18 They've just started to use the Ventana system 19 and maybe they're just getting non-specific 20 staining and maybe the DAKO system was fine. 21 So, that was my initial, sort of, reaction, 22 but as I was talking to him and the issue of 23 internal controls came up and the fact that 24 tests that were being reported without 25 consideration that the internal controls have</p>

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1 to be positive concerned me. And then I
 2 started to wonder about other reasons why,
 3 that may be less than optimal staining
 4 protocol. We were definitely using a DAKO
 5 system ourselves. We've used it for many
 6 years and there's been no problem with it.
 7 So, I was quite sceptical about the DAKO being
 8 blamed as the culprit because it didn't make
 9 sense to me. And so I said, you know, don't
 10 jump to that conclusion yet and let me come
 11 and take a look at these slides because I
 12 hadn't seen their slides before. And then I
 13 might be able to figure out what was going on.
 14 COFFEY, Q.C.
 15 Q. So, don't jump to what conclusion?
 16 DR. BANERJEE:
 17 A. That there's something wrong with the DAKO
 18 system.
 19 COFFEY, Q.C.
 20 Q. Because your own institution was utilizing
 21 that technology, the DAKO, and others.
 22 DR. BANERJEE:
 23 A. It's being used by several institutions, Mount
 24 Sinai included.
 25 COFFEY, Q.C.

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1 Q. So, you indicated that you would come to St.
 2 John's.
 3 DR. BANERJEE:
 4 A. Um-hm.
 5 COFFEY, Q.C.
 6 Q. If we could look, please, at Exhibit P-1979.
 7 Now, Doctor, these two e-mails of August 3rd,
 8 2005, Dr. Cook's first one, the bottom of the
 9 page here.
 10 DR. BANERJEE:
 11 A. Right.
 12 COFFEY, Q.C.
 13 Q. He writes, "I certainly appreciate you coming
 14 to St. John's to review our
 15 immunohistochemistry lab during the dates of
 16 September 15th to the 16th, 2005. We will
 17 reimburse you for the costs. We'll keep in
 18 contact regarding the information you will
 19 need". And he does refer to your consultation
 20 fee and I do want to note that I'm not going
 21 to refer to it after, but in fact, you
 22 subsequently did waive your consultation fee,
 23 didn't you?
 24 DR. BANERJEE:
 25 A. I did.

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1 COFFEY, Q.C.
 2 Q. And then you responded by saying, "Hi Don, I
 3 look forward to the site visit". So, I take
 4 it, Doctor, really within the day of contact
 5 with Dr. Cook, you'd arranged the timeframe
 6 and -
 7 DR. BANERJEE:
 8 A. That's right.
 9 COFFEY, Q.C.
 10 Q. - the other considerations. Doctor, I refer
 11 you then to Exhibit P-1969. And here, Doctor,
 12 actually let me go to page two first; this is
 13 a couple of e-mails. The first one from Dr.
 14 Cook, at the bottom there, indicates, "I'm
 15 assuming everything is still a go for your
 16 visit to St. John's in review of our
 17 immunohistochemistry service" and he asks you
 18 to give him a call. And then the same day,
 19 later the same day, you respond with your
 20 travel arrangements and where you're staying
 21 and you then indicated, right here, "for my
 22 site visit, I will need to review any lab
 23 procedure manuals and a random selection of
 24 IHC slides before and after switching to the
 25 Ventana platform, including positive and

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1 negative control slides, not just for ER and
 2 HER2/neu, but all antibodies on your menu. If
 3 you have cases stained with both old and new
 4 methods on the same block, those would be
 5 helpful as well".
 6 Doctor, why was it then, just so the
 7 Commissioner understands, because you had been
 8 consulted really, initially, about the ER/PR.
 9 DR. BANERJEE:
 10 A. Um-hm.
 11 COFFEY, Q.C.
 12 Q. You'd been told by Dr. Cook, I take it, that
 13 had these number of retests and conversions.
 14 DR. BANERJEE:
 15 A. Yes.
 16 COFFEY, Q.C.
 17 Q. Had he told you at the time why there was
 18 retesting in the beginning and what had
 19 occasioned the retesting? Do you recall that?
 20 DR. BANERJEE:
 21 A. I recall the discussion around the initial
 22 patient that let to this whole investigation
 23 and the fact that they were going to retest
 24 other cases as well. I didn't know
 25 necessarily the extent of the retesting in

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1 terms of the numbers at that time.
 2 COFFEY, Q.C.
 3 Q. You just understood that there were a number
 4 of conversions. What they had retested,
 5 there'd been a number of conversions.
 6 DR. BANERJEE:
 7 A. That's right.
 8 COFFEY, Q.C.
 9 Q. And why then, Doctor, in kind of finalizing--
 10 because you'd be coming later, in fact, that
 11 week--the week of September 12. You weren't
 12 just going to limit yourself to ER/PR or
 13 HER2/neu slides. You wanted a wider
 14 selection. Why is that?
 15 DR. BANERJEE:
 16 A. So, what I was hoping to look for is some kind
 17 of pattern of non-specific staining or false
 18 negative staining as a result of some lack of
 19 optimization and methodology, particularly in
 20 the detection system side which would be
 21 similar, no matter which particular protein
 22 you were looking for. So, instead of looking
 23 just at ER/PR and HER2, I wanted to look at
 24 the full spectrum of what they did and just
 25 kept that view of what the problem might be

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1 due to.
 2 COFFEY, Q.C.
 3 Q. And this was in relation to Ventana stained
 4 slides, I take it.
 5 DR. BANERJEE:
 6 A. Yes.
 7 COFFEY, Q.C.
 8 Q. This wider view.
 9 DR. BANERJEE:
 10 A. I wanted to see both, both the stains through
 11 the DAKO system as well as the Ventana system,
 12 just to get an initial impression of whether
 13 there were some technical problems or not, and
 14 I wasn't necessarily assuming one thing or the
 15 other at that time.
 16 COFFEY, Q.C.
 17 Q. And you were asking for--review any lab
 18 procedure manuals.
 19 DR. BANERJEE:
 20 A. Yes.
 21 COFFEY, Q.C.
 22 Q. And why did you want to see those?
 23 DR. BANERJEE:
 24 A. I wanted to see whether the test optimization
 25 was done in the local lab or were they just

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1 following the manufacturers instructions for
 2 staining.
 3 COFFEY, Q.C.
 4 Q. And why would it be important to know the
 5 answer to that.
 6 DR. BANERJEE:
 7 A. Well, you know, I explained earlier, if you
 8 just take the manufacturers protocols, they
 9 may not necessarily work in your lab because
 10 there are other variables to correct for it.
 11 COFFEY, Q.C.
 12 Q. And what did you, in fact, find in that
 13 regard?
 14 DR. BANERJEE:
 15 A. I found, in general, again, I'm going to be
 16 fairly general, the DAKO system tended to have
 17 lower intensity staining no matter what you
 18 looked for.
 19 COFFEY, Q.C.
 20 Q. Probably if I could, I'll be visiting that,
 21 I'm just asking about the laboratory, were
 22 they using the spec sheets as it were or -
 23 DR. BANERJEE:
 24 A. Actually we didn't get into that.
 25 COFFEY, Q.C.

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1 Q. Okay.
 2 DR. BANERJEE:
 3 A. I don't recall having seen any lab manuals at
 4 the time of the visit.
 5 COFFEY, Q.C.
 6 Q. That's what I was going to ask you because you
 7 had asked to see laboratory or lab procedure
 8 manuals.
 9 DR. BANERJEE:
 10 A. Yes.
 11 COFFEY, Q.C.
 12 Q. And you don't recall, in fact, being presented
 13 with any.
 14 DR. BANERJEE:
 15 A. Right.
 16 COFFEY, Q.C.
 17 Q. Did you ask at the time subsequently whether
 18 there were any?
 19 DR. BANERJEE:
 20 A. No, I didn't because by the time I'd seen all
 21 the slides, I'd figured out what the problem
 22 was.
 23 COFFEY, Q.C.
 24 Q. Yes. Exhibit P-1942. Doctor, this is two e-
 25 mails of September 13th, 2005, the first at

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1 the bottom of the exhibit here is from Dr.
 2 Cook to yourself. He thanks you for your e-
 3 mail of September 12. He indicates he will
 4 pick you up. He says "I will drive you first
 5 to St. Clare's site where I will provide you
 6 with background information including a review
 7 of the IHC slides before and after the Ventana
 8 platform. The focus will be on ER and PRs,
 9 however I will try to get as many
 10 representative IHCs from other antibodies as
 11 possible. Following this I will take you over
 12 to the General site where the cutting and
 13 staining procedures are done and also have you
 14 meet with key individuals at that site. I had
 15 asked the chief tech to provide you with the
 16 lab procedure manual. I will fax you a copy
 17 of the terms of reference of the IHC review
 18 this afternoon. I assume"--he refers to your
 19 fax number and he says, "I will also try to
 20 arrange an exit interview with key leadership
 21 people from the organization on Friday
 22 afternoon. Let me know if this is okay". And
 23 you respond by saying, "thanks, the
 24 arrangements and exit interview are fine".
 25 If we could, please, Exhibit P-1283,

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1 Doctor, that is the background--these are
 2 terms of reference, External Quality Review of
 3 the Immunohistochemistry Service. And the
 4 Commissioner has seen these before, we all
 5 have here. I take it this was faxed to you?
 6 DR. BANERJEE:
 7 A. That's correct, yes.
 8 COFFEY, Q.C.
 9 Q. Doctor, back in early August you'd agreed to
 10 come to St. John's, what was your
 11 understanding of the terms, if any, under
 12 which you were coming and the purpose of your
 13 visit, at that time, early August?
 14 DR. BANERJEE:
 15 A. My understanding was that I was being asked to
 16 figure out what the problem was with their
 17 immunohistochemistry service, and I was
 18 approaching it from the point of view of an
 19 experienced immunopathologist who could
 20 troubleshoot for them and advise them about
 21 how they could improve the process.
 22 COFFEY, Q.C.:
 23 Q. These terms of reference when you look at
 24 them, the purpose is noted to be "To review
 25 the operation and make recommendations as to

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1 the processes involved and the service of the
 2 laboratory medicine program", and you're
 3 described as the external quality review
 4 consultant who will take direction from and
 5 make recommendations to the leadership team of
 6 the laboratory medicine program, and they talk
 7 about the time frame and the responsibilities
 8 are listed there, and then there's a case
 9 summary, which includes as well a reference to
 10 the -- as it turns out it's a lady named Peggy
 11 Deane, which has been referred to here at
 12 times as the index case, and four other
 13 patients, and then reference to what had
 14 happened up to that point in time in terms of
 15 the retesting and he notes -- this terms of
 16 reference notes, "Of the 57 retested on the
 17 Ventana System, 38 now show positive results",
 18 and a reference to the sensitivity of the
 19 Ventana System now being in question, and
 20 finally, "The report of the external quality
 21 review shall be in writing and include the
 22 team's recommendations. The recommendations
 23 will be shared with involved staff members",
 24 and it notes, "The peer review, its
 25 conclusions and a final report are protected

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1 under the Evidence Act, and as such the final
 2 report will not be available to any third
 3 party, and as well the final report is
 4 protected from any subsequent legal
 5 proceedings". Now, Doctor, I will ask you
 6 this because I'll be asking you your views
 7 later on in relation to this idea of peer
 8 review, quality assurance, and protection in
 9 legal proceedings, but at the time you agreed
 10 to come, was peer review or external quality
 11 assurance, was that on your mind or discussed
 12 between you and Dr. Cook, the idea that this
 13 would be a peer review?
 14 DR. BANERJEE:
 15 A. I think it was understood that the whole
 16 procedure would be protected under the
 17 Evidence Act.
 18 COFFEY, Q.C.:
 19 Q. Right from the beginning?
 20 DR. BANERJEE:
 21 A. Right from the beginning, but, you know,
 22 possibly each province does it differently, so
 23 unsure what to expect and what the actual
 24 procedure was going to be. Certainly in other
 25 jurisdictions, in Ontario, and in British

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<p>1 Columbia, somebody from risk management would 2 actually be driving that process, and it 3 wasn't the case here. 4 COFFEY, Q.C.: 5 Q. It wasn't the case here. 6 DR. BANERJEE: 7 A. No. 8 COFFEY, Q.C.: 9 Q. It was Dr. Cook. Doctor, just again so the 10 Commissioner can perhaps put this into 11 context, have you ever, yourself, conducted 12 peer reviews of other peers or been involved 13 in that? 14 DR. BANERJEE: 15 A. Yes, those would be based on individual 16 pathologists being reviewed as opposed to a 17 program review of this type, or external 18 reviews of an academic department when they're 19 looking for new leadership or whatever. 20 COFFEY, Q.C.: 21 Q. So you have done external reviews of an 22 academic department when you've been asked to 23 -- 24 DR. BANERJEE: 25 A. Yes.</p>	<p>1 DR. BANERJEE: 2 A. Anywhere else in the country, you mean? 3 COFFEY, Q.C.: 4 Q. Yes, that you're aware of. 5 DR. BANERJEE: 6 A. Yes, I was asked about another one, which they 7 turned me down as a reviewer for some reason. 8 Probably I was too expensive or something. 9 COFFEY, Q.C.: 10 Q. But I take it that as you've been involved in 11 your field for decades, that this is a 12 relatively rare -- as far as you know, a 13 relatively rare approach? 14 DR. BANERJEE: 15 A. Yes, doing a system review of a particular 16 aspect of a lab based on concern about the 17 quality of the results, yes, that would be 18 unusual. 19 COFFEY, Q.C.: 20 Q. Exhibit -- Doctor, I'm going to ask you -- 21 I'll be referring you to a couple of 22 documents, but I'm going to ask you to tell 23 the Commissioner -- it's about five to eleven, 24 Commissioner, so rather than embark upon that, 25 perhaps we could take the morning break, and</p>
<p>Page 74</p> <p>1 COFFEY, Q.C.: 2 Q. When they're looking for a particular -- like, 3 a head of a department? 4 DR. BANERJEE: 5 A. Right. 6 COFFEY, Q.C.: 7 Q. You've done that in the past, and you've been 8 asked to be involved in peer reviews of 9 individuals? 10 DR. BANERJEE: 11 A. Correct. 12 COFFEY, Q.C.: 13 Q. Have you ever been involved in this sort of a 14 review, the one that occurred here in St. 15 John's, a review of a whole department or 16 system? 17 DR. BANERJEE: 18 A. No. 19 COFFEY, Q.C.: 20 Q. This is your first. 21 DR. BANERJEE: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. Do you know of any other such review that has 25 occurred?</p>	<p>Page 76</p> <p>1 I'm going to come back and ask you to recount 2 then what you recall about what happened, 3 Doctor, when you arrived in St. John's in 4 September. 5 DR. BANERJEE: 6 A. Right. 7 COMMISSIONER: 8 Q. Okay, we'll take the morning break. 9 (BREAK) 10 COMMISSIONER: 11 Q. Mr. Coffey. 12 COFFEY, Q.C.: 13 Q. Thank you, Commissioner. Dr. Banerjee, could 14 you tell us then please about your visit to 15 St. John's in September, 2005? 16 DR. BANERJEE: 17 A. Certainly. If I recall correctly, I met with 18 Dr. Cook who took me to St. Clare's site 19 first, then the General site, and at the St. 20 Clare's site, we looked at selection of cases 21 that he had put together for my review, which 22 included the ER stains from the DAKO System 23 and the Ventana System, and other 24 immunohistochemistry preparations that I could 25 sort of look at a pattern of the staining</p>

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1 problems that they're having. So we sat down
 2 and looked at the slides together using a
 3 double-headed microscope. For each case we
 4 looked at, I had some comments that I made. I
 5 didn't record my observations on a piece of
 6 paper because I was really looking for
 7 patterns across multiple cases, and at the end
 8 of that review, I could see where the problems
 9 were, and it was a combination of fixation
 10 problems as well as optimization of the stain
 11 protocols. Clearly the DAKO System had a
 12 lower intensity staining than the Ventana
 13 System, which to me would suggest that there
 14 was either a problem with antigen retrieval or
 15 the antibody concentrations being used, or the
 16 detection system concentrations being used,
 17 were not optimal. We did discuss the issue of
 18 the internal controls, which I could see was a
 19 major problem in that all of the cases that he
 20 showed me that had converted between the DAKO
 21 and the Ventana Systems have the same kinds of
 22 characteristics, i.e. fixation not being
 23 adequate. The second thing was that many of
 24 the cases which included the benign breast
 25 epithelium showed no staining of the benign

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1 epithelium for estrogen receptors, and to me
 2 that would invalidate the particular report on
 3 that case since the internal controls did not
 4 work. Now since the Ventana System was
 5 picking up more positive cases, then one would
 6 have to conclude that fixation was not the
 7 only culprit since if the protein was
 8 completely destroyed because of inadequate
 9 fixation, neither system would have produced a
 10 positive result without creating huge
 11 background staining. So there was a
 12 combination of fixation problems and method
 13 optimization that led to the false negative
 14 staining, which because the Ventana System has
 15 really pre-diluted the reagents and has the
 16 antigen retrieval process built into the
 17 machine, it has, to a large extent, overcome
 18 problems related to fixation. However, I
 19 don't believe it can be completely overcome as
 20 there's surely some protein loss because of
 21 fixation problems. So those were my
 22 conclusions, and I verbally gave it to him,
 23 and commented about the need for dedicated
 24 technologists who understood how to
 25 troubleshoot, and the fact that they did not

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1 have a designated pathologist responsible for
 2 that service, and that was a major concern of
 3 mine. So it boils down to accountability for
 4 the quality assurance system in the lab, and
 5 that seemed to be -- if you want to look at
 6 the root cause of quality problems, it relates
 7 to accountability and who is responsible for
 8 quality.
 9 COFFEY, Q.C.:
 10 Q. Doctor, I'm going to ask you a little bit more
 11 about that. Before we go on, you were shown a
 12 variety of slides that Dr. Cook chose?
 13 DR. BANERJEE:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. The slides for estrogen receptors for the DAKO
 17 slides and the corresponding Ventana slides
 18 for that particular patient, approximately how
 19 many patients ER slides would you have dealt
 20 with?
 21 DR. BANERJEE:
 22 A. It was not a large number. I think it was
 23 roughly about 20 cases.
 24 COFFEY, Q.C.:
 25 Q. About 20.

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1 DR. BANERJEE:
 2 A. Yes, plus other cases for different --
 3 COFFEY, Q.C.:
 4 Q. Yes, and the others -- there would be 30 odd,
 5 I take it, of the other cases.
 6 DR. BANERJEE:
 7 A. Approximately.
 8 COFFEY, Q.C.:
 9 Q. In total, but they were other stains, not ER
 10 stains?
 11 DR. BANERJEE:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Not ER stains, they were other stains.
 15 DR. BANERJEE:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. And I'll ask you what you found with respect
 19 to those in a moment, but the sampling of 20
 20 cases that -- and all of which had converted.
 21 DR. BANERJEE:
 22 A. Uh-hm.
 23 COFFEY, Q.C.:
 24 Q. You understood from the ER DAKO slide to the
 25 ER Ventana slide --

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<p>1 DR. BANERJEE: 2 A. Correct. 3 COFFEY, Q.C.: 4 Q. Had all converted. Doctor, a sample size of 5 20, of course, is not necessarily all that 6 large. How comfortable did you feel at the 7 time that you had identified the source of the 8 problem, as it were? 9 DR. BANERJEE: 10 A. I was pretty comfortable because I could see 11 the recurrent problems around the fixation and 12 the lack of positivity in the internal 13 controls. So I didn't feel that I needed to 14 see more cases. If I only found one or two 15 cases of that nature, then I would have said 16 this isn't enough for me to make a conclusion. 17 COFFEY, Q.C.: 18 Q. If out of the 20, there was only one with a 19 fixation problem -- 20 DR. BANERJEE: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. Or an internal control that was present, but 24 hadn't stained, you would have had to go 25 looking for something else?</p>	<p>1 not a lab physician. 2 COFFEY, Q.C.: 3 Q. And Dr. Cook expressed that to you at the 4 time? 5 DR. BANERJEE: 6 A. Yes, and so did the other pathologists that 7 I've interviewed. 8 COFFEY, Q.C.: 9 Q. I was going to ask you then, Doctor, at the 10 St. Clare's site, did you speak with anyone 11 else at the time, do you recall? 12 DR. BANERJEE: 13 A. I didn't keep notes, and my recollection is 14 not very good, but I met with pathologists 15 individually. I think I spent the greatest 16 time with Dr. Edgecombe, whom I had known from 17 my previous training in Ottawa, he was a 18 trainee at the same time. 19 COFFEY, Q.C.: 20 Q. So you would have seen him on your visit in 21 September at the General Hospital site, I take 22 it? 23 DR. BANERJEE: 24 A. That's right. 25 COFFEY, Q.C.:</p>
<p>1 DR. BANERJEE: 2 A. That's correct. 3 COFFEY, Q.C.: 4 Q. Doctor, just while we're on this because 5 you've referred to it just now, and just so I 6 don't omit to go back to it, you referred to 7 the idea of organization and root cause? 8 DR. BANERJEE: 9 A. Uh-hm. 10 COFFEY, Q.C.: 11 Q. Perhaps we'll come back to that because that's 12 in your report itself and you addressed that, 13 and we'll address it then. 14 DR. BANERJEE: 15 A. Right, okay. 16 COFFEY, Q.C.: 17 Q. Did you discuss the management issue or the 18 organization issue with Dr. Cook at the time? 19 DR. BANERJEE: 20 A. I did, and one of his concerns, and obviously 21 it was frustrating him, was the fact that he 22 was the clinical chief of the lab, but he did 23 not have any authority over the technologist, 24 budget, space, etc, and that was under the 25 jurisdiction of the program director who was</p>	<p>1 Q. While you were at St. Clare's that day, do you 2 recall if you spoke with Beverley Carter, Dr. 3 Carter? 4 DR. BANERJEE: 5 A. I did speak with her, but I can't remember 6 where it was. 7 COFFEY, Q.C.: 8 Q. So it was brief, I take it -- 9 DR. BANERJEE: 10 A. Relatively brief, yes. 11 COFFEY, Q.C.: 12 Q. So you're with Dr. Cook, you examined the 13 slides, the conversation you referred to. 14 What if anything did you notice about the non 15 ER slides, this other sampling of slides? 16 What do you recall about those? 17 DR. BANERJEE: 18 A. What I recall about those were in the DAKO 19 System the intensity was rather pale, the 20 staining intensity, not what I would accept as 21 a very good result, and again looking at 22 internal controls for the various proteins 23 that we were looking at, there were clearly 24 cells that should have been positive that were 25 not. So I said this isn't optimized for these</p>

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1 particular tests as well. In looking at the
 2 Ventana, the intensity was certainly higher,
 3 but there was also more background staining,
 4 which is what I had expected to see, because
 5 all other labs were having the same problem
 6 with the Ventana System.
 7 COFFEY, Q.C.:
 8 Q. These were labs --
 9 DR. BANERJEE:
 10 A. Which were all not, you know, optimizable.
 11 COFFEY, Q.C.:
 12 Q. So I take it the Ventana slides, there was
 13 more background staining than from your
 14 perspective you would want?
 15 DR. BANERJEE:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. And you attributed that to a failure to have
 19 optimized the Ventana System?
 20 DR. BANERJEE:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. Did you discuss those two aspects of the
 24 matter with Dr. Cook?
 25 DR. BANERJEE:

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1 A. Yes, I did.
 2 COMMISSIONER:
 3 Q. Excuse me, Mr. Coffey, I'm not sure this is
 4 the right place to go down this road, but can
 5 you tell me a little more about what you're
 6 looking for when you're optimizing?
 7 DR. BANERJEE:
 8 A. Yes, certainly. So what we look for is -- I
 9 think the starting point is what manufacturer
 10 of the reagent would say this the dilution you
 11 use, etc, and this is the antigen retrieval
 12 method you should use. That's the starting
 13 point, but we then go through a process
 14 whereby we do multiple dilutions of the
 15 primary antibody, and try different heat --
 16 antigen retrieval protocols, enzyme versus
 17 heat, and then optimize the detection system
 18 which is a set of reagents that bind to the
 19 primary antibody, and all of that is what we
 20 call a checkerboard type of titration process.
 21 So what we're looking for is a crisp intense
 22 staining in the cells that you expect to be
 23 positive with a clean background, no staining
 24 at all in cells that are expected to be
 25 completely negative, and once you've done

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1 that, you then look at a range of examples of
 2 clinical samples to make sure that that is the
 3 correct setting for that test. So it corrects
 4 individual variations that might result from
 5 changes in fixation protocol, etc. Remember
 6 we are reference labs, so we do that because
 7 we know that when we get tissue blocks from
 8 other hospitals, they're not all going to be
 9 identically processed, so we have to modify
 10 our technique accordingly, but in a lab that
 11 only works with their own processed tissue,
 12 it's a little easier to actually establish the
 13 optimal protocols.
 14 COMMISSIONER:
 15 Q. Okay. So then as I understand what you're
 16 saying -- I think from other witnesses, I've
 17 understood a little bit about the process in
 18 the sense of you have these parameters of what
 19 you might want to use, and then you use
 20 incremental amounts, etc.
 21 DR. BANERJEE:
 22 A. That's correct.
 23 COMMISSIONER:
 24 Q. And examine the result, but the -- what you --
 25 the test of it, as it were, is what you see on

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1 the slide, and that is in terms of these
 2 things about minimizing background, optimizing
 3 what should be positive being positive, and
 4 what should be negative not showing, as it
 5 were?
 6 DR. BANERJEE:
 7 A. That's correct.
 8 COMMISSIONER:
 9 Q. Okay, and then in your case, because you're
 10 using or dealing with material which comes
 11 from different locations, you would want to
 12 make sure that the best choice for ideal
 13 circumstances will work with the varieties of
 14 fixation, etc, that you would expect to deal
 15 with?
 16 DR. BANERJEE:
 17 A. That's correct.
 18 COMMISSIONER:
 19 Q. Okay, and you said something this morning
 20 about being able to make anything positive, so
 21 how do you -- is it the fact that you have a
 22 known quantity on that slide that you're
 23 really doing the test, the initial test on,
 24 what makes you confident that, in fact, this
 25 is the appropriate thing?

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1 DR. BANERJEE:
 2 A. No. In fact, you know very little about how
 3 much of that protein is actually there in the
 4 tissue.
 5 THE COMMISSIONER:
 6 Q. Okay.
 7 DR. BANERJEE:
 8 A. There is no gold standard. So what you really
 9 look for is the cell type that should be
 10 expressing that particular protein, whether
 11 it's positive or not, because you can
 12 recognize different cell types just from the
 13 morphology of the cells.
 14 THE COMMISSIONER:
 15 Q. Okay.
 16 DR. BANERJEE:
 17 A. And based on the literature and examples from
 18 the studies that established the method, you
 19 then understand the intensity or expectancy.
 20 Intensity is not going to be identical for
 21 every type of protein, so it would depend on
 22 the protein. I think more important than
 23 intensity is the location of the positive
 24 reaction. So for something like estrogen
 25 receptors, which is a nuclear protein, one

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1 would not expect to see it in the cytoplasm of
 2 the cell. So it has to be a nuclear stain,
 3 and if you see anything outside of the
 4 nucleus, then one would again question whether
 5 the method has been optimized or not. So each
 6 protein you're looking for has particular
 7 characteristics about where it is expressed,
 8 what is known about how much of the protein is
 9 expressed in the cancer cell, etcetera, and
 10 that knowledge is really based on cancer cell
 11 lines which have been analyzed quantitatively
 12 for the protein, but translating that into
 13 clinical samples is quite difficult because
 14 there is no quantitative method in
 15 immunohistochemistry yet. It is a semi-
 16 quantitative method because there's so many
 17 steps of amplification required to create the
 18 sensitivity of the method that it loses its
 19 linear relationship to protein concentration.
 20 So no matter how automated the process is, it
 21 is a semi-quantitative--the end result, the
 22 interpretation of the result is very semi-
 23 quantitative and I think trying to standardize
 24 the grading of intensity is probably asking
 25 too much. Standardizing based on the

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1 percentage of cells being positive is perhaps
 2 more logical than trying to grade intensity,
 3 because it's not a linear relationship with
 4 the protein concentration.
 5 THE COMMISSIONER:
 6 Q. So that the person involved in this process
 7 has to be a person who is current with the
 8 literature?
 9 DR. BANERJEE:
 10 A. Yes.
 11 THE COMMISSIONER:
 12 Q. And the studies have made some, presumably,
 13 determination about the validity of some of
 14 these studies?
 15 DR. BANERJEE:
 16 A. Yes.
 17 THE COMMISSIONER:
 18 Q. And the key thing is what you know, on the
 19 basis of those studies, about what you should
 20 see?
 21 DR. BANERJEE:
 22 A. That's correct.
 23 THE COMMISSIONER:
 24 Q. And what the results should be. Okay, thank
 25 you.

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1 COFFEY, Q.C.:
 2 Q. Doctor, just on that point the Commissioner
 3 has raised with you, for example, in British
 4 Columbia, Vancouver, I take it that's where
 5 you're based at work, you're providing or you
 6 see and deal with blocks that come from
 7 different hospitals?
 8 DR. BANERJEE:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Variety of hospitals, and in this optimization
 12 process, you account for the fact that we're
 13 not just dealing with blocks from the second
 14 floor of our own building. These are blocks
 15 from a particular region or even a larger -
 16 DR. BANERJEE:
 17 A. The whole province.
 18 COFFEY, Q.C.:
 19 Q. The whole province, in effect, in your case.
 20 So that sort of an optimization process, which
 21 I take it has to occur in respect of each
 22 stain that's utilized?
 23 DR. BANERJEE:
 24 A. Um-hm.
 25 COFFEY, Q.C.:

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1 Q. If, at Eastern Health, the General Hospital,
 2 you visited in September 2005, is providing
 3 the same service, in effect, in terms of IHC,
 4 to the entire province here and in the course
 5 of doing so, is receiving blocks from
 6 hospitals, a number of hospitals throughout
 7 Newfoundland and Labrador, the same, not only
 8 optimization for their own fixation quality
 9 locally would have to occur, but as well, they
 10 would have to take into account the fact that
 11 they are going to be processing blocks from
 12 all over the province?
 13 DR. BANERJEE:
 14 A. That's correct.
 15 COFFEY, Q.C.:
 16 Q. The same sort of process would have to occur.
 17 Perhaps with fewer IHC tests here in St.
 18 John's, but the same process that occurs in
 19 Vancouver would have to occur here.
 20 DR. BANERJEE:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. The approach that is utilized in Vancouver in
 24 that regard, does the protocol used vary
 25 depending upon the hospital you get the block

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1 from or is it just the one--for example, for
 2 ER, is it -
 3 DR. BANERJEE:
 4 A. No, that would be too difficult to do. So we
 5 end up with a bit of a compromise. There are
 6 protocols designed to work with virtually all
 7 the material we receive. If there's a
 8 particular problem with a particular hospital,
 9 then we would discuss that with that hospital.
 10 But in British Columbia, I don't see that as a
 11 major problem, for whatever reason. I think
 12 it's a smaller province than Ontario and there
 13 are fewer hospitals involved and there's a lot
 14 more of a cohesive network of people who have
 15 been working together for many years. It's
 16 not really a problem there.
 17 COFFEY, Q.C.:
 18 Q. And Doctor, just while we've on it, because
 19 you've indicated that when you were looking at
 20 these slides with Dr. Cook, the approximately
 21 20 ER--pairs of ER slides and the other slides
 22 as well, the non-ER ones, you referred to and
 23 noted the fact that you'd recognized fixation
 24 problems?
 25 DR. BANERJEE:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Fixation issues. What is it that caused you
 4 to reach that conclusion, based upon what you
 5 saw? What is it that you were seeing that led
 6 you to that result?
 7 DR. BANERJEE:
 8 A. See, basically, you start out with the
 9 routinely stained section, that's the
 10 hematoxylin eosin stained preparation or H&E
 11 stain preparation, and you look at general
 12 sort of morphology of the tissue and how crisp
 13 the cells are. Are they easily identified or
 14 they look smudgy, etcetera, and the staining
 15 intensity is appropriate or not and that gives
 16 you, immediately, a reasonably good clue as to
 17 whether the tissue is well fixed and well
 18 processed, and as a general rule, if the
 19 tissue hasn't been well fixed or well
 20 processed, no matter what you do subsequent to
 21 the tissue being processed, in terms of
 22 special stains or immunohistochemistry, the
 23 results will not be optimal and even the
 24 morphology of the cells are distorted so that
 25 it may be difficult to actually identify the

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1 cancer type or whether there's cancer or
 2 benign tissue in there, particularly with
 3 smaller biopsies. So these are all kind of
 4 fundamental things you look for, and I could
 5 see that right from the get-go, looking at the
 6 H&E, that there was a problem with fixation.
 7 COFFEY, Q.C.:
 8 Q. And that's just the H&E slides that you saw at
 9 St. Clare's?
 10 DR. BANERJEE:
 11 A. That's right. And then, so if I describe the
 12 distortion a little more. So what you might
 13 see would be excessive shrinkage of cells. So
 14 there'll be gaps around the cells, between the
 15 stroma and the epithelium, for instance, or
 16 the nucleus would be swollen up or not as well
 17 defined as you would like to see, and the
 18 nucleus stains would be pale or very dark,
 19 depending on whether there's shrinkage or
 20 swelling and so on. So if you then choose a
 21 block which tells you that the tissue hasn't
 22 been fixed and processed adequately and you do
 23 the heat antigen retrieval on a section that's
 24 been cut and placed on a slide, the likelihood
 25 of that tissue actually staying on the slide

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1 is very low. It tends to fall off because
 2 it's a very harsh treatment, that high
 3 temperature. Or it starts to wrinkle or parts
 4 of it falls off or parts of the tumour might
 5 fall off, so you can't interpret your stain
 6 and so on. So it's critical to have that
 7 initial processing step optimized. Otherwise
 8 you have these kinds of problems. The
 9 morphology gets worse after the heat antigen
 10 retrieval and if you have bad morphology to
 11 start with, it just looks worse and worse. So
 12 it just compounds the problem.

13 COFFEY, Q.C.:

14 Q. Doctor, that sort of recognition of fixation
 15 not having been optimal or, in fact, having
 16 been relatively poor, looking at the H&E
 17 stained slides, would any pathologist who had
 18 gone through the residency program in Canada,
 19 for example, would they recognize that, do you
 20 think?

21 DR. BANERJEE:

22 A. Not necessarily, because it depends on--like
 23 if you were in training program in a teaching
 24 hospital that hadn't optimized its fixation
 25 process, you wouldn't recognize that there was

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1 a problem because every case would look
 2 similar and you sort of work around the
 3 problem.

4 COFFEY, Q.C.:

5 Q. Okay.

6 DR. BANERJEE:

7 A. I'll give you some anecdotal experience about
 8 that. When I first moved to London, Ontario,
 9 the University of Western Ontario, I
 10 specialized in lymphoma pathology, so these
 11 are lymph nodes with lymph gland cancer, and I
 12 could see that they had a fixation problem
 13 because they would place the entire lymph node
 14 in formalin, leave it in for hours and then
 15 cut it and process it. And of course,
 16 formalin takes a long time to penetrate tissue
 17 and fix it. It takes hours. So the thicker the
 18 tissue, the longer it'll take, and the centre
 19 of the tissue, in the meantime, would start to
 20 degrade because it hasn't been fixed yet. So
 21 I changed the protocol, saying you know, you
 22 have to take the fresh lymph node and slice it
 23 into thin slices, two to three millimetres
 24 maximum thickness, then fix it, and you'll see
 25 much better morphology, and what happened was

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1 because the morphology suddenly became better,
 2 people actually had difficulty in recognizing
 3 the cancer because now they're looking at
 4 cells which are bigger and looked horrible, in
 5 terms of malignant characteristics, and so
 6 there's a new learning curve for that because
 7 if you're used to badly processed tissue and
 8 you still can make a diagnosis, you're sort of
 9 reading through the artifact and if you remove
 10 the artifact, then somehow you have to reset
 11 your mind about, you know, how to interpret
 12 morphology all over again, and we have to go
 13 through that.

14 So if a hospital hasn't done that, then
 15 all of the residents in training will learn to
 16 read through the artifacts and they'll accept
 17 that as normal, and I think another factor
 18 that leads to this is that virtually all
 19 pathology training programs, the first year of
 20 training tends to focus on autopsy pathology,
 21 and certainly my training was like that as
 22 well. So the first year is just doing
 23 hundreds of autopsies, until you learn the
 24 pathology, and then you were allowed to go
 25 into surgical pathology as the next phase.

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1 Autopsy pathology, you're already starting
 2 with degraded tissue because cells start to
 3 degrade as soon as the patient dies, and of
 4 course, it takes hours before you actually
 5 begin the autopsy. So when you look at the
 6 morphology from autopsy tissue, it looks
 7 terrible, but you learn how to read that. So
 8 then when you go to surgical pathology and if
 9 your fixation is terrible, then you'd say
 10 "well, this is sort of what I'm use to
 11 anyway." So you'd sort of perpetuate that
 12 problem.

13 COFFEY, Q.C.:

14 Q. And so it's depending upon the local fixation
 15 practices from place to place, you wouldn't
 16 find it surprising to come in--for example, in
 17 your case, when you arrived here in St.
 18 John's, September 2005, and noted what you
 19 interpreted, saw interpreted as fixation
 20 issues on these slides, is it possible that
 21 Dr. Cook, for example, just would not have
 22 recognized it as a problem in the same way
 23 that you did?

24 DR. BANERJEE:

25 A. It is possible. It would depend on where he

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1 had trained and where he had practised,
 2 whether he had seen other examples. IF your
 3 practice is limited to the local professional
 4 practice, then you may see only a spectrum of
 5 quality. If you were in our situation,
 6 because we are looking at tissue from not only
 7 other hospitals in the province, but across
 8 the country, from other parts of the world, we
 9 saw a full spectrum of what's good and what
 10 isn't good, and we learned from that as well
 11 ourselves.
 12 COFFEY, Q.C.:
 13 Q. So Doctor, is there anything else you recall
 14 about the visit to St. Clare's that day?
 15 DR. BANERJEE:
 16 A. No, it's quite vague in my mind.
 17 COFFEY, Q.C.:
 18 Q. And you then, I take it, were taken over to
 19 the General Hospital?
 20 DR. BANERJEE:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. And what happened there?
 24 DR. BANERJEE:
 25 A. So there, I actually went to the lab that does

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1 the immunohistochemistry and talked to the
 2 technologists, looked at how the lab was set
 3 up. I wasn't particularly looking at how they
 4 do their work, but I was just asking them
 5 questions about what else they did and it was
 6 clear that they were not dedicated to that
 7 section in the lab, that they had other
 8 responsibilities elsewhere and they had felt
 9 it was hard for them to keep up with the
 10 knowledge base required to do a good job, but
 11 that's not unusual. This is a common problem
 12 across the country.
 13 COFFEY, Q.C.:
 14 Q. And your purpose in going to that site was
 15 what, the General Hospital site? Did you look
 16 at slides at the General Hospital site, do you
 17 recall?
 18 DR. BANERJEE:
 19 A. I don't recall whether I saw another set of
 20 slides. I don't think so.
 21 COFFEY, Q.C.:
 22 Q. So then your purpose then -
 23 DR. BANERJEE:
 24 A. It was more sort of interviewing other
 25 pathologists at that site.

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1 COFFEY, Q.C.:
 2 Q. You've indicated that you did, while you were
 3 in St. John's, at that time, speak to Dr.
 4 Ejeckam?
 5 DR. BANERJEE:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And you had known Dr. Ejeckam before?
 9 DR. BANERJEE:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Could you tell the Commissioner how it was you
 13 happen to know Dr. Ejeckam?
 14 DR. BANERJEE:
 15 A. Well, when I was in training in Ottawa, he was
 16 also a trainee, at not the same hospital I was
 17 in, but we met at the Canadian Tumour
 18 Reference Centre. We were both doing a month
 19 elective time there, and we got to know each
 20 other, and I've seen him off and on over the
 21 years and I know that he was very interested
 22 in immunohistochemistry, and certainly very
 23 knowledgeable, and so I asked him his opinion
 24 of what was going on. He sort of confirmed
 25 some of my conclusions. He was clearly not in

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1 charge of the lab, but he sort of had a -
 2 COFFEY, Q.C.:
 3 Q. Okay, I was going to ask you about that.
 4 DR. BANERJEE:
 5 A. - he really wanted to do something about it.
 6 COFFEY, Q.C.:
 7 Q. Doctor, so before September 2005, you
 8 understood that Dr. Ejeckam had more than a
 9 passing acquaintance with IHC techniques?
 10 DR. BANERJEE:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. He knew more than the average pathologist
 14 about it?
 15 DR. BANERJEE:
 16 A. I think so, yes.
 17 COFFEY, Q.C.:
 18 Q. And then finding him here on the ground, as it
 19 were, in St. John's, in the course of doing
 20 this, you would have, as you've indicated,
 21 asked him "what do you think is going on,
 22 Gershon?"
 23 DR. BANERJEE:
 24 A. Um-hm.
 25 COFFEY, Q.C.:

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1 Q. What was it--do you recall what it was he told
 2 you? And not only what was going on, but his
 3 position here in St. John's?
 4 DR. BANERJEE:
 5 A. Right. So he was obviously quite concerned
 6 about the quality of the immunohistochemistry
 7 lab and he sort of volunteered to try and help
 8 the lab to do a better job and he spent a lot
 9 of time actually teaching the technologists
 10 and providing them with reference books and
 11 textbooks, but clearly he didn't actually have
 12 the authority to make the additional changes
 13 that were required, and this was a recurrent
 14 theme amongst the pathologists, that they
 15 didn't feel they had any authority to change
 16 the way the lab was functioning.
 17 COFFEY, Q.C.:
 18 Q. Do you recall at that time, well do you
 19 remember what Dr. Ejeckam did--you speak about
 20 or did you learn while you were in St. John's
 21 at the time, either from him or anyone else
 22 that back in 2003 that Dr. Ejeckam had, for a
 23 period of time, stopped or caused to be
 24 stopped the utilization of eight stains, two
 25 of which were ER/PR, were you made aware of

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1 that while you were -
 2 DR. BANERJEE:
 3 A. Yes, he did discuss it with me and I think
 4 shared a memorandum here, circulated at the
 5 time as to why he wanted to stop the service
 6 and he introduced some changes in the lab that
 7 improved the staining process.
 8 COFFEY, Q.C.:
 9 Q. Do you recall if he told you what those
 10 changes were?
 11 DR. BANERJEE:
 12 A. I think working with the technologists to
 13 optimize each of the stains. At the time they
 14 were using, I believe they were using the DAKO
 15 system.
 16 COFFEY, Q.C.:
 17 Q. DAKO. Anything you recall about your meeting
 18 with Dr. Ejeckam at the time?
 19 DR. BANERJEE:
 20 A. Well we spent a fair bit of time talking about
 21 his role and he was perhaps a little concerned
 22 that I would sort of finger him as the culprit
 23 and I assured him that that wasn't what I was
 24 there for. I was trying to figure out whether
 25 from his observations that my conclusions were

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1 actually on the right track and he did come up
 2 with the same observations that I had.
 3 COFFEY, Q.C.:
 4 Q. And was it your understanding in speaking to
 5 him at that time that he had his own views or
 6 his own vision for perhaps what he wanted to
 7 achieve here -
 8 DR. BANERJEE:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. - but was not able to.
 12 DR. BANERJEE:
 13 A. That is correct.
 14 COFFEY, Q.C.:
 15 Q. That would summarize it, I take it.
 16 DR. BANERJEE:
 17 A. Uh-hm.
 18 COFFEY, Q.C.:
 19 Q. What then happened, Doctor? You had your
 20 round of interviews, did you meet with Mr.
 21 Terry Gulliver or Barry Dyer?
 22 DR. BANERJEE:
 23 A. Yes, I did.
 24 COFFEY, Q.C.:
 25 Q. At the General site?

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1 DR. BANERJEE:
 2 A. Correct.
 3 COFFEY, Q.C.:
 4 Q. What do you recall about that?
 5 DR. BANERJEE:
 6 A. I recall both gentleman as very eager to do a
 7 good job and they're very much in touch with
 8 the industry side of lab operations. The
 9 issue of accountability and governance, I did
 10 not discuss with them. They felt that they
 11 were perhaps not as appreciated by the
 12 pathologists as they would like, in terms of
 13 bringing innovation to the lab and that
 14 acquired some new equipment which was sitting
 15 idle because the pathologists weren't
 16 interested, so to me, that suggested that
 17 there wasn't a team approach to building the
 18 department and there was some separation of
 19 medical and technical staff in terms of
 20 planning quality assurance and so on.
 21 COFFEY, Q.C.:
 22 Q. And we understand as well, we're heard or
 23 understand that you met with a Dr. Dan
 24 Fontaine?
 25 DR. BANERJEE:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And had you known Dr. Fontaine before?
 4 DR. BANERJEE:
 5 A. I had known about it but I hadn't personally
 6 met him until that visit.
 7 COFFEY, Q.C.:
 8 Q. And in what context then here in St. John's
 9 did you meet him at the time?
 10 DR. BANERJEE:
 11 A. Just one of the few people that I interviewed
 12 and I think he was my host for dinner that
 13 first night.
 14 COFFEY, Q.C.:
 15 Q. We understand as well, I gather that you met
 16 with Dr. Denic, did you meet Dr. Denic at the
 17 time?
 18 DR. BANERJEE:
 19 A. Yes, I did.
 20 COFFEY, Q.C.:
 21 Q. And again, what was the purpose of your
 22 meeting with Dr. Denic?
 23 DR. BANERJEE:
 24 A. Just to get his impression about what the
 25 solution should be. We spent probably a

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1 significant amount of time talking about a
 2 problem with retaining pathologists on staff
 3 and a high turn over which Dr. Cook had also
 4 discussed with me and it was pretty well known
 5 across the country that pathologists in this
 6 province were not paid at the same level as
 7 some of the other provinces and they kept
 8 losing staff to other provinces for that
 9 reason. So I felt that that was perhaps one
 10 of the factors that led to perhaps a lack of
 11 continuity on the medical side of running the
 12 labs. When you don't have that stability,
 13 it's hard to develop a team.
 14 COFFEY, Q.C.:
 15 Q. Doctor, I understand that this visit to St.
 16 Clare's and the General would have occurred
 17 your first day, your first full day in St.
 18 John's.
 19 DR. BANERJEE:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Anything else other than going to dinner that
 23 evening, anything else that you were involved
 24 in that day?
 25 DR. BANERJEE:

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1 A. I can't think of anything right now.
 2 COFFEY, Q.C.:
 3 Q. How about the next day?
 4 DR. BANERJEE:
 5 A. Yeah, I think the next day was more, sort of
 6 more discussions about my observations with
 7 Dr. Cook and then I remember the exit
 8 interview, there were a number of people in
 9 the room, not just pathologists and I
 10 basically summarized my findings and then
 11 headed to the airport after that, sent in my
 12 written report within a few weeks.
 13 COFFEY, Q.C.:
 14 Q. Doctor, we do have some notes that refer to
 15 this exit interview, if I could ask, please,
 16 Exhibit P-2148? Now I appreciate these are
 17 not your notes, Doctor, but they are of an
 18 exit interview of September 16th, 2005, it's
 19 described as an external review there and your
 20 name is there, description of who you are or
 21 the position you had at the time. And there's
 22 a note here in paragraph one, "providing a
 23 comparable service with the rest of Canada.
 24 In some areas we are above average. There is
 25 lots of potential in the division of

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1 anatomical pathology with both pathologists
 2 and managers wanting to"--and it's very
 3 difficult for me to read, but I gather the
 4 point was -
 5 MR. BROWNE:
 6 Q. "Achieve the same end point".
 7 COFFEY, Q.C.:
 8 Q. "Achieve the same end point which is a good
 9 quality reliable service." Thank you.
 10 Doctor, do you recall telling the people in
 11 the exit interview that from your perspective
 12 they were providing a comparable service to
 13 elsewhere in the country?
 14 DR. BANERJEE:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. And in what context was that said?
 18 DR. BANERJEE:
 19 A. In the context of a full spectrum of hospital-
 20 -slides from various hospitals I've seen over
 21 the years, in terms of their peer groups, if
 22 you like.
 23 COFFEY, Q.C.:
 24 Q. And the peer group in this context would be
 25 which group?

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1 DR. BANERJEE:
 2 A. Combination of teaching and non-teaching
 3 hospitals.
 4 COFFEY, Q.C.:
 5 Q. Now that comment, was that made in relation to
 6 the ER/PR or -
 7 DR. BANERJEE:
 8 A. Immunohistochemistry in general.
 9 COFFEY, Q.C.:
 10 Q. Immunohistochemistry, generally, okay.
 11 DR. BANERJEE:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. The absence of internal control tissue or the
 15 presence of it and it's non-staining in the
 16 cases that you had look at the day before, had
 17 you ever encountered that before?
 18 DR. BANERJEE:
 19 A. Oh yes.
 20 COFFEY, Q.C.:
 21 Q. In other places.
 22 DR. BANERJEE:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. And I wanted to ask you about that, when you

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1 arrived in St. John's and looked at the
 2 slides, particularly those first 20 or so
 3 pairs of slides, were you surprised by what
 4 you saw?
 5 DR. BANERJEE:
 6 A. No, not really.
 7 COFFEY, Q.C.:
 8 Q. And why is that?
 9 DR. BANERJEE:
 10 A. We've seen it before, many times.
 11 COFFEY, Q.C.:
 12 Q. That people would have reported slides that
 13 either didn't have internal--ER slides that
 14 didn't have internal controls or had them and
 15 didn't stain appropriately.
 16 DR. BANERJEE:
 17 A. Right, yes.
 18 COFFEY, Q.C.:
 19 Q. You'd seen that in the past.
 20 DR. BANERJEE:
 21 A. Uh-hm.
 22 COFFEY, Q.C.:
 23 Q. Before you arrived in St. John's, had you
 24 anticipated seeing that or -
 25 DR. BANERJEE:

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1 A. No, actually I was thinking more about non-
 2 specific background staining as the culprit,
 3 perhaps difficulty in interpretation -
 4 COFFEY, Q.C.:
 5 Q. In relation to the Ventana.
 6 DR. BANERJEE:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. Perhaps overcalling, as it were.
 10 DR. BANERJEE:
 11 A. Yes, that's right.
 12 COFFEY, Q.C.:
 13 Q. But when you first saw the 20 pairs of slides
 14 and the attendant H&E stained slides -
 15 DR. BANERJEE:
 16 A. I changed my mind about that.
 17 COFFEY, Q.C.:
 18 Q. But what you were seeing didn't surprise you?
 19 DR. BANERJEE:
 20 A. No.
 21 COFFEY, Q.C.:
 22 Q. Doctor, here there's a note here, No. 2, there
 23 are issues, deals with the problem of--refers
 24 to a problem of adequate fixation of tissue,
 25 effect the reliability of immunoperoxidase

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1 testing, and need for pathology assistants and
 2 I'll be taking you through the report itself,
 3 but paragraph 3 then, you refer to the need
 4 for highly specialized immunoperoxidase
 5 concerned technologists, dedicated to that,
 6 you talked about the technologist issue being
 7 dedicated. One thing you refer to here is the
 8 issue of proper documentation and the antigen
 9 retrieval method, which is paragraph four. So
 10 what, if anything, had you learned about that?
 11 DR. BANERJEE:
 12 A. Well I think they were clearly using Ventana's
 13 protocol for antigen retrieval, but the
 14 machine can be set to several combinations of
 15 temperature and the duration of the heat
 16 treatment and I wasn't clear whether they had
 17 gone through that process to optimize it
 18 because there was no documentation of how they
 19 actually decided which of the various
 20 protocols available in the Ventana system was
 21 actually chosen. So I wanted to make sure
 22 they went through a process of optimization
 23 and then documenting that, so that the
 24 technologist would use that in the future
 25 runs.

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1 COFFEY, Q.C.:

2 Q. And then in paragraph 5, there's a reference

3 to the need for subspecialization and that

4 would be amongst the pathologists?

5 DR. BANERJEE:

6 A. Amongst the pathologists.

7 COFFEY, Q.C.:

8 Q. And reference to with an adequate compensation

9 package and I'll be talking to you a bit more

10 about that, so the issues discussed in the

11 main during the exit interview, at least

12 according to the notes here, were the fixation

13 aspect of the matter, the need for dedicated

14 technologists, attention being paid to proper

15 documentation and optimization of the antigen

16 retrieval methodology and the need for

17 subspecialization amongst pathologists. Do

18 you recall during that exit interview if the

19 idea of or the concern about internal controls

20 came up?

21 DR. BANERJEE:

22 A. I don't think there was much discussion about

23 that.

24 COFFEY, Q.C.:

25 Q. How about Dr. Cook? You had told Dr. Cook

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1 about this the day before.

2 DR. BANERJEE:

3 A. Right, so I thought that was covered under the

4 discussion about fixation.

5 COFFEY, Q.C.:

6 Q. Doctor, what I want to ask you is when you

7 raised the matter of internal controls with

8 Dr. Cook, do you recall whether or not he, at

9 the time appeared already aware of that?

10 DR. BANERJEE:

11 A. He seemed to be aware of that, but the initial

12 phone call in the conversation, the initial

13 phone call, I was surprised that they were

14 allowing those reports to go out without the

15 internal controls being positive.

16 COFFEY, Q.C.:

17 Q. Had he raised it during the phone call

18 initially or had you -

19 DR. BANERJEE:

20 A. No, I had questioned him on that point because

21 I wanted to make sure that the interpretation

22 was not the issue, didn't seem to be.

23 COFFEY, Q.C.:

24 Q. And when he said that no, he knew or by then

25 knew that some cases were being reported

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1 without the internal controls that's being

2 stained positive and he told you that, you

3 thought well maybe interpretation may be an

4 issue here too?

5 DR. BANERJEE:

6 A. Right, he raised the point about cases where

7 the internal control was negative, but the

8 tumour was positive, which as I said, that's

9 okay, so when both are negative, it's hard to

10 make a conclusion.

11 COFFEY, Q.C.:

12 Q. That came up during that August 2nd phone

13 call?

14 DR. BANERJEE:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. And it would have arisen then again, I take

18 it, on September 15th, the first day you were

19 in St. John's looking through the microscope

20 together.

21 DR. BANERJEE:

22 A. Right, discussed that, every example we looked

23 at.

24 COFFEY, Q.C.:

25 Q. Exhibit P-0046 please? Now, Doctor, this is a

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1 copy, well the first page is your covering

2 letter of October 17th, 2005 to Dr. Cook and

3 it's Re: "External Quality Review of

4 Immunoperoxidase Service". Signed by yourself

5 and then the second page of the exhibit is, of

6 course, the cover page of the report. Before

7 I delve into this, we understand at the time

8 you were in St. John's, Dr. Bob Williams,

9 Robert Williams was the VP Medical?

10 DR. BANERJEE:

11 A. That's correct.

12 COFFEY, Q.C.:

13 Q. Do you recall meeting with Dr. Williams?

14 DR. BANERJEE:

15 A. Yes, I did actually, I think probably twice, I

16 can't remember the exact number of meetings I

17 had with him, but definitely the exit

18 interview was in his administrative office

19 area.

20 COFFEY, Q.C.:

21 Q. So he was present for that?

22 DR. BANERJEE:

23 A. Yes.

24 COFFEY, Q.C.:

25 Q. You note here, Doctor, "Please find enclosed

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1 my report" and you offer to clarify any issues
 2 that may arise, and then you stated, "In
 3 addition, please convey to Dr. Williams that
 4 beyond the specifics of my report, there
 5 should be recognition of the following issues
 6 that have bearing on the sustainability of the
 7 quality laboratory program. No. 1,
 8 pathologist compensation should be competitive
 9 with those of other provinces; otherwise your
 10 department will face ongoing staff turn over
 11 as pathologists move to more rewarding
 12 positions elsewhere. Unless this revolving
 13 door syndrome is dealt with, it will only lead
 14 to the deterioration of the quality of staff
 15 as you will continue to lose your best people.
 16 No. 2, "For high quality cancer program in the
 17 province, your department must invest in
 18 subspecialization, continuing education and
 19 central pathology review for the entire
 20 province in order to provide the highest
 21 quality of service in cancer diagnosis, so
 22 that your oncologists can manage their
 23 patients optimally. All cancer patients
 24 deserve the same standard of care, regardless
 25 of where they live. Accurate pathology

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1 diagnosis, grading and staging are essential
 2 for clinical decision making and these
 3 activities cannot be compromised. With the
 4 two recommendations implemented, you will be
 5 able to attract and retain the best
 6 pathologists." Now, Doctor, I take it the two
 7 recommendations in this context are those two
 8 above?
 9 DR. BANERJEE:
 10 A. That's correct.
 11 COFFEY, Q.C.:
 12 Q. Because there are a number in your report
 13 itself. Doctor, the reference to "central
 14 pathology review for the entire province" what
 15 are you referring to there?
 16 DR. BANERJEE:
 17 A. What I'm referring to is, well if you look at
 18 how patients with cancer are diagnosed, the
 19 initial diagnostic procedure could be a biopsy
 20 or a resection by a surgeon and that could
 21 happen anywhere, in any hospital with surgical
 22 facilities. And usually the report is then
 23 generated by the local pathologists at that
 24 hospital. It's my personal belief that to be
 25 a good cancer pathologist, you'd need to see a

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1 significant number of cases every year to keep
 2 your skills up and in some of the smaller
 3 community hospitals, they don't see enough
 4 cases to achieve that level of skill. I also
 5 believe that cancer pathology should be
 6 practised by people who have received
 7 additional education and training beyond the
 8 Royal College certification, particularly in
 9 high volume cancer centres either in Canada or
 10 the United States. So I personally recruit
 11 people with at least one or two years of post
 12 Royal College certification experience in a
 13 specific area of pathology, preferentially in
 14 a cancer centre. The reason for that is
 15 cancer is a complex disease, there are many
 16 different kinds. The common cancers are easy
 17 to diagnose because people are familiar with
 18 them, but the uncommon cancers presenting as
 19 if they are a common cancer is where the
 20 problem lies, so there may be under-diagnosis,
 21 under-grading, over-grading, all of that sort
 22 of thing. I know from my own experience in
 23 Toronto and now in Vancouver that in general
 24 there is--when you do a central review, that's
 25 done before the patient actually begins

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1 treatment at one of the cancer centres, that
 2 you tend to uncover some details that the
 3 oncologist actually needs to make a decision
 4 about the best management of that patient. We
 5 have quantified that and when I was at the
 6 Princess Margaret Hospital, I did a survey of
 7 how many changes were made as a result of that
 8 central review that would affect patient
 9 management. It was not an insignificant
 10 number, on average of 26 percent, so that's a
 11 pretty big number. British Columbia, it's in
 12 the order of 15 percent. We also see cases
 13 from other provinces and patients have been
 14 referred to, BC Cancer Agency and the
 15 discrepancy rates could be even higher than
 16 the 15 percent we see in BC. If you then
 17 convert that into something other than
 18 statistics, and you say all right, how many
 19 breast cancer patients are diagnosed every
 20 year in the province? In BC we have about
 21 2700 cases a year, multiply that with 15
 22 percent discrepancy rates, so you have several
 23 hundred patients who are maybe undercalled or
 24 overcalled that would receive the wrong
 25 treatment.

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1 COFFEY, Q.C.:

2 Q. In the absence of this central -

3 DR. BANERJEE:

4 A. In the absence of the central review. And

5 this is not surprising, this is reported

6 widely in the literature and every

7 jurisdiction these kinds of problems exist.

8 The American Cancer Centre, by rule, will

9 always review the outside pathology before a

10 patient is treated, unless it's an emergency

11 situation. In Canada there is no such rule,

12 except--and some cancer centres lack, BC

13 Cancer Agency and the Princess Margaret

14 Hospital et cetera, and the reason why this is

15 not widely practised, a pathologist don't like

16 to be second guessed or have their work

17 reviewed by someone else, a natural sort of

18 reaction.

19 COFFEY, Q.C.:

20 Q. I take it that's not peculiar you expect of

21 pathologists.

22 DR. BANERJEE:

23 A. Sorry?

24 COFFEY, Q.C.:

25 Q. That's not peculiar or unique to pathologists.

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1 DR. BANERJEE:

2 A. No, many, any professional would be

3 uncomfortable with that situation; however, if

4 you translate the statistics into the

5 individual patient, then it becomes very clear

6 that ethically this is what we need to do

7 because I've been accused of wasting

8 taxpayer's dollars by doing central reviews, I

9 say, it's okay, I'm looking at what the

10 patient needs and that's what I'm basing my

11 policy on.

12 COFFEY, Q.C.:

13 Q. And so at the time you wrote this in October

14 of 2005, from your perspective and again,

15 you're coming in from the outside to Eastern

16 Health and in particular, St. Clare's and the

17 General Hospital sites, bearing in mind what

18 you were then given to understand about how

19 cancer patients were treated in the province,

20 all the IHC staining being done at the General

21 Hospital, the original diagnosis often being

22 made elsewhere, that even in the context of

23 this province, to set up a central pathology

24 review for the entire province, was

25 appropriate you -

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1 DR. BANERJEE:

2 A. Yes, I believe every province should have some

3 kind of central review policy.

4 COFFEY, Q.C.:

5 Q. And that would not be limited to ER/PR or

6 breast cancer.

7 DR. BANERJEE:

8 A. No.

9 COFFEY, Q.C.:

10 Q. It would be across the board.

11 DR. BANERJEE:

12 A. Across the board. We tend not to review cases

13 where the management wouldn't change, if

14 somebody presents with metastatic disease and

15 there are very few options for the patient,

16 then we wouldn't do the review.

17 COFFEY, Q.C.:

18 Q. But for, certainly primary cancers, initial

19 diagnosis of cancer -

20 DR. BANERJEE:

21 A. Yes, and the policy is developed with

22 discussion with oncologists about we ensure

23 that we're not being frivolous about the

24 central review and it's done for the right

25 reasons.

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1 COFFEY, Q.C.:

2 Q. Now this central pathology review, I take it

3 that, the idea of that, that's an across the

4 board thing, that's not a particular patient

5 or is it every 10th patient or every patient -

6 DR. BANERJEE:

7 A. No, it's every patient. Historically, I mean,

8 even at the Princess Margaret Hospital when I

9 first arrived there, it was--the second

10 opinion was triggered by an oncologist looking

11 at the original report and saying, you know,

12 something doesn't sound right or doesn't fit,

13 I had better get this reviewed. And then

14 explain to them that if you only go by whether

15 the report looks right or wrong, I could

16 create a report that looks beautifully

17 correct, but could be completely wrong because

18 the data in the report may be totally wrong.

19 And how do you know that? So that led to, you

20 know, I went to the Medical Advisory Committee

21 and persuaded them to change that policy, so

22 that every patient in certain categories would

23 be reviewed centrally.

24 COFFEY, Q.C.:

25 Q. Just, I want to clarify, Ms. Chaytor asked me

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1 to clarify this, is this all patients, all
 2 cancer patients across the board or is it
 3 cancer patients just in particular categories?
 4 DR. BANERJEE:
 5 A. It would be certain cancer types where
 6 treatment options are multiple and hinge on
 7 particular characteristics of the individual
 8 patient pathology, yeah.
 9 COFFEY, Q.C.:
 10 Q. Does breast cancer fall into that category?
 11 DR. BANERJEE:
 12 A. It does.
 13 COFFEY, Q.C.:
 14 Q. If we could then look at the body of the
 15 report itself, I will tell you this, the
 16 Commissioner has seen this report a number of
 17 times and various parts of it, in the incident
 18 problem case, you note here in the second
 19 paragraph, "It should be noted that invasive
 20 lobular carcinomas are frequently ER positive
 21 92 percent." And you have a footnote there
 22 for that cited, "Thus the initial negative
 23 result should have been questioned."
 24 DR. BANERJEE:
 25 A. Right.

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1 COFFEY, Q.C.:
 2 Q. And we look, the particular article in
 3 question you've cited in the footnote is the
 4 Journal of Clinical Oncology 2005 and that, I
 5 take it, is what you cited for the 92 percent.
 6 Doctor, had the patient originally, of course,
 7 been tested in 2002, was it generally known in
 8 2002 and before 2002 that invasive lobular
 9 carcinomas should be ER positive?
 10 DR. BANERJEE:
 11 A. Yes, it was known. I used that reference
 12 because that actually quantitated the
 13 positivity rate.
 14 COFFEY, Q.C.:
 15 Q. I'm sorry?
 16 DR. BANERJEE:
 17 A. It had actually provided a quantitation of the
 18 positivity rate.
 19 COFFEY, Q.C.:
 20 Q. A quantitation, the figure of 92 percent.
 21 DR. BANERJEE:
 22 A. Yeah, in general practice it's almost
 23 virtually 100 percent.
 24 COFFEY, Q.C.:
 25 Q. And you say, "Thus the initial negative

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1 results should have been questioned." Now,
 2 from your perspective, questioned by whom?
 3 DR. BANERJEE:
 4 A. By the pathologist and the oncologist, both.
 5 Both groups should have been aware.
 6 COFFEY, Q.C.:
 7 Q. You go on to note then, Doctor, you talk about
 8 and I take it the four other patients
 9 previously tested were also retested and that,
 10 in fact is referred to in the terms of
 11 reference, I believe, and in any case you
 12 would have become aware of that while you were
 13 here in St. John's dealing with Dr. Cook and
 14 company. The conversation rate would be based
 15 upon figures given to you by Dr. Cook.
 16 DR. BANERJEE:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. Then you, under review of cases, you reviewed
 20 a number of cases from the retrospective
 21 testings with Dr. Donald Cook and that would
 22 be the ER cases?
 23 DR. BANERJEE:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. That retrospective group and that would be, as
 2 you quantified it here, approximately 20 such
 3 cases?
 4 DR. BANERJEE:
 5 A. That's correct.
 6 COFFEY, Q.C.:
 7 Q. And you conclude your comment here by saying,
 8 "It is apparent that too much reliance is
 9 being placed on external positive controls
 10 with no attention paid to internal controls".
 11 I take it that your conclusion, "No attention
 12 being paid to internal controls", is based
 13 upon what, what kind of reasoning were you
 14 using there?
 15 DR. BANERJEE:
 16 A. Oh, that cases were being called positive --
 17 negative, rather, even though the internal
 18 controls were either not there, there's no
 19 normal epithelium to look at, or if it was
 20 present, it was negative as well. So in our
 21 practice, we would not report those, we would
 22 call them inconclusive.
 23 COFFEY, Q.C.:
 24 Q. And then, Doctor, you refer to a literature
 25 review of the DAKO versus Ventana

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1 immunostainer performance.
 2 DR. BANERJEE:
 3 A. Right.
 4 COFFEY, Q.C.:
 5 Q. And you note that that particular study
 6 published in '98 may not be relevant, and in
 7 any case, I take it, Doctor, as we'll see
 8 later in your report, the problem in St.
 9 John's, from your perspective, wasn't per se
 10 the DAKO or the Ventana systems?
 11 DR. BANERJEE:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. Perhaps through utilization?
 15 DR. BANERJEE:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. Doctor, here there's a note, you begin at the
 19 bottom of the page here by saying, "Fixation
 20 time in formalin does not affect the ER
 21 results as long as two millimetre thick slices
 22 of tissue are placed in fixative within
 23 fifteen minutes of surgical excision, and
 24 adequate heat induced antigen retrieval is
 25 performed". Would that mean that any minimum

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1 amount of time, fixation time?
 2 DR. BANERJEE:
 3 A. No, I should have provided more detail there.
 4 There is a minimum time of six to eight hours
 5 that's recommended in the literature. In
 6 general, I think, the smaller the biopsy, the
 7 less time required. That's just a general
 8 guideline. The larger samples like the
 9 lumpectomies and mastectomies require more
 10 time than that just because of the volume of
 11 tissue involved.
 12 COFFEY, Q.C.:
 13 Q. Doctor, you do go on then at some length and
 14 discuss this matter fixation. On the top of
 15 the second page, you note, "Since the Ventana
 16 System did detect ER protein in previously
 17 negative cases, one must conclude that even if
 18 there was partial loss of ER protein due to
 19 poor fixation, the failure of the DAKO System
 20 was largely due to inadequate antigen
 21 retrieval or inadequate antibody and/or
 22 detection system optimization, or a
 23 combination of these factors", which I take it
 24 is a written form of what you told us earlier
 25 --

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1 DR. BANERJEE:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. You told Dr. Cook. The second last sentence
 5 here in this paragraph, Doctor, you write, "It
 6 remains possible that even with complete
 7 optimization of antigen retrieval and
 8 immunostaining protocols, if fixation is not
 9 optimized, there will be an irreducible number
 10 of false negative cases".
 11 DR. BANERJEE:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. So I take it -- do I understand that to mean
 15 then in my layman's terms that no matter how
 16 careful you are with your antigen retrieval
 17 and immunostaining procedures, if the fixation
 18 is done poorly enough, then no matter what we
 19 do in the lab, it will not be able to correct
 20 the problem?
 21 DR. BANERJEE:
 22 A. That's correct, yes.
 23 COFFEY, Q.C.:
 24 Q. Doctor, the choice of antibodies, could you
 25 explain -- tell us, please, just expand upon

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1 this a bit in terms of what antibody was being
 2 used here in St. John's, and from your
 3 perspective, the advantages and disadvantages
 4 of switching?
 5 DR. BANERJEE:
 6 A. If I recall correctly, they were using the 1D 5
 7 antibody, which is widely used. The other
 8 widely used one is 6F11, and in some labs 6F 11
 9 performs better than ID5; in other labs
 10 they're about equivalent. They're both
 11 capable of demonstrating the protein in
 12 formalin fixed tissue provided to the antigen
 13 retrieval. Now in the last few years,
 14 additional anti -- monoclonal antibodies have
 15 been developed which are derived from rabbits
 16 as opposed to mice. Now rabbit immune systems
 17 are a little different from the mouse in that
 18 they seem to have more stronger reaction to
 19 whatever the immunizing antigen is. So
 20 rabbits historically have been used for the
 21 preparation of antibodies, polyclonal
 22 antibodies, not monoclonals, and rabbit
 23 antibodies tend to have higher affinity to
 24 bind more tightly to the antigen that they're
 25 directed against. So now that the technology

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1 to develop monoclonal antibodies from rabbits
 2 has been introduced, some of the newer
 3 antibodies are coming out with much higher
 4 affinity than the mouse antibodies, and in
 5 various labs that have compared the mouse
 6 antibodies with the rabbit antibodies, they
 7 find that the rabbit antibodies are of such
 8 affinity that even if you don't do antigen
 9 retrieval, they will yield a positive result,
 10 which is interpretable quite easily. So one
 11 could debate whether or not they need to
 12 switch, but in general in our hands the SP1
 13 antibody seems be more reproducible, less
 14 variation from case to case, but others have
 15 found that if you compare the 1D5 and SP1,
 16 clearly SP1 is better, but if you compare with
 17 6F11 and SP1, in one report there is no
 18 difference; in another report the SP1 is
 19 better. So the differences are fairly minor,
 20 but the intensity is a little better with SP1,
 21 it's easier to interpret, and cases that have
 22 been negative by 1D5 have turned out to be
 23 positive with the SP1, even in our lab. So
 24 there is some benefit to switching, but again
 25 if you haven't dealt with the fixation issue,

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1 it's probably not the area to invest in.
 2 COFFEY, Q.C.:
 3 Q. Yes. In fact, we do come across if we jump
 4 ahead to recommendation 3, in this context
 5 you're only comment was consideration should
 6 be given to switching to SP1, you weren't
 7 telling them to switch to it, you were just
 8 pointing out here, I take it, the pros and
 9 cons as known at the time to you, and
 10 ultimately in your recommendation leaving it
 11 to them?
 12 DR. BANERJEE:
 13 A. Uh-hm, yes.
 14 COFFEY, Q.C.:
 15 Q. Doctor, you've noted here, inter-laboratory
 16 variability, "A number of publications
 17 indicate poor concordance between laboratories
 18 for ER assays, especially for the weakly
 19 positive cases", and this is attributed to
 20 variation in antigen retrieval protocols",
 21 citing footnote seven and eight, and when we
 22 look, we'll see that footnote seven is an
 23 American Journal of Clinical Pathology article
 24 of 2002, and then an article in 2001, or
 25 publication. Doctor, in particular, could

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1 you, if you can, please, elaborate a little on
 2 the reference to "especially for the weakly
 3 positive cases".
 4 DR. BANERJEE:
 5 A. Right.
 6 COFFEY, Q.C.:
 7 Q. You alluded to this earlier too.
 8 DR. BANERJEE:
 9 A. Right. So if you look at the publication that
 10 compared the biochemical test with the
 11 immunohistochemistry assays, the discordance
 12 between the two methods were particularly
 13 prominent in the cases with low estrogen
 14 receptor content from the biochemical assay.
 15 So it's clear that even immunohistochemistry
 16 might miss positive cases in that range of
 17 concentration, and those particular
 18 publications, I actually don't have copies
 19 with me right now, but there's a similar
 20 publication which I mentioned earlier, which
 21 is from the UK quality assurance program, the
 22 Rhodes and Jasani paper. That sort of came to
 23 similar conclusions and they thought the
 24 antigen retrieval was the main culprit for the
 25 inter-lab variability, but as I mentioned

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1 earlier, they also excluded cases that had
 2 fixation problems, so -- they didn't quantify
 3 that.
 4 COFFEY, Q.C.:
 5 Q. And weakly positive cases are problematic, in
 6 particular, why? I take it there's so little
 7 --
 8 DR. BANERJEE:
 9 A. Yes, there's not enough protein. So if your
 10 method is not sensitive enough, you'll have a
 11 negative result. However, from a clinical
 12 perspective, those patients are eligible for
 13 Tamoxifen therapy and may respond. So it
 14 could lead to denial of therapy to women with
 15 low positive (unintelligible).
 16 COFFEY, Q.C.:
 17 Q. Doctor, you go on here then with your
 18 conclusions about the reasons for test
 19 failure. You posed the question, "Is the DAKO
 20 System faulty", and I take it that, in effect,
 21 in the course of coming to St. John's, that
 22 was one of the questions posed to you?
 23 DR. BANERJEE:
 24 A. Right.
 25 COFFEY, Q.C.:

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1 Q. And you say this us unlikely, and then you
 2 give the reason for test failure was most
 3 likely due to, and you - lack of test
 4 optimization, including antigen retrieval
 5 method and antibody detection system titration
 6 as positive controls showed a weak staining in
 7 general, and internal controls failed in all
 8 the false negative cases, and we've already
 9 discussed most of this. One thing I do want
 10 to ask you about is "positive controls showed
 11 weak staining, in general".
 12 DR. BANERJEE:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. What are you referring to there?
 16 DR. BANERJEE:
 17 A. So those are the external positive controls
 18 that they were using for each run, and when I
 19 looked at them, they were of lower intensity
 20 than I would be used to seeing in our lab.
 21 COFFEY, Q.C.:
 22 Q. And what, if anything -- bearing in mind that
 23 these positive controls were generally
 24 staining weakly, from your perspective as a
 25 pathologist, what if anything should be the

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1 thought process when faced with that kind of a
 2 positive control that's staining weakly? What
 3 should that alert you to, if anything?
 4 DR. BANERJEE:
 5 A. So my concern would be that you've chosen a
 6 positive control with detectable staining, but
 7 it was of low intensity and that was probably
 8 your best case because that's how labs choose
 9 their positive control, and if that's the
 10 case, then there's something wrong with your
 11 methods, not sensitive enough, because I've
 12 seen a lot more intense staining in our lab.
 13 COFFEY, Q.C.:
 14 Q. So I understand this correctly, if that
 15 positive control slide is staining --
 16 DR. BANERJEE:
 17 A. Uh-hm.
 18 COFFEY, Q.C.:
 19 Q. But if that's the most intense -- you're
 20 saying to the Commissioner, what your
 21 understanding as an outside would be, if
 22 that's your most intensely stained positive ER
 23 slide that you have, then that can't be
 24 correct?
 25 DR. BANERJEE:

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1 A. That's right.
 2 COFFEY, Q.C.:
 3 Q. Because there would be patients who would be
 4 better than that, more positive staining, more
 5 intense positive staining?
 6 DR. BANERJEE:
 7 A. Correct.
 8 COFFEY, Q.C.:
 9 Q. And, therefore, that should have alerted the
 10 reader of the slide to there's something wrong
 11 with the process here generally for ER?
 12 DR. BANERJEE:
 13 A. That's right, but --
 14 COFFEY, Q.C.:
 15 Q. And it wouldn't be particular to that run
 16 then, I take it, it would be in general?
 17 DR. BANERJEE:
 18 A. In General, yes. The positive control -- the
 19 external positive controls is usually one
 20 block from one case that they keep using over
 21 and over again. So it's the same tissue,
 22 newer sections being cut from the block and
 23 then used in the stain, but just to go back to
 24 that discussion, it would also -- I mean,
 25 looking back at why that would be the case, it

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1 would also suggest that when they were setting
 2 up the staining protocols, that they hadn't
 3 actually received or asked for examples from
 4 other labs. So ask for positive control from
 5 a different lab, for instance, with the
 6 original lab slides, immunohistochemistry
 7 preparations to compare with, because if you
 8 have no comparator, how do you set your
 9 threshold. If you're using your own external
 10 positive controls and you say, well, this is
 11 as intense as it's getting, then you think
 12 that's probably okay because you haven't seen
 13 other examples where the intensity is much
 14 greater than that.
 15 COFFEY, Q.C.:
 16 Q. Doctor, if--I'll ask you this. If an external
 17 positive control that you are seeing on a
 18 routine basis and it's staining the way you
 19 would expect, it's strongly--you're looking
 20 for a strong positive. You're expecting that
 21 and you're seeing that, one day to the next,
 22 and then on a particular day, on a Thursday,
 23 you happen to see external positive control
 24 had stained, but it's not nearly as strong as
 25 it was in the weeks before that, what, if

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1 anything, would that cause you to inquire
 2 into?
 3 DR. BANERJEE:
 4 A. Yes, so that would trigger us asking the
 5 technologist, you know, "what has changed?
 6 Have you got a new batch of antibody that
 7 needs to be reoptimized, you know,
 8 retitrated?" That kind of discussion needs to
 9 occur. Sometimes a block--see, as you cut
 10 into the block and you put the block back in
 11 storage, the technologist usually puts more
 12 wax on it to cover the cut surface, because
 13 once you expose the cut surface to oxygen, all
 14 proteins will deteriorate over time. So
 15 that's why we don't pre-cut sections for
 16 immunohistochemistry. We try to cut fresh
 17 sections from the block. So sometimes a block
 18 itself will deteriorate or you're cutting
 19 deeper into the tumour and there's tumour
 20 heterogeneity which will also account for loss
 21 of intensity. Different parts of the tumour
 22 may express different levels of protein.
 23 COFFEY, Q.C.:
 24 Q. So I take it the point being that, you know,
 25 faced with that situation, it's time to make

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1 inquiries of the technologist?
 2 DR. BANERJEE:
 3 A. Yes, and that might lead to choosing a
 4 different block. So just to finish up the
 5 discussion about the external controls. It is
 6 not appropriate to choose the most intense
 7 case as your positive control, because your
 8 clinical cases may have lower protein
 9 concentration. So it's better to have two or
 10 three different samples. One is a low
 11 expresser and medium and high expressing
 12 tumour. And really concentrate on the lowest
 13 protein concentration case and make sure
 14 that's always positive, because that's where
 15 your threshold is.
 16 COFFEY, Q.C.:
 17 Q. And Doctor, in terms of then external
 18 controls, you know, such external controls, I
 19 take it in evaluating whether or not external
 20 control is staining appropriately, one would--
 21 the individual in question would have to have
 22 some expectation and experience with what to
 23 expect?
 24 DR. BANERJEE:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. In order to make any kind of valid judgment
 3 about it perhaps?
 4 DR. BANERJEE:
 5 A. Yes. You almost have to have a mental image
 6 of what it looked like the last time or go
 7 back and get those slides and say, you know,
 8 has this really changed, because the control
 9 slides are kept on file, so you can always go
 10 back to them.
 11 COFFEY, Q.C.:
 12 Q. And you did see external control slides when
 13 you were in St. John's?
 14 DR. BANERJEE:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Paragraph two, Doctor, "is the Ventana system
 18 too sensitive?" and you've indicated "there's
 19 no evidence it creates false positive
 20 results." You did note the system here in St.
 21 John's, I take it, still requires optimization
 22 to avoid non-specific cytoplasmic staining?
 23 DR. BANERJEE:
 24 A. Right.
 25 COFFEY, Q.C.:

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1 Q. Are you talking about Ventana in general or
 2 just St. John's or both here, the system still
 3 requires--bearing in mind that you had seen
 4 non-specific cytoplasmic staining?
 5 DR. BANERJEE:
 6 A. Right. It was definitely the Ventana system
 7 being more sensitive than the protocol being
 8 used on the DAKO system, but as I said, you
 9 know, it's a matter of switching protocols on
 10 the Ventana system to reduce that non-specific
 11 staining.
 12 COFFEY, Q.C.:
 13 Q. Doctor, paragraph three, you pose the
 14 question, "is there a problem with tissue
 15 fixation?" You note "there appears to be
 16 inadequate attention paid by the grossing
 17 pathologist to the thickness of tissue slides,
 18 quality and adequacy of fixation and there's
 19 no standardized fixation protocol that
 20 everyone adheres to." Now what led you to
 21 believe or to reach those conclusions?
 22 DR. BANERJEE:
 23 A. I think the fixation problems were evident in
 24 the morphology of the slides I was looking at
 25 and it was clear that there wasn't actually

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1 written down policy about standard fixation
 2 protocols and that since all of the
 3 pathologists were taking turns grossing, that
 4 would lead to variability in the quality of
 5 fixation. I think part of the issue is that
 6 when the pathologist is grossing tissue, they
 7 have other things waiting for them to do like
 8 a stack of slides on the desk back at the
 9 office, etcetera. So there's a tendency to
 10 move quickly and do your work quickly and that
 11 could lead to variability as well.
 12 COFFEY, Q.C.:
 13 Q. So did you actually, yourself, witness at the
 14 time pathologists, you know, cutting tissue
 15 too thickly or -
 16 DR. BANERJEE:
 17 A. No.
 18 COFFEY, Q.C.:
 19 Q. - this was something, an observation based
 20 upon just the sheer number of pathologists and
 21 residents who are rotating through that?
 22 DR. BANERJEE:
 23 A. That's correct. I didn't actually observe
 24 them grossing.
 25 COFFEY, Q.C.:

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1 Q. But in knowing the numbers that went through
 2 there and based upon your experience, you
 3 inferred that there would be differences in
 4 the thickness and the approach?
 5 DR. BANERJEE:
 6 A. Yeah, it's nothing unusual. You see that
 7 everywhere.
 8 COFFEY, Q.C.:
 9 Q. Doctor, then paragraph four deals with the
 10 issue of internal controls. Is there anything
 11 further, just looking at that, that you'd want
 12 to elaborate upon in paragraph four?
 13 DR. BANERJEE:
 14 A. Not really, I think we've gone over that.
 15 COFFEY, Q.C.:
 16 Q. Yes. You've already noted that from your
 17 perspective, because of the condition of the
 18 internal controls, in terms of at least the
 19 slides you looked at, that in your view, where
 20 the internal controls hadn't stained and they
 21 were being reported as negatives -
 22 DR. BANERJEE:
 23 A. Right.
 24 COFFEY, Q.C.:
 25 Q. - the tumour, then they should not have been

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1 released in that context?
 2 DR. BANERJEE:
 3 A. That is correct
 4 COFFEY, Q.C.:
 5 Q. Or at least looking further into the matter?
 6 DR. BANERJEE:
 7 A. Right.
 8 COFFEY, Q.C.:
 9 Q. The idea, Doctor, here, the notion here that
 10 you pose here, "it should have been noted in
 11 the reports as uninterpretable due to the
 12 failure or absence of internal controls." I
 13 take it then you're not against the idea of a
 14 pathologist saying, in writing, "look, for
 15 this and this reason, I'm not prepared to make
 16 a call"?
 17 DR. BANERJEE:
 18 A. Right. For instance, if there were no other
 19 blocks to go to, for instance, let's say it's
 20 a small core biopsy and there was a single
 21 block and that wasn't properly fixed, you're
 22 basically stuck with that, and you can't
 23 interpret that case.
 24 COFFEY, Q.C.:
 25 Q. And then you just can't, then that's what

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1 you'd tell the oncologist?
 2 DR. BANERJEE:
 3 A. So in that situation, the oncologist, you
 4 know, would say that the core biopsy was not
 5 sufficient for us to assess the estrogen
 6 receptor content and they would wait for the
 7 lumpectomy or mastectomy specimen and repeat
 8 the test on that.
 9 COFFEY, Q.C.:
 10 Q. Doctor, other system flaws--well, first of
 11 all, I should ask you, is there anything
 12 further, Doctor? You're satisfied that that
 13 covers the issue of internal controls?
 14 DR. BANERJEE:
 15 A. I think I'm satisfied, yes.
 16 COFFEY, Q.C.:
 17 Q. Then "other system flaws observed" and you
 18 refer to the lack of dedicated
 19 immunohistochemistry technologists and the
 20 rotations--you know, the rotation system is
 21 being used and the potential consequences of
 22 that for their inability to gain in-depth
 23 knowledge or expertise. Now "lack of an
 24 officially designated pathologist as director
 25 of immunohistochemistry service.

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1 Technologists thus get conflicting feedback
 2 from a large number of pathologists" and you
 3 go on to note "there is no accountability for
 4 the quality of the service." I want to ask
 5 you about two aspects of this, Doctor. What
 6 led you to believe that the technologists were
 7 getting conflicting feedback?
 8 DR. BANERJEE:
 9 A. I think during my conversation with them, they
 10 would say Doctor so-and-so would say "I want
 11 it done this way," and somebody else would
 12 say, "no, I don't agree with that. I want it
 13 this way," and so on, and they would be
 14 confused because nobody was actually coming up
 15 with a consensus direction for them.
 16 COFFEY, Q.C.:
 17 Q. And you go on and you conclude by saying,
 18 "there is no accountability for the quality of
 19 the service" and I take it you were linking
 20 that with the lack of an officially designated
 21 pathologist as director of immunochemistry
 22 service?
 23 DR. BANERJEE:
 24 A. Right, so it seemed that the pathologists felt
 25 it was not their responsibility to make that

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1 lab better because it was run by non-medical
 2 personnel, management, and the technologists
 3 didn't really have a sufficient knowledge base
 4 to troubleshoot by themselves, so it naturally
 5 led to suboptimal results.
 6 COFFEY, Q.C.:
 7 Q. Paragraph four here, you refer to "lack of
 8 subspecialization amongst pathologists." I
 9 take it that you saw subspecialization, as you
 10 indicated, perhaps "led at the time to a lack
 11 of in-depth knowledge about IHC technical
 12 interpretation details and pitfalls." Your
 13 conclusion about that lack of in-depth
 14 knowledge, was that based upon, for example,
 15 the internal controls issue in the ER slides?
 16 DR. BANERJEE:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. It was apparent to you that, in your world, if
 20 you knew the difference, you wouldn't report
 21 the case?
 22 DR. BANERJEE:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. And that is if you, a pathologist, knew the

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1 difference, you wouldn't report it, and as
 2 these were being reported, you were drawing
 3 the inference that they perhaps didn't know--
 4 or you're assuming they didn't know about the
 5 internal controls?
 6 DR. BANERJEE:
 7 A. That's correct. I also remember I saw some
 8 other preparations which were not ER/PR
 9 related and could see that if people were
 10 accepting that quality and reporting on them,
 11 then there was something missing in their own
 12 knowledge base.
 13 COFFEY, Q.C.:
 14 Q. Paragraph five, you talk about the "disconnect
 15 between laboratory program director, division
 16 manager, clinical site chief and laboratory
 17 director in decision making" and you go on
 18 then to talk about "the organizational charts
 19 indicate a complex separation of reporting
 20 structures" and this is all written out there,
 21 Doctor. I'm going to ask you to generally
 22 describe then, for the Commissioner, your
 23 understanding of how it was functioning here
 24 and your concerns about the way it was
 25 functioning.

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1 DR. BANERJEE:
 2 A. Well, the way it was set up was that the
 3 clinical chief, i.e. the lab director, Dr.
 4 Cook, had no jurisdiction or authority over
 5 the technical side of the lab. That meant
 6 budgets, staff, you know, how they were hired,
 7 who was hired, who was--whether they were
 8 being trained, etcetera. He had no authority
 9 over that. So in looking at the org chart
 10 that existed at the time, it would seem that
 11 there was a dual management structure.
 12 There's the medical side and the technical
 13 side, each reporting separately to the Vice
 14 President of Medical Services, Dr. Williams.
 15 So in essence, Dr. Williams was the lab
 16 director.
 17 COFFEY, Q.C.:
 18 Q. Yes, that's--in essence, that's -
 19 DR. BANERJEE:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. - the one person who's responsible for the
 23 entire lab was Dr. Williams?
 24 DR. BANERJEE:
 25 A. For everything, that's correct.

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1 COFFEY, Q.C.:

2 Q. Under that organizational arrangement?

3 DR. BANERJEE:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. And I take it it was your understanding that

7 Dr. Williams, in fact, had really perhaps no

8 day-to-day contact with the lab itself?

9 DR. BANERJEE:

10 A. Not on a day-to-day basis, nor would he have,

11 in his own training, and I can't remember what

12 his specialty is, but certainly not a lab

13 physician.

14 COFFEY, Q.C.:

15 Q. Doctor, you had noted above, in paragraph two,

16 you had concluded there by saying "there is no

17 accountability for the quality of the service"

18 and did that have anything as well--it's

19 stated in the context of the lack of a

20 Director of Immunohistochemistry there.

21 DR. BANERJEE:

22 A. Right.

23 COFFEY, Q.C.:

24 Q. But did that also, from your perspective, have

25 anything to do with the lab structure itself,

Page 158

1 in terms of who ultimately was accountable for

2 this?

3 DR. BANERJEE:

4 A. I mean, looking at the structure, I'd say

5 there was no accountability for quality

6 because there are two aspects to quality. One

7 is the technical quality assurance piece,

8 quality controls, etcetera. But there's the

9 professional interpretation side, which is

10 also part of the quality, and if the two sides

11 are so separate they don't talk to each other,

12 then there is no real accountability. They're

13 only looking at parts of the process, not the

14 entire process.

15 COFFEY, Q.C.:

16 Q. And based upon the org chart, at least that

17 you had seen, and your understanding at the

18 time, that connect only finally occurred in

19 the person of Dr. Williams, the VP Medical?

20 DR. BANERJEE:

21 A. Yes, that's correct.

22 COFFEY, Q.C.:

23 Q. You do conclude paragraph five by saying

24 "superior outcomes could be achieved by

25 ensuring better linkages between technical,

Page 159

1 managerial and medical leadership"?

2 DR. BANERJEE:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. Doctor, from your perspective, you certainly

6 suggested a director of immunohistochemistry?

7 DR. BANERJEE:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. Paragraph two. How about having one

11 particular individual in charge of the lab who

12 is actually day-to-day involved with the lab?

13 DR. BANERJEE:

14 A. I certainly believe that is necessary. That's

15 my opinion. There are lots of differences of

16 opinion on that point across the country,

17 including my own province. But I do believe

18 that in the eyes of the courts, the law, the

19 medical director is responsible for the

20 quality of the lab.

21 COFFEY, Q.C.:

22 Q. I take it at least in the province where you

23 are?

24 DR. BANERJEE:

25 A. Definitely in British Columbia, and that means

Page 160

1 total authority over all aspects of lab

2 operations.

3 COFFEY, Q.C.:

4 Q. Doctor, you, in paragraph six, suggest that

5 there should be "attendance by medical and

6 technical staff at various conferences with a

7 focus on new technology should be encouraged"

8 and you "encourage consensus driven innovation

9 should be the goal" or you say that that

10 should be the goal. You then refer to

11 pathology assistants, "dedicated pathology

12 assistants to ensure gross room consistency in

13 tissue handling, trimming and fixation." I

14 take it that that has the advantage of cutting

15 down on the sheer number of people involved?

16 DR. BANERJEE:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. In St. John's, it could be 15 to 20, for

20 example, pathologists, I gather, involved in

21 breast grossing.

22 DR. BANERJEE:

23 A. That's correct.

24 COFFEY, Q.C.:

25 Q. And you would limit it to whatever the number

Page 161

1 required?

2 DR. BANERJEE:

3 A. Right.

4 MR. COFFEY:

5 Q. What are the advantages then, in a practical

6 way, of having pathology assistants, from your

7 perspective?

8 DR. BANERJEE:

9 A. Well, there are two advantages. One is that

10 you can train them to follow protocols and

11 they tend to follow that religiously because

12 they don't believe that they have enough

13 medical knowledge to decide when the protocol

14 needs to be modified, so they tend to be

15 consistent because of that reason alone.

16 Secondly, by having pathologist assistants

17 doing the grossing, it frees up the

18 pathologists to do their other work, which is

19 the microscopy, attending patient care rounds,

20 etcetera, and that feeling of being rushed all

21 the time goes away and cutting corners because

22 of lack of time then is dealt with.

23 MR. COFFEY:

24 Q. In particular, to use the phrase, you just

25 used "cutting corner" as a word, like feeling

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1 time pressure -

2 DR. BANERJEE:

3 A. That's right.

4 MR. COFFEY:

5 Q. - to get your tissue handing done, your

6 trimming done -

7 DR. BANERJEE:

8 A. Um-hm.

9 MR. COFFEY:

10 Q. - would no longer then apply to the

11 pathologists because they wouldn't be involved

12 in it, unless they happened to be asked to be

13 consulted on a particular matter, the

14 pathology assistants would be doing it?

15 DR. BANERJEE:

16 A. And that's exactly the way it should be set

17 up, so that the pathologist is still

18 responsible for the grossing but the way that

19 larger hospitals have done that is the

20 pathologists will actually spend the first

21 part of the morning of the afternoon with the

22 pathologist assistants taking a quick look at

23 what the specimens are, what the nature of the

24 specimens are and providing specific

25 instructions if there's some unusual specimen

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1 to deal with. But in general, the experienced

2 pathologist assistants become very good at

3 handling complex cases as well.

4 MR. COFFEY:

5 Q. And, Doctor, then you make a series of

6 recommendations, they're numbered one through

7 ten here. Subspecialization for pathologists

8 is the first; section medical direction for

9 immunohistochemistry service is the second.

10 You already canvassed those. Consideration

11 being given to switching to SP-1.

12 DR. BANERJEE:

13 A. Um-hm.

14 MR. COFFEY:

15 Q. Dedicated technologists, and the appropriate

16 number of the IHC. Doctor, under the

17 paragraph 4 you note, "technologists should be

18 capable of quality assurance of each staining

19 run and not release slides if internal and

20 external controls have failed. QA, QC failures

21 noted by the reporting pathologist should be

22 documented and reviewed periodically by the

23 section medical director with corrective

24 measures implemented as soon as possible."

25 The reference to the technologists not

Page 164

1 releasing the slides if internal and external

2 controls have failed, I take it that that

3 suggests that perhaps they should be involved

4 in the reading of internal and external

5 controls?

6 DR. BANERJEE:

7 A. Oh, yes. And they have to--they can't do it

8 without looking down a microscope, so they

9 need to be trained as to what to look for.

10 They're not necessarily experts in

11 histopathology, but over time they gain enough

12 experience by looking at slides with the

13 pathologist, section medical director, for

14 instance, and then can get to that level of

15 comfort, particularly with specific tests

16 where that, that needs to be reported. Not

17 all labs do that. I think it has two

18 benefits: one is the QC, QA activity becomes

19 much more stringent; the other thing is that

20 technologist actually learn a lot more about

21 what they're doing as a result of that

22 interaction with the pathologist.

23 MR. COFFEY:

24 Q. And but you, as you just acknowledged, there

25 are different approaches by various

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1 laboratories across the country to whether the
 2 technologists examine the external controls
 3 alone or look at the internal and external
 4 controls?
 5 DR. BANERJEE:
 6 A. That's correct.
 7 MR. COFFEY:
 8 Q. And in any case, whichever of the two or of
 9 both it's your view and you were suggesting, I
 10 take it that, they should be, of course,
 11 appropriately trained?
 12 DR. BANERJEE:
 13 A. Yes.
 14 MR. COFFEY:
 15 Q. If they're going to be involved, they need to
 16 be trained?
 17 DR. BANERJEE:
 18 A. Right.
 19 MR. COFFEY:
 20 Q. Doctor, then, you then conclude by saying that
 21 in five you refer to a necessity for tumour
 22 pathology, "pathologist leaders must regularly
 23 attend appropriate educational and scientific
 24 conferences to stay current." And I take it
 25 tumour site pathologists leaders would be the

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1 kind of subspecialists, as it were?
 2 DR. BANERJEE:
 3 A. That's correct.
 4 MR. COFFEY:
 5 Q. The leaders in breast, the leaders in lung,
 6 whatever?
 7 DR. BANERJEE:
 8 A. Um-hm.
 9 MR. COFFEY:
 10 Q. Whatever system you're dealing with?
 11 DR. BANERJEE:
 12 A. Yes.
 13 MR. COFFEY:
 14 Q. Pathologists assistants are referred to here,
 15 should be hired and trained. The Sakura
 16 continuous flow tissue processing system to
 17 allow the implementation of it, they should
 18 jointly redesign work flow practices. The
 19 Sakura system, Doctor, because it's referred
 20 to earlier in your report, as well, were you
 21 advising them to adopt the Sakura or not?
 22 DR. BANERJEE:
 23 A. Well, they had already acquired the system but
 24 it wasn't actually in action because it was a
 25 decision made without input from the

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1 pathologists so there was an immediate push
 2 back from the pathologists. I actually
 3 believe that eventually that will be the
 4 standard down the road. Not many hospitals
 5 have adopted that system. It's a different
 6 kind of tissue process, it uses microwave
 7 technology that reduces processing time from
 8 overnight processing to one hour or two hours
 9 at the most but doesn't deal with the fixation
 10 issues, that is a separate issue. And it's a
 11 continuous flow system, so it's not a batch
 12 processor. And so if you're familiar with
 13 lean manufacturing practice that's now being
 14 adopted by health care systems, we are moving
 15 away from batch processing to single flow
 16 processing and that for the individual patient
 17 biopsy means very short turn around times, but
 18 it means pathologists and technologists have
 19 to completely redesign how they work during
 20 the day, so it's a complex thing to do.
 21 MR. COFFEY:
 22 Q. And you do note here, they should joint--they
 23 would have to jointly redesign their work flow
 24 practices -
 25 DR. BANERJEE:

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1 A. Right.
 2 MR. COFFEY:
 3 Q. - if it's going to work at all.
 4 DR. BANERJEE:
 5 A. Yeah.
 6 MR. COFFEY:
 7 Q. You at paragraph 8 say "The Ventana system is
 8 performing adequately and with improvement and
 9 standardization of fixation protocols there's
 10 no reason that the service could not be
 11 resumed without further delay." That would be
 12 the ER/PR service in this context?
 13 DR. BANERJEE:
 14 A. That's correct.
 15 MR. COFFEY:
 16 Q. But you were saying there was improvement in
 17 and standardization, improvement in and
 18 standardization of fixation protocols were
 19 certainly going to be necessary?
 20 DR. BANERJEE:
 21 A. Yes.
 22 MR. COFFEY:
 23 Q. And perhaps even optimization?
 24 DR. BANERJEE:
 25 A. Absolutely, yeah.

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1 MR. COFFEY:
 2 Q. There's a reference then to external quality
 3 assurance programs such as CAP or NEQAS, the
 4 laboratory should prescribe to them. At the
 5 time do you recall whether or not it was your
 6 understanding that they were--were they, at
 7 that point, involved in either of these?
 8 DR. BANERJEE:
 9 A. No, they were not.
 10 MR. COFFEY:
 11 Q. And then the organizational chart should be
 12 redesigned to provide better joint technical
 13 and medical accountability, planning and
 14 communication. So, Doctor, I take it that in
 15 paragraph 10 you weren't really saying you
 16 should have a medical director in charge, per
 17 se?
 18 DR. BANERJEE:
 19 A. I wasn't saying that, but I wish I had said
 20 that.
 21 MR. COFFEY:
 22 Q. Yes. But in any case, the organizational
 23 chart would be required to be, from your
 24 perspective, redesigned to ensure that at
 25 least everybody knew everybody else's role and

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1 they interacted appropriately?
 2 DR. BANERJEE:
 3 A. That's correct.
 4 MR. COFFEY:
 5 Q. To achieve the best result. If we could,
 6 Commissioner, I'm going to go on then to -
 7 COMMISSIONER:
 8 Q. Time to break?
 9 MR. COFFEY:
 10 Q. If you would, please?
 11 COMMISSIONER:
 12 Q. All right. We'll reconvene at 2:15.
 13 (LUNCH BREAK)
 14 COMMISSIONER:
 15 Q. Please be seated. Mr. Coffey.
 16 COFFEY, Q.C.:
 17 Q. Thank you, Commissioner. Registrar, Exhibit
 18 P-1312, please? And, Doctor, this is an
 19 exchange of e-mails from October 21st through
 20 the, well, actually, and the 22nd between
 21 yourself and Dr. Cook. And the first of them
 22 on the 21st he acknowledges receipt of your
 23 report. And you responded by saying "Hi Don,
 24 best of luck." Doctor, you know, having had
 25 the opportunity to come to St. John's

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1 September, make your observations, go away and
 2 think about it and make your report and reduce
 3 it to writing, Doctor, from your perspective
 4 at the time, could the problems have been
 5 detected earlier, do you think?
 6 DR. BANERJEE:
 7 A. I believe so. I think the problems should
 8 have been detected earlier and I think Dr.
 9 Edgecombe was probably one of the first people
 10 to judgely--raise some concerns about the
 11 immunohistochemistry service. I think the
 12 whole transition from the biochemistry test
 13 and the immunohistochemistry test should have
 14 been handled in a different way to get the
 15 correlations done, comparisons done between
 16 the two methods before you switch over to the
 17 new method. And that's our task because, I
 18 mean, it's a permanent task because in our
 19 business new methods are constantly being
 20 developed and for us to switch from an
 21 existing method to a new one there is a
 22 process we have to follow to make sure it's
 23 validated.
 24 COFFEY, Q.C.:
 25 Q. Now we have heard evidence from Dr. Khalifa,

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1 who was the physician who, in effect,
 2 introduced ER/PR IHC methodology to the
 3 province and there was certainly some
 4 correlation effort in the first year or so
 5 involving the biochemical assay that was then
 6 being done in St. John's and the ER/PR IHC
 7 slides that the lab at the General Hospital
 8 was producing. Even after that, between '97
 9 and then you showed up in 2005 and you
 10 understood Dr. Ejeckam had some concerns
 11 dating back to certainly 2003?
 12 DR. BANERJEE:
 13 A. Right.
 14 COFFEY, Q.C.:
 15 Q. What is it then that you think in terms of
 16 who, and not so much the individuals as is
 17 what groups might have been able to identify
 18 that there was a problem earlier and what do
 19 you think they might have seen to do so?
 20 DR. BANERJEE:
 21 A. I think probably rather than trying to solve
 22 the problem through internal review and
 23 process redesign that would have been probably
 24 the best time to get some external experts to
 25 come in and take a look.

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1 COFFEY, Q.C.:

2 Q. And when was that, Doctor?

3 DR. BANERJEE:

4 A. So as soon as the concerns were raised in 2003

5 I think that would have been the right time to

6 bring in some external consultants just to

7 make sure that the methods were set up

8 correctly. Because even though Dr. Edgecombe

9 had raised his concerns, I mean, I wasn't

10 clear what external benchmarks were available

11 to him to make the judgment whether they were

12 doing the task or not.

13 COFFEY, Q.C.:

14 Q. And, Doctor, you did, when you were here in

15 September of 2005, see these slides for

16 approximately 20 patients. And we understand

17 that most of those slides probably were from

18 the year 2002, is our understanding because

19 most of the retesting that had occurred

20 involved 2002.

21 DR. BANERJEE:

22 A. Possibly. I don't quite remember it, so -

23 COFFEY, Q.C.:

24 Q. And you wouldn't have reported that. I'm

25 saying we understand it because we've seen, of

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1 course, and heard evidence concerning what

2 year, the year from which particular patients

3 had been retested up to the point you arrived.

4 DR. BANERJEE:

5 A. Um-hm.

6 COFFEY, Q.C.:

7 Q. And in the main it was 2002 cases. Doctor,

8 with that in mind, for example, in looking at

9 those particular slides, if the pathologist at

10 the time who examined them had been aware of

11 the internal control requirement and had

12 noticed that particular internal controls

13 weren't staining and they were reporting the

14 tumours as negative, if inquiries had been

15 made at that point, for instance, well, I

16 can't report this and in fact this is the

17 second one I've seen in a month or whatever.

18 DR. BANERJEE:

19 A. Um-hm.

20 COFFEY, Q.C.:

21 Q. Do you think any inquiries at that point, if

22 there had been inquiries made then, you know,

23 people who were faced with that might have

24 recognized the problem at the time?

25 DR. BANERJEE:

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1 A. I think so, yes.

2 COFFEY, Q.C.:

3 Q. If we could look at, please, at Exhibit P-

4 2095? Doctor, page 92, please? Doctor, this

5 is two e-mails, October 23rd, one from Dr.

6 Cook to yourself, and the subject is a

7 possible agenda item for CAP meeting in

8 November. And he writes, "Hi Diponkar, Mr.

9 George Tilley, CEO of Eastern Health and Bob

10 Williams, VP, have asked me if we could

11 discuss the issue of national standards for

12 immunohistochemistry at the Canadian

13 Association of Pathologists. Maybe we could

14 put on the agenda for the November meeting as

15 an item we could bring to the federal minister

16 of health. This could be part of a much

17 larger issue such as national standards of

18 practice for laboratory medicine in Canada. I

19 would appreciate your thoughts. Regards,

20 Don." And you responded the next day saying

21 "I agree, this is an important topic that

22 needs discussion. We should add it to the

23 agenda along with the national standards of

24 practice topic." And I will be asking you

25 more about this, Doctor, but. So as we get

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1 into the last week of October of '04 Dr. Cook

2 raised this with you and you were certainly,

3 at that point you were president, I take it,

4 of the association?

5 DR. BANERJEE:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. And this November meeting, where was that to

9 occur, do you recall where?

10 DR. BANERJEE:

11 A. I can't remember. It was either Ottawa or

12 Toronto.

13 COFFEY, Q.C.:

14 Q. Okay. And I'll be asking you a bit more

15 about, to elaborate upon what happened then

16 and what has happened since concerning

17 national standards for immunohistochemistry

18 and generally for the practice of laboratory

19 medicine. If we could look at Exhibit P-0662?

20 And here, Doctor, I take it, this is a letter

21 of October 24th, 2005. It's addressed to

22 yourself, it's from Dr. Cook, copied to Dr.

23 Williams. It's Dr. Williams' copy we have.

24 And I take it this is just the formal request

25 reflecting the e-mail we just looked at?

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1 DR. BANERJEE:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. Exhibit P-2095, please, 2095? Page 45.
 5 Doctor, this is a letter on Canadian
 6 Association of Pathologists letterhead, it's
 7 from yourself, it's to Dr. Cook. And this is
 8 responding to his letter of October 24th and
 9 advising him that "I've asked that this topic
 10 be placed on the agenda for the November
 11 meeting." And the topic in question is
 12 national standards for immunohistochemistry
 13 testing.
 14 DR. BANERJEE:
 15 A. Right.
 16 COFFEY, Q.C.:
 17 Q. Exhibit P-0679. Doctor, this is, in
 18 particular, the e-mail of November 2nd at the
 19 bottom of the exhibit here. It's from
 20 yourself. Daniele -
 21 DR. BANERJEE:
 22 A. Saintonge.
 23 COFFEY, Q.C.:
 24 Q. Saintonge. Who is Daniele Saintonge?
 25 DR. BANERJEE:

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1 A. She works at the Royal College and provides
 2 administrative support to Canadian Association
 3 of Pathologists.
 4 COFFEY, Q.C.:
 5 Q. And you had asked her, "Could you please add
 6 the following item to the November agenda."
 7 And national standards for laboratory
 8 immunohistochemistry--laboratories
 9 immunohistochemistry testing. "Dr. Cook and
 10 I," that's yourself, "will speak on this
 11 topic." Doctor, what then happened in
 12 November, do you recall?
 13 DR. BANERJEE:
 14 A. As I recall, we discussed the need for
 15 national standards, and wondered how to bring
 16 this to the attention of both the federal and
 17 provincial jurisdictions of health care.
 18 Since we didn't feel that the Canadian
 19 Association of Pathologists in its current
 20 configuration and membership would really be
 21 able to do much without the resources required
 22 to set up such a system, that we needed help
 23 from both provincial and federal governments
 24 to do this properly.
 25 COFFEY, Q.C.:

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1 Q. And so that was yourself and Dr. Cook, I take
 2 it, raised that at the time?
 3 DR. BANERJEE:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. And was there any decision as to how to go
 7 forward at that point?
 8 DR. BANERJEE:
 9 A. So the decision was made that I would write to
 10 various stakeholders in the business of cancer
 11 care across the country and solicit their
 12 support in approaching provincial and federal
 13 governments on this particular issue, which I
 14 did.
 15 COFFEY, Q.C.:
 16 Q. And I'll be asking you in a more general way
 17 to take the Commissioner through what had
 18 happened before that in this regard and what
 19 has happened since. Exhibit P-1973. Here,
 20 Doctor, there's two e-mails of December 2nd,
 21 2005. The first of them is from Dr. Cook to
 22 yourself and the subject is institution of
 23 ER/PR services and it says, "As I mentioned to
 24 you in Ottawa", perhaps where the meeting then
 25 was --

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1 DR. BANERJEE:
 2 A. Yes, that's right.
 3 COFFEY, Q.C.:
 4 Q. "We will be receiving funding for the
 5 upgrading of your immunohistochemistry
 6 services. We will be planning a number of
 7 meetings with our keys pathologists and
 8 technical people concerning implementation of
 9 recommendations. I would appreciate your
 10 advice and guidance, and I wonder if you can
 11 participate in some of these meetings in a
 12 conference call. I predict there will be a
 13 number of differing options on how to
 14 implement and when to decide on a start up
 15 date. I would certainly welcome an outside
 16 perspective in helping me achieve a consensus
 17 approach to full implementation", and you
 18 responded saying, "Hi Don, yes, I would also
 19 request that Dr. Malcolm Hayes and our head
 20 technologist, Bev Thomas, also be invited to
 21 join at least for some of the meetings so we
 22 can benefit from their experience. Regards,
 23 Diponkar".
 24 DR. BANERJEE:
 25 A. Uh-hm.

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1 COFFEY, Q.C.:

2 Q. Doctor, why did you suggest that if you were

3 to be involved in this, that you would want

4 Bev Thomas and Dr. Malcolm Hayes involved?

5 DR. BANERJEE:

6 A. Dr. Malcolm Hayes is one of our best pathology

7 experts, and at the time he was also

8 overseeing the immunohistochemistry lab at the

9 BC Cancer Agency, and Bev Thomas at the time

10 was the head histotechnologist responsible for

11 that service, and she had considerable

12 experience and skills in immunohistochemistry,

13 so I felt that she could provide some detailed

14 technical guidance to people at Eastern

15 Health.

16 COFFEY, Q.C.:

17 Q. Exhibit P-2008. Doctor, this is an e-mail of

18 December 5th, 2005, from Dr. Cook responding,

19 I take it, to the last e-mail I just looked

20 at, "Thanks for your help. I will contact you

21 when I have the meetings arranged. Regards,

22 Don". Doctor, were there ever such meetings,

23 at least that you were involved in?

24 DR. BANERJEE:

25 A. I was not involved in any. I wasn't aware of

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1 when the meetings were actually held.

2 COFFEY, Q.C.:

3 Q. Exhibit P-2036. Doctor, this is two e-mails;

4 one from Dr. Cook of January 13th, 2006, to

5 yourself. It involves the subject -- he

6 styles it as ER/PR issue, and he says, "Dr.

7 Kara Laing, out clinical chief, oncology,

8 received a phone call from an oncologist in

9 Fredericton, New Brunswick, stating that

10 problems with ERs and PRs have been identified

11 for a particular year from a Fredericton lab

12 and was looking for information on what

13 happened and how we handled the issue. Dr.

14 Laing advised the oncologist that a more

15 thorough review, other than the year in

16 question, is needed. As for an explanation as

17 to what is happening in Fredericton lab

18 reports, they have a pH issue according to Dr.

19 Laing. I anticipate that this may spread to

20 other regions in Canada as the problem becomes

21 more widely known. From a Canadian Association

22 of Pathologists perspective, I think we need

23 to stay on top of this issue and liaise very

24 closely with the Canadian Association of

25 Oncologists and be ready for possible media

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1 interviews. I will keep you posted. Regards,

2 Don", and you responded the Monday following

3 that saying, "Thanks". Doctor, the issue --

4 the ER/PR issue, as Dr. Cook styled it here,

5 other than St. John's, has that arisen

6 anywhere else in the sense of since that time

7 in this kind of a -- become public, anyway?

8 DR. BANERJEE:

9 A. I haven't been made aware of similar issues.

10 Other than this e-mail, I didn't get any

11 further information about the Fredericton lab

12 problem.

13 COFFEY, Q.C.:

14 A. And at the end of his e-mail, he refers to the

15 Canadian Association of Oncologists, and

16 liaising closely with them. How much liaising

17 from your perspective has gone on between the

18 Association of Pathologists and that of

19 oncologists?

20 DR. BANERJEE:

21 A. Very little.

22 COFFEY, Q.C.:

23 Q. It's not --

24 DR. BANERJEE:

25 A. And historically, there hasn't been much, and

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1 I don't believe there's any current

2 interaction.

3 COFFEY, Q.C.:

4 QQ. And do you think that there should be?

5 DR. BANERJEE:

6 A. Oh, absolutely, because we are all dealing

7 with the same patient population.

8 COFFEY, Q.C.:

9 Q. Exhibit P-2006. Doctor, again this is an

10 exchange of e-mails between yourself and Dr.

11 Cook, February 20th. He says, "In regard to

12 the ERs and PRs, we are in the implementation

13 phase of many of the recommendations brought

14 forth by the review process. We are hoping to

15 restart this system by the end of March. I

16 would appreciate if you could fly to St.

17 John's sometime near the end of March and

18 review the progress we have made. We would

19 value any observations and recommendations

20 that you make regarding implementation of the

21 system. We will, of course, reimburse you for

22 your expenses and time involved. I look

23 forward to hearing from you and hope you can

24 visit", and then you got back to him the next

25 day saying, "I have left you a voice mail

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1 message. Please call me", and your cell
 2 number, "and send me an e-mail if the dates
 3 I've suggested will work for you", and you
 4 advised him of your then current location.
 5 Doctor, up until toward the end of February of
 6 '06, other than that e-mail exchange where Dr.
 7 Malcolm Hayes is referenced, and Bev Thomas,
 8 had you been at all involved otherwise with
 9 this?
 10 DR. BANERJEE:
 11 A. No.
 12 COFFEY, Q.C.:
 13 Q. So this is the - your reintroduction to the
 14 idea of re-implementing ER/PR in St. John's,
 15 your involvement, potential involvement in it?
 16 DR. BANERJEE:
 17 A. This is the first time I was aware of that.
 18 COFFEY, Q.C.:
 19 Q. Yes, and to your knowledge, I take it, no one
 20 else from your institution had been involved
 21 up to this point?
 22 DR. BANERJEE:
 23 A. No.
 24 COFFEY, Q.C.:
 25 Q. Doctor, at that point in time -- up to that

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1 point in time, had you been aware of Trish
 2 Wegrynowski's involvement?
 3 DR. BANERJEE:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. And, in fact, we will now come to your coming
 7 back to St. John's in the spring of 2006. You
 8 weren't aware of her involvement then either,
 9 I take it?
 10 DR. BANERJEE:
 11 A. No.
 12 COFFEY, Q.C.:
 13 Q. When did you first become aware that the chief
 14 technologist from Mount Sinai was involved in
 15 this?
 16 DR. BANERJEE:
 17 A. I think after this Commission of Inquiry was
 18 announced.
 19 COFFEY, Q.C.:
 20 Q. Okay. Doctor, in the meantime in terms of
 21 what else was going on, Exhibit P-0165,
 22 please.
 23 DR. BANERJEE:
 24 A. That's not the right --
 25 COFFEY, Q.C.:

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1 Q. No, no, P-0165, not 2165, 165, please. Thank
 2 you. I'm going to go to page two first,
 3 Doctor. Now, Doctor, this is a letter on
 4 Canadian Association of Pathologists
 5 letterhead, February 1st, 2006. It's
 6 addressed to the Honourable John Ottenheimer,
 7 Minister of Health, here in St. John's. The
 8 subject is "re; laboratory medicine specialist
 9 pathologists in Newfoundland". It's signed by
 10 yourself as President of the Canadian
 11 Association of Pathologists, and generally a
 12 description of the various positions you then
 13 held underneath your signature at the
 14 University of British Columbia and the British
 15 Columbia Cancer Agency, etc. Now, Doctor, how
 16 was it you came to write this letter?
 17 DR. BANERJEE:
 18 A. Well, I think during my first visit to Eastern
 19 Health, and during my discussions with the
 20 pathologists, the whole issue of retention and
 21 turnover of pathologists was raised, and I
 22 think the current head of pathology was in the
 23 middle of negotiations with the Government on
 24 compensation levels for pathologists and he
 25 asked whether I would be willing to support

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1 their case by writing a letter as President of
 2 the Canadian Association of Pathologists, and
 3 I agreed to do that because I could see that
 4 compensation was certainly a big factor in the
 5 whole retention issue. So I prepared this
 6 letter and had it transferred to letterhead
 7 and submitted to the Minister at the time.
 8 COFFEY, Q.C.:
 9 Q. And, Doctor, you do write here, "80 percent of
 10 all medical decisions are based on laboratory
 11 reports issued by pathologists, yet pathology
 12 services usually cost less than 5 percent of
 13 the health care budget in most jurisdictions".
 14 That figure of -- and I appreciate this is
 15 being written in early 2006, "80 percent of
 16 all medical decisions are based on laboratory
 17 reports issued by pathologists", that sort of
 18 a figure, where would you have gotten that
 19 from at the time?
 20 DR. BANERJEE:
 21 A. That's sort of a generally accepted figure in
 22 the literature and that's across the board in
 23 terms of lab services. I would say in an
 24 oncology setting, you're probably looking at a
 25 higher percentage that drives clinical

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1 decision making.
 2 COFFEY, Q.C.:
 3 Q. Higher than 80?
 4 DR. BANERJEE:
 5 A. Higher than 80.
 6 COFFEY, Q.C.:
 7 Q. And you note -- you go on to say, "We are
 8 facing a severe and growing pathologist
 9 manpower shortage across the country, and
 10 Newfoundland is likely to face a crisis very
 11 soon". You then go on to say, "Unless you are
 12 prepared", and that is "you", I take it, in
 13 the royal sense, the Government of the day" -
 14 DR. BANERJEE:
 15 A. Um.
 16 COFFEY, Q.C.:
 17 Q. "prepared to address, in the immediate future,
 18 the fact that pathologists in your province
 19 are among the lowest paid professionals in the
 20 nation, please do not be surprised if your
 21 province experience even greater difficulty in
 22 attracting and retaining pathologists than you
 23 face now. Not addressing is false economy, as
 24 patient care will be adversely affected by the
 25 lack of high quality pathologists in the

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1 province. You have already experienced a
 2 recent example of the effects of not investing
 3 in high quality pathology when the errors in
 4 breast cancer estrogen receptor status were
 5 discovered, affecting hundreds of patients in
 6 your province."
 7 Doctor, in referring there to "the lack
 8 of high quality pathologists in the province,"
 9 what were you--and then "not investing in high
 10 quality pathology" in the next sentence, what
 11 are you referring to there?
 12 DR. BANERJEE:
 13 A. I'm referring to the fact that if you have a
 14 compensation issue and you haven't addressed
 15 it, then the potential of keeping your best
 16 pathologists in the province would be damaged
 17 since they would seek employment elsewhere in
 18 the country or perhaps even outside of the
 19 country, and no matter what else happened, you
 20 know, compensation is definitely a factor that
 21 influences professionals in terms of where
 22 they practice. So it's kind of a fundamental
 23 sort of economic fact. The problem of--
 24 there's a difference in the two sentences.
 25 One, I'm talking about high quality

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1 pathologists and retaining them, and the
 2 second sentence is talking about high quality
 3 pathology, which is more of the infrastructure
 4 in which these professionals would work. So
 5 you can't just improve compensation without
 6 dealing with all of the other issues about how
 7 to run a high quality lab service, which means
 8 you have the right number of technologists,
 9 appropriately qualified technologists, you
 10 have the right equipment, the appropriate
 11 budget for supplies, etcetera. All of that is
 12 part of the equation. So if you're cutting
 13 corners, cutting costs, ultimately this is
 14 quite predictable as to what's going to
 15 happen, and this is a long standing issue in
 16 Newfoundland, not something that happened
 17 overnight.
 18 COFFEY, Q.C.:
 19 Q. And so in this last sentence in the second
 20 paragraph, you here seemingly attribute the
 21 recent example of errors in breast cancer
 22 estrogen receptor status, which is from your
 23 perspective, you understood it affected
 24 hundreds of patients in this province, were
 25 ultimately caused by not having invested in

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1 high quality pathology, and pathology in a
 2 wider sense than just the pathologists?
 3 DR. BANERJEE:
 4 A. That's correct.
 5 COFFEY, Q.C.:
 6 Q. The whole system?
 7 DR. BANERJEE:
 8 A. Um-hm.
 9 COFFEY, Q.C.:
 10 Q. I take it then, Doctor, that the lack of money
 11 has the--or lack of money, particularly a lack
 12 of investment financially over an extended
 13 period of time has what effect or could have
 14 what effects, in the clinical laboratory
 15 setting?
 16 DR. BANERJEE:
 17 A. I think it affects the kind of expertise you
 18 can keep in your laboratory. It affects the
 19 infrastructure, the quality of the equipment,
 20 the age of the equipment, whether using
 21 current technology or not, all of that is
 22 affected by lack of investment.
 23 COFFEY, Q.C.:
 24 Q. I take it, you then go on to say here, Doctor,
 25 "historically your province has relied heavily

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1 on foreign trained pathologists who are
 2 unlikely to stay on in the province as more
 3 attractive jobs come up elsewhere in the
 4 nation" and you ask that "this cycle be broken
 5 by promoting and protecting your best assets."
 6 I take it, in effect, by increasing their
 7 compensation or at least addressing the issue
 8 is what you were urging here?
 9 DR. BANERJEE:
 10 A. Right.
 11 COFFEY, Q.C.:
 12 Q. Now Doctor, and we're going to look at the
 13 response in a moment, but here, were you in
 14 any way suggesting that foreign trained
 15 pathologists had caused the problem here?
 16 DR. BANERJEE:
 17 A. No. Actually, what I'm saying is that if you
 18 have a retention problem and you're dependent
 19 on foreign trained pathologists to fill your
 20 vacant positions, and you haven't dealt with
 21 the compensation issue and the infrastructural
 22 problems, there's nothing going to hold them
 23 in this province, because they don't have
 24 family connections, etcetera. So they're more
 25 likely to leave than say people who grew up in

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1 this province, were educated in this province.
 2 They're frustrated in their jobs, but couldn't
 3 leave because of their family connections. So
 4 that's the point I was trying to make.
 5 COFFEY, Q.C.:
 6 Q. Page one of this exhibit, Doctor, is the
 7 response that came more than two months later.
 8 It's dated April 18th, 2006. It's addressed
 9 to yourself. It's from Tom Osborne, the
 10 Minister, and I should tell you here, Doctor,
 11 that Tom Osborne has testified here and he has
 12 told the Commissioner that other than you
 13 being the president of the Canadian
 14 Association of Pathologists, he had no idea at
 15 all that you had been involved in reviewing
 16 the lab here in St. John's. So I'll just let
 17 you know that. He does conclude by--he
 18 acknowledges, at the end of the second
 19 paragraph, "all parties have recognized that
 20 physician compensation is about one of the
 21 many challenges facing this specialized group"
 22 and the group in question, I take it, are the
 23 laboratory medicine specialists referred to in
 24 the first paragraph. He then says "I do take
 25 exception to your suggestion that the recent

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1 errors in breast cancer screening experienced
 2 in this province were as a result of not
 3 having invested in high quality pathologists."
 4 He attributes -
 5 DR. BANERJEE:
 6 A. Um-hm.
 7 COFFEY, Q.C.:
 8 Q. - doesn't make the distinction between the two
 9 sentences that you did. Were you suggesting,
 10 had you ever suggested that the pathologists
 11 here were not high quality pathologists? Were
 12 you ever asked that question?
 13 DR. BANERJEE:
 14 A. No, not really, but I could see how they would
 15 interpret my letter along those lines, but I
 16 think I've explained to you what I meant by
 17 that and how do you assess quality of
 18 pathologists without checking their work? And
 19 I was only looking at one aspect of the work,
 20 so I don't believe I've done a thorough review
 21 of that to come to a conclusion about their
 22 quality.
 23 COFFEY, Q.C.:
 24 Q. And your review had been in respect of just
 25 the ER/PR staining?

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1 DR. BANERJEE:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. And perhaps a little bit more IHC generally?
 5 DR. BANERJEE:
 6 A. Right.
 7 COFFEY, Q.C.:
 8 Q. And you had found certain things that were,
 9 from your perspective, wanting or lacking in
 10 that regard?
 11 DR. BANERJEE:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. In that particular field, and that was it?
 15 DR. BANERJEE:
 16 A. Um-hm.
 17 COFFEY, Q.C.:
 18 Q. You go on to say, there has been--well, not
 19 you, I'm sorry, Mr. Osborne went on to say "it
 20 has been recognized that the tests associated
 21 with this procedure are fraught with errors in
 22 reproduction, as well as changes in national
 23 standards." Now would you have disagreed with
 24 that assertion?
 25 DR. BANERJEE:

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1 A. I would say it's not fraught with errors of
 2 reproduction. It's certainly not an easy
 3 assay to do. And there were no national
 4 standards to compare against, so I'm not sure
 5 what he means by that.

6 COFFEY, Q.C.:

7 Q. And so in address--or speaking of the
 8 procedure being fraught with errors in
 9 reproduction, you would have disagreed with
 10 that. I take it your position would be that
 11 it can be done correctly. You just have to go
 12 about it properly?

13 DR. BANERJEE:

14 A. That's correct.

15 COFFEY, Q.C.:

16 Q. Doctor, he concludes by saying "your letter
 17 suggests that the pathologists employed by
 18 Eastern Health are less than qualified, which
 19 is a great disservice to your peers
 20 represented by your organization," and that's
 21 the letter of February 1st. At the time, did
 22 you feel that you had suggested that the
 23 pathologists employed in Newfoundland were
 24 less than qualified?

25 DR. BANERJEE:

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1 A. No, I didn't feel that.

2 COFFEY, Q.C.:

3 Q. Did you ever respond to this letter, Doctor?

4 DR. BANERJEE:

5 A. I did not.

6 COFFEY, Q.C.:

7 Q. Did you ever talk to anybody else or
 8 communicate with anybody about it?

9 DR. BANERJEE:

10 A. I might have joked about it with colleagues.

11 COFFEY, Q.C.:

12 Q. Do you recall--with colleagues, would that be
 13 within British Columbia? Did you ever talk to
 14 anybody in Newfoundland about it, that you
 15 recall?

16 DR. BANERJEE:

17 A. I don't recall specifically discussing it,
 18 other than that I didn't receive a very
 19 constructive response from the Minister.

20 COFFEY, Q.C.:

21 Q. Now Doctor, we understand that you did return
 22 to St. John's. If we could look, please, at
 23 Exhibit P-2148? In particular, Doctor, I want
 24 to take you to page three of this. These are
 25 notes of what is styled an exit meeting, April

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1 25th, 2006. You'll see your name is there as
 2 number one, Dr. Bob Williams, Dr. Donald Cook,
 3 Dan Fontaine, Gershon Ejeckam. It says Bev
 4 Fontaine; presumably that should be Bev
 5 Carter.

6 DR. BANERJEE:

7 A. Carter.

8 COFFEY, Q.C.:

9 Q. And Dr. Joy McCarthy. Doctor, can you tell
 10 us, please, then what you recall about your
 11 second visit?

12 DR. BANERJEE:

13 A. So my second visit, I reexamined some of the
 14 slides that were more currently or recently
 15 prepared, and I could see that there was a
 16 significant improvement in their quality,
 17 intensity of staining. Background problems
 18 had been dealt with, so there were clean
 19 backgrounds. The internal controls seemed to
 20 be working in the cases I looked at. We also
 21 again looked at other immunohistochemistry
 22 preparations other than estrogen receptors.

23 COFFEY, Q.C.:

24 Q. So the slides you're talking about just now,
 25 they're estrogen receptor slides?

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1 DR. BANERJEE:

2 A. Right.

3 COFFEY, Q.C.:

4 Q. So you also looked at others, I'm sorry?

5 DR. BANERJEE:

6 A. That's right, and when I looked at the other
 7 stains, other than the receptor stains, they
 8 also showed significant improvement in the
 9 quality of the staining, the specificity of
 10 the stain or the right cells were staining and
 11 the cells that were supposed to be negative
 12 were negative, etcetera. So I was quite happy
 13 with the improvement I saw.

14 COFFEY, Q.C.:

15 Q. What was the situation in respect of fixation?

16 DR. BANERJEE:

17 A. Fixation, there was still remaining problem.
 18 Again, I didn't look at a very large number of
 19 slides from different hospitals. It's hard
 20 to--hard for me to give you a general sort of
 21 impression of how well the fixation issues had
 22 been dealt with, but I was under the
 23 impression that they were certainly moving in
 24 the direction of getting pathologists
 25 assistants and I felt confident that the

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1 variability in fixation and tissue processing
 2 would have been dealt with and clearly some of
 3 the improvement in immunohistochemistry was
 4 related to better fixation, but it was not
 5 entirely resolved, from my recollection.
 6 COFFEY, Q.C.:
 7 Q. And Doctor, during your second visit, do you
 8 recall where it was you actually--like where
 9 you went?
 10 DR. BANERJEE:
 11 A. Not really.
 12 COFFEY, Q.C.:
 13 Q. Okay, you just--your second visit compared to
 14 your first, was your second visit a shorter or
 15 more focused?
 16 DR. BANERJEE:
 17 A. I think it was, yeah, a little shorter, but I
 18 think we were essentially in the same
 19 locations as before when we were looking at
 20 the slides.
 21 COFFEY, Q.C.:
 22 Q. Doctor, there's a note here, or at least these
 23 notes, I understand that these are Dr. Cook's,
 24 he attributes the following comments to Dr.
 25 Ejeckam, and the notes do indicate Dr. Ejeckam

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1 was present. Actually, well perhaps I'll
 2 begin with what he attributes to you.
 3 "Pleased to see recommendations have been
 4 implemented. Reviewed ER and PR stains.
 5 Stains are working," that may be okay, I'm not
 6 sure. "Lab is performing as well as expected.
 7 Good to see dedicated technologists. Good to
 8 see"--I apologize, I'll just go up here.
 9 "Good to see dedicated medical supervisor of
 10 lab. Good to see external QA. Some
 11 variability is a function of tissue from other
 12 hospitals, still present. 8. Need to set out
 13 guidelines--or send out guidelines to other
 14 hospitals regarding fixation. 9. Fixation and
 15 processing of tissue needs to be standardized.
 16 10. No hesitation in restarting the lab" and
 17 in that context, you mean ER/PR?
 18 DR. BANERJEE:
 19 A. Right.
 20 COFFEY, Q.C.:
 21 Q. So I take it that suggests, at least to me,
 22 Doctor, that you, during your visit, became
 23 aware that some of the tissue at least was
 24 coming from other places?
 25 DR. BANERJEE:

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1 A. Right.
 2 COFFEY, Q.C.:
 3 Q. And fixation and processing of tissues needs
 4 to be standardized and the guidelines for
 5 other hospitals, regarding fixation, had to
 6 come from somewhere, and perhaps be sent out
 7 from St. John's?
 8 DR. BANERJEE:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Then there are notes or references to Dr.
 12 Ejeckam's comments. "Need to have a stipend
 13 for director of immunohistochemistry. Need to
 14 recognize workload. Need time for monitoring"
 15 that should perhaps be, "the lab and
 16 documentation need clerical support. Need
 17 clerical support for document control," which
 18 is indicated to be supported by yourself.
 19 "Need CME," continuing medical education, "for
 20 the techs. Need succession plans for younger
 21 people into immunohistochemistry" and he goes
 22 on from there, "preferably people" and he
 23 describes the type of individual he'd be
 24 looking in a succession plan, and attribute to
 25 Dr. Ejeckam, "can start ER/PR immediately, and

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1 work on optimization of HER2/neu."
 2 Doctor, your overall sense then, you
 3 know, bearing in mind what you saw when you
 4 came in April of 2006, and during the meeting
 5 you had, the exit meeting, was what, compared
 6 to what you'd seen in September?
 7 DR. BANERJEE:
 8 A. Well, it was much improved, and I think the
 9 results were interpretable and the whole issue
 10 of internal controls had been addressed. So I
 11 felt that they were doing as well as most
 12 hospitals that I've seen.
 13 COFFEY, Q.C.:
 14 Q. Now here on the second page of the notes,
 15 fourth page of the exhibit, toward the end,
 16 attribute to you, Banerjee saying "breast
 17 pathologists must get together with
 18 oncologists to discuss ongoing issues". And I
 19 should point out that they attributed, above
 20 that, certain comments during the meeting to
 21 Dr. McCarthy. "And have to do literature
 22 review to decide what cut-off to use or is to
 23 be" -
 24 DR. BANERJEE:
 25 A. Yes.

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1 COFFEY, Q.C.
 2 Q. - "to get on track, have to"--it says
 3 something to NCIC guidelines, 10 percent cut-
 4 off, need to get standards across the country,
 5 set up a breast site group, pathologists,
 6 radiologists, surgeons and oncology". So, was
 7 it your view that they should set up a breast
 8 site group here?
 9 DR. BANERJEE:
 10 A. Yes.
 11 COFFEY, Q.C.
 12 Q. And in terms of the interaction of
 13 pathologists with oncologists, the advantage
 14 of a breast site group would be what, in that
 15 regard?
 16 DR. BANERJEE:
 17 A. The advantage would be that there would be
 18 appropriate forum for discussion about that
 19 policies, guidelines about clinical decision
 20 making based on pathology observations and how
 21 that should be reported and to make it
 22 standardized in terms of reporting. And also
 23 when there's debates about what is the
 24 appropriate cut-off point for calling
 25 something positive or negative, that should be

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1 based on a thorough literature review which
 2 oncologists and pathologists have to do
 3 together to then decide whether they're going
 4 to use one percent or ten percent. Most
 5 people are now using one percent as their cut-
 6 off. And again, the formation of the site
 7 group allows a new development to be planned
 8 for and new lab tests to be introduced in a
 9 systematic manner.
 10 COFFEY, Q.C.
 11 Q. Exhibit P-0049, please. Doctor, was there
 12 anything else of note during your time in St.
 13 John's that we haven't covered, that the
 14 Commissioner should know, do you think?
 15 DR. BANERJEE:
 16 A. I think the only thing that perhaps didn't
 17 come out during this discussion today was the
 18 HER2/neu testing for herceptin therapy, that I
 19 felt was not ready to be restarted until they
 20 had finished their validation against the gold
 21 standard method in situ hybridization and I'm
 22 not sure exactly what happened with that,
 23 whether that's still not being offered locally
 24 or whether that's already being offered. So,
 25 I don't have much information on that.

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1 COFFEY, Q.C.
 2 Q. And looking at this, Doctor, it's a letter of
 3 May 23rd, 2006 on page one of the exhibit and
 4 it's to Dr. Williams and you send a copy of
 5 your report based on your last site visit,
 6 your report on immunohistochemistry service.
 7 We look at page two of this, cover page, May
 8 21st, 2006 and you've indicated, at the
 9 request of Dr. Williams, you reviewed the
 10 performance of the IHC lab on April 24th, 2006
 11 in order to determine whether the quality of
 12 IHC has improved since your last visit and
 13 "whether my previous recommendations have been
 14 implemented". You've already addressed, just
 15 now, your view as to whether it had improved.
 16 I take it here under the charts we have here,
 17 Doctor, that follow, you simply listed your
 18 prior recommendations verbatim and made a
 19 comment upon them.
 20 DR. BANERJEE:
 21 A. Right, yes.
 22 COFFEY, Q.C.
 23 Q. And I'll just simply go through them. The
 24 first of them was the idea of pathologists
 25 subspecializing and you noted here, "in

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1 progress" you are advised at that point.
 2 DR. BANERJEE:
 3 A. Yes.
 4 COFFEY, Q.C.
 5 Q. One pathologist should be appointed as section
 6 medical director for the IHC service, is
 7 recommendation number two. You noted,
 8 implemented, Drs. Fontaine and Elms were
 9 appointed.
 10 DR. BANERJEE:
 11 A. Right.
 12 COFFEY, Q.C.
 13 Q. Doctor, in that regard, in terms of a person
 14 being the section medical director for IHC,
 15 from your perspective and you do have, I
 16 gather, a significant amount of experience as
 17 an IHC director yourself, what sort of
 18 training or experience should such a director
 19 have? Because I take it, from time to time,
 20 of course, the director will change, people
 21 will move on or their term will expire. What
 22 sort of training should the person have?
 23 DR. BANERJEE:
 24 A. I think that they definitely need to have
 25 spent some time in one of the reference

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<p>1 laboratories within the US or in Canada to 2 make sure that they have understood what it 3 will take them to be effective as a section 4 medical director and to be able to help the 5 technologist to troubleshoot and make sure 6 that when they select the technologists for 7 the lab that it's done with technical 8 knowledge in mind. So, yes, I think that 9 requires some additional training and it would 10 depend on where they went and how quickly they 11 saw the full spectrum of even the 12 histochemistry procedures and sign out with 13 whoever is in charge of the lab at the 14 training site. So, it could be something that 15 would take a month, maybe a couple of weeks 16 depending on the volume going through that 17 particular lab.</p> <p>18 COFFEY, Q.C. 19 Q. Doctor, is there a formal training program 20 that you're aware of for a person who might be 21 a section medical director for an IHC service?</p> <p>22 DR. BANERJEE: 23 A. No, there is no such formal training, but it 24 can be arranged through correspondence with a 25 particular lab that you want to go and train</p>	<p>1 was under discussion. Do you recall what the 2 situation was, under discussion, why was it 3 still under discussion or -</p> <p>4 DR. BANERJEE: 5 A. No, it's just that I don't think they had 6 decided to make the switch yet because their 7 existing antibodies seemed to be working 8 better, So -</p> <p>9 COFFEY, Q.C.: 10 Q. And you had seen slides stained with the -</p> <p>11 DR. BANERJEE: 12 A. Yeah.</p> <p>13 COFFEY, Q.C.: 14 Q. - recently then and from your perspective they 15 were fine?</p> <p>16 DR. BANERJEE: 17 A. Yes.</p> <p>18 COFFEY, Q.C.: 19 Q. Paragraph 4 on the next page, I apologize, is 20 the No. 4 recommendation. And then you've 21 noted here, and this deals with the 22 appropriate number of technologists being 23 dedicated to the IHC service and accountable 24 to the section medical director. You've 25 noted, "Implemented, three dedicated</p>
<p>1 at, some kind of visiting scientist kind of 2 arrangement could be made. We also run 3 workshops at the annual meeting of the 4 association which often covers details of 5 immunohistochemistry, but in the context of 6 specific tumour types and so on.</p> <p>7 COFFEY, Q.C. 8 Q. So, right now, such training, such as it 9 exists is on an informal basis.</p> <p>10 DR. BANERJEE: 11 A. It is.</p> <p>12 COFFEY, Q.C. 13 Q. And should involve a reference laboratory.</p> <p>14 DR. BANERJEE: 15 A. Yes.</p> <p>16 COFFEY, Q.C. 17 Q. And the extent of the period of time required 18 would depend upon the individual pathologists 19 background and experience to date.</p> <p>20 DR. BANERJEE: 21 A. Yes, right.</p> <p>22 COFFEY, Q.C. 23 Q. Then in paragraph three here, the 24 consideration should be given to switching to 25 the SP-1 and I take it, you've noted here, it</p>	<p>1 Page 212 2 technologists have been assigned to the 3 service. However, a succession plan is 4 required now in order to minimize future 5 problems related to attrition due to 6 retirements. The phenotype of future staff 7 for this section should be based on their 8 knowledge based and minimum educational 9 standards as this area will experience much 10 expansion and highly skilled staff are 11 required for implementing new antibodies, 12 probes of FISH, troubleshooting and 13 maintaining high standards. University 14 graduates at BSc or MSc level should be 15 recruited and trained to perform IHC/FISH at 16 reputable laboratories." Doctor, to your 17 knowledge are there any standards for IHC 18 technologists?</p> <p>19 DR. BANERJEE: 20 A. No, there are not that I am aware of. I made 21 this recommendation because this is a 22 recommendation I make to any hospital lab in 23 any part of the world because this is an area 24 that's expanding very rapidly, and as I said, 25 as new targeted therapies become available it's going to be critical to do these tests as</p>

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1 accurately as possible. And I think investing
 2 in well trained technologists is extremely
 3 important, otherwise we will continue to have
 4 problems with immunohistochemistry tests,
 5 particularly the newer ones that we will be
 6 obliged to provide.
 7 COFFEY, Q.C.:
 8 Q. Which, I gather, you anticipate that they have
 9 recently and will continue into the future to
 10 require more and more scientific knowledge
 11 just to even understand what it is you're
 12 doing?
 13 DR. BANERJEE:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. As a technologist?
 17 DR. BANERJEE:
 18 A. Yes. The danger is that if you don't do that,
 19 you're at the mercy of the vendors of machines
 20 and reagents who will tell you that they have
 21 worked out all the bugs and we just run with
 22 it.
 23 COFFEY, Q.C.:
 24 Q. And her, Doctor, paragraph, or recommendation
 25 No. 5, this is the tumour site pathologists

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1 leaders must attend appropriate educational
 2 and scientific conferences. You understood
 3 that was in progress?
 4 DR. BANERJEE:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. Ongoing medical education. "Pathologist
 8 assistants should be hired and trained."
 9 You've noted it's implemented, three PAs were
 10 hired. And you go on to say, "Issues around
 11 qualifications and training to be discussed
 12 with senior human resource consultants, as
 13 these are individuals who will perform
 14 delegated medical tasks requiring a minimum
 15 level of education (currently the Canadian
 16 Association of Pathologists) guidelines
 17 indicate that these should be at a master's
 18 level, with formal training as PAs."
 19 DR. BANERJEE:
 20 A. Okay.
 21 COFFEY, Q.C.:
 22 Q. So, the Canadian Association of Pathologists
 23 did have, at that time, had guidelines as to
 24 what the background should be for pathology
 25 assistants.

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1 DR. BANERJEE:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Did you make any inquiries, do you recall or
 5 were you told at the time as to whether these
 6 3 PAs who were being hired, had been hired and
 7 were being trained, met the CAP guidelines?
 8 DR. BANERJEE:
 9 A. I don't remember the discussion specifically,
 10 but I believe they hadn't met the guidelines,
 11 but they could achieve that through additional
 12 training.
 13 COFFEY, Q.C.:
 14 Q. Paragraph 7, recommendation 7 is related to
 15 the Sakura processing system, you know, not
 16 been implemented yet. Was there any
 17 discussion about that, do you recall?
 18 DR. BANERJEE:
 19 A. No, and I didn't think that would
 20 significantly change the issue around ER/PR
 21 testing. So, it wasn't that important.
 22 COFFEY, Q.C.:
 23 Q. Paragraph 8 refers to, recommendation 8 refers
 24 to the Ventana system and you've noted here on
 25 the right hand side, verify that ER and PR IHC

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1 qualities acceptable, HER2/neu staining still
 2 to be validated using FISH as the gold
 3 standard, and you just referred to that
 4 earlier.
 5 DR. BANERJEE:
 6 A. Right.
 7 COFFEY, Q.C.:
 8 Q. When you say "acceptable" Doctor in relation
 9 to ER/PR IHC quality, in that context, what
 10 does the word acceptable mean?
 11 DR. BANERJEE:
 12 A. It means that if I was to be the reporting
 13 pathologist, I would accept the quality of
 14 those slides and be able to report on them.
 15 COFFEY, Q.C.:
 16 Q. From your perspective at the time, did that
 17 mean that they could not be better, they were
 18 as good as they could get or -
 19 DR. BANERJEE:
 20 A. They could be better, but I didn't feel that
 21 we were missing anything that should have been
 22 positive.
 23 COFFEY, Q.C.:
 24 Q. And in terms of being better, what would be
 25 required, what sorts of things, from your

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1 perspective, would have to be done?
 2 DR. BANERJEE:
 3 A. Well, I think the final step is to get that
 4 initial fixation tissue processing step
 5 optimized and that would just make everything
 6 more crisp. So, you'd get cleaner staining
 7 and easier to interpret slides.
 8 COFFEY, Q.C.
 9 Q. And Doctor, recommendation 9 dealt with the
 10 external quality assurance programs and you
 11 noted "implemented" and there had only been a
 12 single survey at that point. In any case, I
 13 take it, such external quality assurance
 14 programs, whether the CAP, the American one or
 15 UK NEQAS or any other for that matter would be
 16 an ongoing process, you anticipated.
 17 DR. BANERJEE:
 18 A. Yes. You can't do it just once in a while.
 19 It has to be done regularly.
 20 COFFEY, Q.C.
 21 Q. Recommendation 10, had been consideration
 22 given to an organizational chart redesign in
 23 order to provide better joint technical and
 24 medical accountability, planning and
 25 communication. You noted here "not

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1 implemented". Was that discussed, do you
 2 recall, this whole organization business when
 3 you were here in April?
 4 DR. BANERJEE:
 5 A. It was very brief discussion. So, I basically
 6 concluded they hadn't done anything about it.
 7 I wasn't clear whether they were planning to
 8 do anything about it at the time.
 9 COFFEY, Q.C.
 10 Q. So, the discussion was such that you couldn't
 11 tell whether they were prepared to act on it
 12 at that point?
 13 DR. BANERJEE:
 14 A. Yes.
 15 COFFEY, Q.C.
 16 Q. And you don't recall any discussion about why
 17 they might not have or what the abstinence or
 18 -
 19 DR. BANERJEE:
 20 A. No.
 21 COFFEY, Q.C.
 22 Q. Under your recommendations here which, I take
 23 it, are one to nine are your current ones in
 24 this report at the time.
 25 DR. BANERJEE:

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1 A. Yes.
 2 COFFEY, Q.C.
 3 Q. ER and PR tests may be resumed effective
 4 immediately. You were happy, satisfied
 5 certainly to recommend that, locally. Cut-off
 6 thresholds for positivity should be based on
 7 current published consensus. So, Doctor, in
 8 relation to that, you weren't telling them or
 9 suggesting to them what that should be, I take
 10 it.
 11 DR. BANERJEE:
 12 A. I mentioned the fact that most labs had moved
 13 to the one percent cut-off.
 14 COFFEY, Q.C.
 15 Q. You told them that, but you weren't actually--
 16 you didn't commit that to writing in the sense
 17 of you would -
 18 DR. BANERJEE:
 19 A. I think there was still a bit of a debate
 20 going on with the oncologists as to what the
 21 cut-off should be. So, I felt that they
 22 needed to reach that conclusion themselves.
 23 COFFEY, Q.C.
 24 Q. And you were recommending, look at the
 25 literature.

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1 DR. BANERJEE:
 2 A. Yes.
 3 COFFEY, Q.C.
 4 Q. Recommendation three, HER2/neu testing should
 5 not be implemented until correlation of
 6 results with FISH has been verified. Other
 7 established IHC tests for diagnostic purposes
 8 may resume effect immediately. Was there some
 9 issue of concern about the other IHC tests
 10 that you were aware or are you just saying
 11 generally?
 12 DR. BANERJEE:
 13 A. Just generally. I think when I looked at the
 14 slides on my first visit, I would have been
 15 concerned about continuing that service
 16 without improving the technology.
 17 COFFEY, Q.C.
 18 Q. Continuing the IHC generally.
 19 DR. BANERJEE:
 20 A. That's right.
 21 COFFEY, Q.C.
 22 Q. Unless they actually did the optimization
 23 required?
 24 DR. BANERJEE:
 25 A. Right.

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1 COFFEY, Q.C.
 2 Q. So, I guess, on that point then, Doctor, in
 3 terms of that, when you'd been here in
 4 September of 2005, did the 20 groupings of
 5 slides and the other thirty odd slides and
 6 based upon the other, once you saw the other
 7 thirty, if they weren't going to do anything
 8 further about it to address the concerns you
 9 raised, you would have had concerns about IHC.
 10 DR. BANERJEE:
 11 A. I would have, but it's not quite the same
 12 level of concern because the other tests are
 13 not stand alone tests. They're in context
 14 with the morphology and the clinical findings
 15 in individual patients and they're more of a
 16 supportive evidence for making a
 17 classification of the cancer as opposed to
 18 deciding whether or not a patient is going to
 19 get a particular drug. So, that's the
 20 difference between the two.
 21 COFFEY, Q.C.
 22 Q. And from your perspective, based upon what you
 23 saw in your second visit in April of '06, you
 24 thought that the improvements not only had
 25 occurred in ER, but had occurred elsewhere and

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1 -
 2 DR. BANERJEE:
 3 A. That's correct.
 4 COFFEY, Q.C.
 5 Q. - any concerns you had about the other sorts
 6 of tests in September, had been alleviated by
 7 what you saw on your return.
 8 DR. BANERJEE:
 9 A. Yes.
 10 COFFEY, Q.C.
 11 Q. Recommendation 5, external quality assurance
 12 should be continued indefinitely and you just
 13 referred to that. In particular you refer to
 14 here, NEQAS which is -
 15 DR. BANERJEE:
 16 A. Yes.
 17 COFFEY, Q.C.
 18 Q. From your perspective, Doctor, we've referred
 19 to the CAP approach, UK NEQAS; I gather there
 20 may even be others. Is there any one or two
 21 of them that are, from your perspective
 22 superior or if it's possible, would you enrol
 23 in the whole group?
 24 DR. BANERJEE:
 25 A. I think either of them are acceptable. The

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1 NEQAS one involves many of the hospitals
 2 because it's not only United Kingdom, but all
 3 the European countries participate in that.
 4 So, the database that they have is
 5 significantly larger than the American CAP and
 6 I think the frequency of the surveys is a
 7 little higher. So, there are more tests per
 8 year that you have to participate in.
 9 COFFEY, Q.C.
 10 Q. And if it's possible, for an institution such
 11 as Eastern Health's General Hospital to enrol
 12 in more than one. Is it -
 13 DR. BANERJEE:
 14 A. Oh yes, not terribly expensive, reasonable.
 15 COFFEY, Q.C.
 16 Q. So, potentially, different ones have different
 17 strengths.
 18 DR. BANERJEE:
 19 A. Yes.
 20 COFFEY, Q.C.
 21 Q. And would be useful, if you can, to avail of
 22 the strengths of all of them, that are
 23 available.
 24 DR. BANERJEE:
 25 A. Yes.

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1 COFFEY, Q.C.
 2 Q. In terms of external proficiency testing, at
 3 the time, Doctor, between the period '97
 4 through 2005, the General Hospital had been so
 5 enrolled in external proficiency testing,
 6 might the problem have been detected at that
 7 point because of that?
 8 DR. BANERJEE:
 9 A. I think it would have been detected,
 10 certainly, I do.
 11 COFFEY, Q.C.
 12 Q. Recommendation 6 deals with the succession
 13 plan and simply duplicates what it referred to
 14 in the chart above. Number 7, Doctor, is
 15 organizational structure design is required to
 16 provide better technical and medical
 17 accountability. So, you're reiterating your
 18 point there?
 19 DR. BANERJEE:
 20 A. Yes.
 21 COFFEY, Q.C.
 22 Q. And subspecialization for pathologists, you're
 23 continuing to urge that. And issues around
 24 qualification of pathologist assistants in
 25 training were to be discussed. Again, you're

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1 urging that they adopt the Canadian
 2 Association of Pathologists guidelines, if
 3 possible.
 4 DR. BANERJEE:
 5 A. Yes and I think, you know, it takes time for
 6 that to happen across the country. So, most
 7 centres have worked with their existing
 8 technologists and got them trained with
 9 pathologists to do that particular job, and
 10 they often do an excellent job, but I think
 11 that whole system has to evolve to more formal
 12 level of education.
 13 COFFEY, Q.C.
 14 Q. Exhibit P-1143. Doctor, this is two e-mails,
 15 on the bottom of the first page here is July
 16 12th, 2006. It's to yourself, copied to--it's
 17 actually to yourself and Dr. Cook. The
 18 subject is QC for immunoperoxidase and it's
 19 from Laurette Geldenhuis.
 20 DR. BANERJEE:
 21 A. Geldenhuis.
 22 COFFEY, Q.C.
 23 Q. Geldenhuis, I apologize, who is the section
 24 head of cytopathology at the QE II in Halifax.
 25 She writes, "Diponkar and Don, I received

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1 these statements from Ermina Torlakovic.
 2 Since we discussed this issue in an executive
 3 meeting recently, I thought you might find
 4 these interesting. I attach". And then if we
 5 go to the next page of the exhibit. There's a
 6 document entitled "Proposal for establishment
 7 of a national external quality assurance
 8 program for clinical/diagnostic
 9 immunohistochemistry" and this thing goes on
 10 for a number of pages. And covers the topics
 11 including class one, two and three tests,
 12 methods and describes and outline, at least,
 13 or proposal for an organization that would be
 14 called CIQC. Doctor, what was this about?
 15 DR. BANERJEE:
 16 A. This was actually happening parallel, this
 17 initiative had been started with two
 18 pathologists, one from British Columbia and
 19 Dr. Torlakovic who had been thinking about the
 20 whole issue of quality assurance,
 21 immunohistochemistry and the lack of a
 22 national system. So, they had been working on
 23 this for a while to come up with a proposal
 24 and it was very timely because of the
 25 situation we were dealing with in Newfoundland

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1 and the CAP executive becoming interested in
 2 the issue of creating such a national program.
 3 So we encouraged Dr. Gilks from Vancouver
 4 General Hospital and Dr. Torlakovic, who had
 5 been working on this, have encouraged them to
 6 submit a formal proposal to us.
 7 Unfortunately, they focused on the more--the
 8 classification type of immunohistochemistry,
 9 as opposed to the predictive
 10 immunohistochemistry. So we actually advised
 11 them to change their priority because we felt
 12 that the smaller subset of breast biomarkers
 13 should be their first priority, rather than a
 14 second priority. So they have now created
 15 such a system and have actually sent out
 16 surveys to various hospital labs across the
 17 country, and the initial results are
 18 encouraging, but not all hospitals have
 19 participated. So it requires further
 20 evolution.
 21 COFFEY, Q.C.:
 22 Q. And Doctor, this is, I take it, this
 23 encouragement that they go with or concentrate
 24 initially on the--I think what she would refer
 25 to here as class two tests?

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1 DR. BANERJEE:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Originally, their proposal, as set out here,
 5 was that they would concentrate on class one
 6 tests as described here?
 7 DR. BANERJEE:
 8 A. That's correct.
 9 COFFEY, Q.C.:
 10 Q. I take it that you, as you just told us, they--
 11 your suggestion was "look, we have--you
 12 should concentrate initially on class two."
 13 They accepted that?
 14 DR. BANERJEE:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. And they've moved on it?
 18 DR. BANERJEE:
 19 A. Right.
 20 COFFEY, Q.C.:
 21 Q. Why the focus on class two, as opposed to
 22 class one tests, from your perspective? Why
 23 the need to do class two first?
 24 DR. BANERJEE:
 25 A. Well, the class two tests are those that

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1 actually trigger a specific medical decision.
 2 Based on the test result alone, regardless of
 3 everything else, and therefore class one,
 4 which is really an adjunct to morphologic
 5 diagnosis, doesn't trigger that specific
 6 medical decision. So we felt that if labs are
 7 having difficulty with immunohistochemistry,
 8 it's better to fix our efforts or focus our
 9 efforts on those tests that make the biggest
 10 difference in medical decisions. So that was
 11 why we chose class two.
 12 COFFEY, Q.C.:
 13 Q. And I take it that's a process of
 14 prioritization?
 15 DR. BANERJEE:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. Doctor, if we could look, please, at Exhibit
 19 P-2273? Now Doctor, I believe this is styled--
 20 this is a portion of a document that's styled
 21 executive meeting July 15th, I think, 2006.
 22 Items for discussion, and under--we go down
 23 through the page here, there's a reference to
 24 restructuring post graduate medical education,
 25 and I will be coming back to that with you.

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1 But, not this particular thing, as that
 2 subject in general, but 5.2, quality
 3 benchmarks workload, and the following is
 4 attributed to you, "Dr. Banerjee noted that
 5 CAP needs to get some standards and the time
 6 is right to set some standards" I'm sorry,
 7 "and the time is right to discuss with the
 8 provinces. A letter was sent to the
 9 provincial pathology presidents and to date,
 10 responses have been received from five
 11 provinces." I know one of them is from Paul
 12 Neil of Newfoundland and Labrador. "The
 13 purpose of the working group is to summarize
 14 all available published literature and
 15 international recommendations pertaining to
 16 pathologist's workload, manpower planning, and
 17 to develop a comprehensive national position
 18 paper on recommended pathologist workload as
 19 applied Canadian medical practice. This needs
 20 to be discussed further and we brought forward
 21 to the old and new executive meetings."
 22 So I take it this is dealing with and
 23 trying to set some benchmarks for workload
 24 across the country?
 25 DR. BANERJEE:

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1 A. That's right.
 2 COFFEY, Q.C.:
 3 Q. And then paragraph 5.4, titled "national
 4 standards for laboratories and immunoperox"
 5 I'm sorry, "immunohistochemistry testing. Dr.
 6 Banerjee noted that a hand-out was circulated
 7 regarding the proposal for the establishment
 8 of a national external quality assurance
 9 program for clinical diagnostic
 10 immunohistochemistry. The proposal was
 11 prepared by Dr. Torlakovic," I think you
 12 pronounced her name, "and Dr. Gilks. A quick
 13 review of the proposal brought forth a few
 14 areas of concerns, in particular last
 15 paragraph on page four regarding the class two
 16 tests and HER2. The members were asked to
 17 carefully read over the proposal and forward
 18 their comments by e-mail to Dr. Banerjee. The
 19 need to develop a working group with the
 20 medical and radiation oncologists, cancer
 21 societies, CAPCA and CCQLM is in progress."
 22 Now Doctor, in relation to this, this was
 23 an executive CAP meeting, I take it?
 24 DR. BANERJEE:
 25 A. Yes, it was.

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1 COFFEY, Q.C.:
 2 Q. Middle of '06, and the proposal in question
 3 that was being referred to here or being
 4 circulated, I take it that's the one we saw or
 5 one similar thereto, the one we just looked
 6 at?
 7 DR. BANERJEE:
 8 A. Yeah, I think it was the same proposal.
 9 COFFEY, Q.C.:
 10 Q. Same one, and you've referred to, or the notes
 11 here refer to "a few areas of concern,
 12 particularly the last paragraph on page four
 13 regarding class two tests and HER2."
 14 DR. BANERJEE:
 15 A. Right.
 16 COFFEY, Q.C.:
 17 Q. And is that the concern you just referred to
 18 then?
 19 DR. BANERJEE:
 20 A. Yeah, I believe that was regarding which
 21 priority they had set for the national
 22 program.
 23 COFFEY, Q.C.:
 24 Q. Which is what you just described.
 25 DR. BANERJEE:

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1 A. Yeah.
 2 COFFEY, Q.C.:
 3 Q. And need to develop a working group with the
 4 medical and radiation oncologists, cancer
 5 societies, CAPCA and CCQLM is in progress."
 6 How did that go, Doctor?
 7 DR. BANERJEE:
 8 A. Didn't go very well. There was some initial
 9 positive responses back, but I think it's the
 10 age-old problem as to who's driving the
 11 process, and somebody else should be doing the
 12 work and "we will be happy to help out," that
 13 sort of response. So it's very difficult to
 14 get people to look beyond their own particular
 15 domain and look at the bigger picture.
 16 There's a lot of inertia and I would say that
 17 we have not yet developed an effective working
 18 group, but there's still comments made
 19 whenever I talk to people or call them up or
 20 meet them at meetings that "yes, yes, this is
 21 an important issue. We need to get to it,"
 22 but there's a lot of inertia.
 23 COFFEY, Q.C.:
 24 Q. Doctor, here, if we could, CAPCA is what?
 25 CACP--CAPCA is what?

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1 DR. BANERJEE:
 2 A. I believe that's the Canadian Association of
 3 Provincial Cancer Agencies.
 4 COFFEY, Q.C.:
 5 Q. And the CCQLM?
 6 DR. BANERJEE:
 7 A. I can't quite remember what that stands for.
 8 COFFEY, Q.C.:
 9 Q. Okay, and Doctor, here in the paragraph 5.5,
 10 just a point for the Commissioner, to bring to
 11 her attention, there's a membership update and
 12 pathology assistants are referenced and "Dr.
 13 Banerjee noted that there are 26 PAs who have
 14 joined CAP as associate members and indicated
 15 that it is encouraging to see that so many
 16 joined." So in terms of the pathology
 17 assistants and where they are in the medical
 18 world, they are invited to join the Canadian
 19 Association of Pathologists?
 20 DR. BANERJEE:
 21 A. Yes, we felt that they needed to be invited to
 22 join so they could feel that they're part of
 23 the team, and not, you know, off on their own,
 24 and there was a lot of enthusiasm, so lots of
 25 people joined up, and we have special programs

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1 for them at the annual meetings.
 2 COFFEY, Q.C.:
 3 Q. Exhibit P-2432.
 4 THE COMMISSIONER:
 5 Q. Mr. Coffey, we'll take the afternoon break
 6 after you deal with this one.
 7 COFFEY, Q.C.:
 8 Q. Thank you, Commissioner. This is a letter,
 9 Doctor, from the Canadian Cancer Society of
 10 August 25th, 2006. Actually, perhaps if I
 11 could, because I could deal with these both
 12 together, Exhibit P-2433? Doctor, this is a
 13 letter--it appears to be a form letter,
 14 September 18th, 2006. It's for your
 15 signature. It's addressed to a number of
 16 different agencies, Canadian Strategy for
 17 Cancer Control and so on. They're all listed
 18 here at the bottom of the page, cc'ed to, and
 19 it's regarding the establishment of national
 20 s t a n d a r d s f o r l a b o r a t o r i e s
 21 immunohistochemistry testing. And if we could
 22 go back then to Exhibit P-2432? About three
 23 weeks before that, you had received this--or
 24 letter dated three weeks before that, August
 25 25th 2006, from the Canadian Cancer Society.

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1 The subject is the establishment of national
 2 s t a n d a r d s f o r l a b o r a t o r i e s
 3 immunohistochemistry testing and they thank
 4 you for your letter about your interest in
 5 collaborating with the Canadian Cancer Society
 6 and it's stated here that they "agree that
 7 national standards are important for
 8 laboratories. Please feel free to contact
 9 Paul Lapierre, who's the director of public
 10 affairs and cancer control," and there's a
 11 note here "Diponkar has only heard from CSC
 12 and Dr. Bert Schacter"
 13 DR. BANERJEE:
 14 A. Brent.
 15 COFFEY, Q.C.:
 16 Q. Brent, I apologize, Brent Schacter.
 17 DR. BANERJEE:
 18 A. Yeah.
 19 COFFEY, Q.C.:
 20 Q. Of CAPCA, and these are Dr. Cook's notes, I
 21 believe.
 22 DR. BANERJEE:
 23 A. Yes, yes.
 24 COFFEY, Q.C.:
 25 Q. So Doctor, I'm just going to bring those to

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1 your attention and we'll come back then and I
 2 want to take this up then to ask you a final
 3 set of questions.
 4 DR. BANERJEE:
 5 A. Thank you.
 6 THE COMMISSIONER:
 7 Q. Afternoon break.
 8 COFFEY, Q.C.:
 9 Q. Thank you, Commissioner.
 10 THE COMMISSIONER:
 11 Q. Thank you.
 12 (BREAK)
 13 THE COMMISSIONER:
 14 Q. Please be seated. Mr. Coffey.
 15 COFFEY, Q.C.:
 16 Q. Thank you, Commissioner. Doctor, I wanted to
 17 ask you then, if I could, Doctor, about really
 18 the subject matter of the caption of these two
 19 letters we just looked at before the break,
 20 establishment of national standards for
 21 laboratories and immunohistochemistry testing.
 22 In particular, if we could look at Exhibit P-
 23 2433? Here, Doctor, and I take it, did you
 24 send this letter on actually afterward,
 25 Doctor?

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1 DR. BANERJEE:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And to the bodies listed at the bottom here?
 5 DR. BANERJEE:
 6 A. That is correct.
 7 COFFEY, Q.C.:
 8 Q. I take it that this grouping listed under the
 9 cc here are in effect, in one sense, a who's
 10 who of cancer treatment throughout the
 11 country?
 12 DR. BANERJEE:
 13 A. That is correct.
 14 COFFEY, Q.C.:
 15 Q. Not necessarily exhaustive, but certainly a
 16 who's who.
 17 DR. BANERJEE:
 18 A. Right.
 19 COFFEY, Q.C.:
 20 Q. You've written then, Doctor, that "the
 21 Canadian Association of Pathologists,
 22 representing over 940 pathologists, wishes to
 23 develop a national external quality assurance
 24 policy in laboratory medicine
 25 immunohistochemistry and would welcome the

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1 opportunity of working collectively with you
 2 on these national standards." Now just before
 3 I go on, Doctor, 940 pathologists, Canadian
 4 Association of Pathologists, are all Canadian
 5 pathologists members of that association?
 6 DR. BANERJEE:
 7 A. No, they're not.
 8 COFFEY, Q.C.:
 9 Q. So approximately how--what proportion would
 10 be?
 11 DR. BANERJEE:
 12 A. I think probably just over half.
 13 COFFEY, Q.C.:
 14 Q. So that would mean that there, at least in
 15 '06, probably were under 2,000 pathologists in
 16 Canada?
 17 DR. BANERJEE:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. You go on to say then, went on to say, "at the
 21 moment, there are different tests, systems and
 22 applications used across the country with
 23 little or no consensus on quality assurance,
 24 inconsistent protocols, valuable criteria"--
 25 I'm sorry, "variable criteria for

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1 interpretation. This is a very high risk area
 2 and by not having national standards on
 3 quality assurance, we will be looking at high
 4 costs down the road. We strongly feel that
 5 the government needs to be made aware of the
 6 importance of having national quality
 7 assurance of laboratories, laboratory tests
 8 and the interpretation of the results. Our
 9 plan is to form a coalition working group to
 10 develop national standards for laboratories,
 11 particularly for immunohistochemistry testing.
 12 This group consists of several stakeholders"
 13 and you've listed them below, "would then
 14 prepare a business plan and present this to
 15 the government as a group. We believe by
 16 working together, our voice will be heard and
 17 acted upon by government. An additional item
 18 for discussion is the timely introduction of
 19 biomarker tests in order to facilitate patient
 20 selection for targeted therapies across the
 21 nation with a clear national process for
 22 evidence based decision making and a
 23 consistent mechanism of credentialling and
 24 funding laboratories to perform these
 25 medically necessary tests. Failure to address

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1 this will lead to inconsistent access to
 2 targeted therapies and inappropriate therapy
 3 or denial of therapy triggered by false
 4 positive or false negative tests respectively.
 5 I will follow this up with a phone call to
 6 discuss the possibility of collaboration. In
 7 the meantime, please feel free to contact me"
 8 at your e-mail address "with any questions and
 9 comments. The Canadian Association of
 10 Pathologists looks forward to working with you
 11 on this important and much needed policy.
 12 Sincerely yours."
 13 Now Doctor, I'm going to ask you a
 14 question and then I'm going to let you answer,
 15 continue as--and I would ask you in as full a
 16 manner as you can possible, how had these
 17 state of affairs come about? How had we come
 18 to this point in the middle of 2006?
 19 DR. BANERJEE:
 20 A. Well, I think partly it's related to how
 21 knowledge is generated, how knowledge is
 22 applied to clinical care and how different
 23 specialty groups, professional groups look
 24 after cancer patients and how they interact.
 25 So in general I would say that medical

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1 discoveries come at us at a rate beyond our
 2 capacity to implement because there is no
 3 formal process by which we review the evidence
 4 for changing practice, whether it's radiation
 5 oncology, medical oncology, all of them face
 6 the same problem, pathologists face the same
 7 problem. It's the rate at which basic science
 8 discoveries are going to impact clinical care
 9 has reached a point where the application of
 10 discoveries is going to be the biggest
 11 bottleneck we have, and that is largely
 12 historically related to how research is
 13 funded, how clinical care is funded and the
 14 validation process in between the research
 15 discovery and the application to clinical care
 16 is funded. And this is true world wide; I'm
 17 not blaming Canadian granting agencies, but
 18 Canadian granting agencies fund basic research
 19 and they fund clinical trials which are, in
 20 essence, testing new drugs against standard
 21 therapy to see if they're any better. What's
 22 happening now is because of the human geno
 23 project. The knowledge of human genomics and
 24 the fallout of that is such that we know that
 25 our current practice in making medical

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1 decisions about individual patients requires a
 2 complete redesign. In the cancer field, if
 3 you look at drug-based therapies in general,
 4 not just in oncology, it is known that about
 5 40 percent of drugs don't actually work. If
 6 you look at oncology across the spectrum of
 7 cancer types, 75 percent of drugs don't work.
 8 In other words, there is no clinical benefit.
 9 And the problem is due to the fact that drugs
 10 are approved on the basis of clinical trials
 11 and the outcome of that clinical trial may
 12 show a benefit to a group of patients. But
 13 what human genomics had taught us is that each
 14 individual has his or her own characteristics
 15 on top of what the cancer genes tell you so
 16 that even if a drug works on, say, 25 percent
 17 of patients in a particular category, we don't
 18 know exactly why it worked and why the 75
 19 percent that didn't respond did not respond.
 20 But there's clearly evidence coming out that
 21 there's something about the genetics of the
 22 tumour itself and the patient that actually
 23 influences how they respond to a particular
 24 drug. So the industry in terms of the
 25 pharmaceutical industry is moving towards

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1 targeted therapies, ie, they target a
 2 particular gene or the product of that gene
 3 with the hope of having more effective
 4 therapies. At the same time they realize that
 5 that therapy cannot work for everyone unless
 6 they express the target in the tumour, and
 7 they don't all express the target, so what you
 8 need is some process by which we identify
 9 those patients that express the appropriate
 10 target and therefore would be eligible for
 11 therapy using those targeted therapies. That
 12 means you have to then design a test that
 13 looks at the target to make sure it accurately
 14 reflects the presence of that target in the
 15 tissue and it withstands formalin fixation,
 16 all of that sort of stuff. So that process by
 17 which we validate a research finding and make
 18 it a practical kind of test for clinicians to
 19 make decisions on is not funded by anyone,
 20 nobody funds it, not the granting agencies,
 21 not the health care systems. It's a
 22 completely neglected area of development. So
 23 what we try and do is, again, using evidence-
 24 based decision making, look at options whereby
 25 we can introduce those tests without a clear

<p style="text-align: right;">Page 245</p> <p>1 funding mechanism for it. So we might say 2 we're going to replace this old test with a 3 new one and hopefully can do it for the same 4 money or less, automated, etcetera. It's a 5 hit or miss game; and there is no process in 6 any province that actually has a logical step 7 wise decision-making process that says if the 8 medical oncologists now want to bring in 9 another targeted therapy against whatever 10 cancer, that that process by which the 11 government decides to approve that therapy and 12 fund it has to be packaged with a patient- 13 selection testing process. Right now it isn't 14 packaged that way, so they might approve the 15 drug, but when the labs ask for the funding 16 for the test, they say, sorry, we don't have 17 any money for you guys, just figure it out 18 yourselves. Well, that may have worked in the 19 past because of, you know, getting rid of 20 obsolete tests and improving efficiencies, but 21 labs across the country have gone through all 22 the efficiency gains, they've down sized, 23 etcetera, etcetera, so that buffer zone is no 24 longer available. So I keep arguing with our 25 oncologists saying that the next time you ask</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Doctor, just in a concrete way here on this, 3 as an example, Herceptin.</p> <p>4 DR. BANERJEE:</p> <p>5 A. Right.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Targeted therapy and the HER2/neu.</p> <p>8 DR. BANERJEE:</p> <p>9 A. Right.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Herceptin being approved and I think -</p> <p>12 DR. BANERJEE:</p> <p>13 A. And the test -</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. - we've seen some evidence that it happened in 16 Newfoundland, for example, at one point in 17 this scenario that we've heard. And you're 18 saying that, well,, okay, it's all very well 19 and good to fund Herceptin, to agree to make, 20 accept the oncologists' proposal that that be</p>
<p style="text-align: right;">Page 246</p> <p>1 for a new drug and it requires a predictive 2 test, you should package your request 3 appropriately so the test is also funded, 4 which is a very, very small fraction of the 5 total cost of that particular therapy.</p>	<p style="text-align: right;">Page 247</p> <p>1 done?</p> <p>2 DR. BANERJEE:</p> <p>3 A. Um-hm.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. But what about the HER2, funding the HER2/neu 6 tests required to decide whether the 7 individual patients should, or it's 8 appropriate to give them?</p> <p>9 DR. BANERJEE:</p> <p>10 A. That's correct.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Herceptin?</p> <p>13 DR. BANERJEE:</p> <p>14 A. Right.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Is that an example of -</p> <p>17 DR. BANERJEE:</p> <p>18 A. That is the, that's the primary example, 19 that's the prototype of what's to come.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Okay. I apologize -</p> <p>22 DR. BANERJEE:</p> <p>23 A. And governments have not understood the issue. 24 So a \$45,000 drug is funded which you multiply 25 by the number of patients available for the</p>

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1 drug, it's in the millions of dollars. The
 2 test itself may cost less than \$100 per
 3 patient and that doesn't get funded. So
 4 what's the logic in that?
 5 COFFEY, Q.C.:
 6 Q. I'm sorry, Doctor, I interrupted you.
 7 DR. BANERJEE:
 8 A. So since health care is a provincial
 9 jurisdiction that there's variability in how
 10 provincial ministries of health deal with
 11 these kinds of issues, I would say that it has
 12 been not a systems approach but more like an
 13 ad hoc approach, so if you make a case, you
 14 might get the money, the drug gets funded but
 15 the test is not funded. Some provinces have
 16 funded the test. In British Columbia it is
 17 not funded, so we have had to find resources
 18 from within the budget to do it. That means
 19 probably denying something else that we could
 20 be doing for other patients' benefits. So
 21 this has to be addressed across the country
 22 and there has to be an understanding of the
 23 future of cancer therapy is going to be more
 24 and more targeted. There are approximately
 25 2600, probably more than that by now, new

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1 drugs in the pipeline in development which is
 2 all targeted types of therapies, so each one
 3 of them will need a test for patient
 4 selection. Now, who's going to do that and
 5 how well is it going to be done? And if the
 6 patients know that, you know, they're all
 7 desperate for something that'll work, and if
 8 they know that is the test result that
 9 influences the decision whether or not they
 10 get the drug and there's no quality assurance
 11 in the system -
 12 COFFEY, Q.C.:
 13 Q. In relation to the test?
 14 DR. BANERJEE:
 15 A. - they'll go shopping for a lab that can
 16 produce a positive result. And who knows
 17 whether that's a real positive, you know. So
 18 I think it's, it's a huge risk to patients in
 19 not addressing this problem.
 20 COFFEY, Q.C.:
 21 Q. And how has it come about, Doctor, that from
 22 your perspective there have been at least not
 23 the appropriate efforts to address it at least
 24 -
 25 DR. BANERJEE:

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1 A. Yeah, I think it's because although we have
 2 organized cancer systems in various provinces
 3 that the individual specialties within a
 4 cancer care delivery system tend to focus on
 5 their particular subspecialty. They don't
 6 necessarily wish to address the system
 7 approach and the way they are funded
 8 influences that. So if a medical oncology
 9 department needs funding for a new drug, there
 10 is a process for them to fight for funding,
 11 and they will do it regardless of whether or
 12 not the tests required for that drug is
 13 required to be established in the lab. So
 14 Herceptin got approved in British Columbia
 15 before we had any funding for the test. So
 16 the next drug that they'll go after will have
 17 the same problem and then what will happen is
 18 we will say, well, we don't have the test
 19 established, it's not funded, we can't offer
 20 it to you, so then they'll have to send all
 21 that stuff to the United States to some other
 22 lab that has the test set up and that's going
 23 to cost us probably three times what it would
 24 cost us to provide the test locally. So all
 25 of this is going to come to a head unless

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1 people are willing to look at the entire
 2 system in some kind of logical manner and
 3 ministries have to fund patient care in a more
 4 holistic manner as opposed to, well, we have
 5 only so much money, we'll give you this amount
 6 of money for the drugs and you worry about,
 7 you know, how you're going to pay for the
 8 pharmacists, the nurses to deliver the drugs,
 9 that's your problem and for the labs to
 10 provide the test, that's your problem. Well,
 11 you know, there isn't enough money in the
 12 system for us to keep adding to the burden of
 13 the lab without giving something else up. And
 14 we have reached a point where we can't give
 15 anything up without affecting other patients
 16 in their care.
 17 COFFEY, Q.C.:
 18 Q. Doctor, other than--just looking at the
 19 second-last paragraph of your letter and, of
 20 course, even thinking about Herceptin and the
 21 HER2/neu test, testing process, in principle
 22 really is there any difference between the
 23 target therapy of Tamoxifen or any Aromatase
 24 inhibitor -
 25 DR. BANERJEE:

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1 A. No, it's the same principle -
 2 COFFEY, Q.C.:
 3 Q. - and ER/PR, the ER/PR in that world function
 4 is the correspondence to the HER2/neu test and
 5 the Tamoxifen corresponds to the Herceptin in
 6 terms of the targeted -
 7 DR. BANERJEE:
 8 A. Yes, it's the same principle.
 9 COFFEY, Q.C.:
 10 Q. Same principle.
 11 DR. BANERJEE:
 12 A. One could ask why was this not an issue when
 13 Tamoxifen and ER became relevant in breast
 14 cancer and part of it is that it happened
 15 during an era where budgets were reasonable
 16 and annually the increments were reasonable,
 17 but that's no longer the case. Also, the drug
 18 costs were quite low. Tamoxifen is not an
 19 expensive drug compared to Herceptin or the
 20 new targeted therapies. Those are in the tens
 21 of thousands per patient. So that, you know,
 22 the economics of the argument are
 23 significantly different now.
 24 COFFEY, Q.C.:
 25 Q. Doctor, in respect of the ER and PR testing,

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1 you pointed out there are different test
 2 systems and applications, I take it, with
 3 little or no consensus on quality assurance,
 4 inconsistent protocols and variable criteria
 5 for interpretation. Would that apply in
 6 Canada to ER and PR?
 7 DR. BANERJEE:
 8 A. Oh, yes, yes.
 9 COFFEY, Q.C.:
 10 Q. And how can, again, looking back on it from
 11 your perspective having worked in pathology in
 12 Canada for decades, how had that come about in
 13 an era when even at times going back at one
 14 point there was money, perhaps going back to
 15 the '80s, how could there be a situation where
 16 IHC, ER/PR testing gets introduced, utilized,
 17 but it varies, as it does, I gather, across
 18 the country, different approaches, you know,
 19 no requirement for quality assurance, external
 20 proficiency testing, how could that come
 21 about?
 22 DR. BANERJEE:
 23 A. Because no one takes responsibility for any of
 24 those issues and the, if you look across the
 25 country how labs are funded, that's variable

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1 too. So if I was running a private sector
 2 lab, I would bill the government for the work
 3 I would do and I would get paid, so it's
 4 volume sensitive funding. If I work in a
 5 public sector hospital lab, then, particularly
 6 the cancer agency, everything we do is not
 7 billable to the government, it's block funding
 8 and the block funding was based on when the
 9 cancer agency was first created in 1935 or
 10 something like that, and then there was some
 11 incremental funding on an annual basis out of
 12 which administrators would decide how much the
 13 lab got and how much everybody else got, et
 14 cetera, et cetera. So the basic problem is
 15 there is no volume sensitive funding
 16 mechanism, there is no process by which you
 17 add new tests to the fee schedule. In some
 18 provinces, there is no fee schedule; other
 19 provinces there are. In British Columbia
 20 there's a fee schedule for certain tasks, but
 21 not others, so it's a hodge-podge of things.
 22 Compare that with the American system,
 23 everything is billable and everything is
 24 listed and there is a consensus on the cost of
 25 every test because there's a daily or at least

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1 annual battle between insurance companies and
 2 the health care providers, but at least there
 3 is some volume sensitivity. We don't have
 4 that in Canada.
 5 COFFEY, Q.C.:
 6 Q. Doctor, I want to ask you about the matter of
 7 the Royal College of Physicians in Canada,
 8 okay, in terms of whether or not they are
 9 involved, at least from your perspective or
 10 have been to date involved in the concerns or
 11 trying to address the concerns for example
 12 raised in the letter which is on the screen
 13 here.
 14 DR. BANERJEE:
 15 A. Absolutely not, the Royal College has not been
 16 interested in the practise of subspecialty or
 17 the speciality groups, other than their
 18 certification and now continuing education
 19 towards maintenance of certification; however,
 20 they have not been involved in manpower
 21 planning. They have not been involved in
 22 creating a more dynamic curriculum for
 23 training of pathologists. There is still
 24 training in the mode that we train people in
 25 the early 60's and 70's and the newer

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1 technologies are considered, new technologies
 2 that require maybe some elective time during
 3 training and perhaps some of them have matured
 4 to the point of being mandatory, but they are
 5 fairly short training periods and it's
 6 insufficient for these programs to actually
 7 generate trained pathologists who are fully
 8 versed in these technologies, that is
 9 something they have to learn after their Royal
 10 College certification, so that they do through
 11 informal connections with reference
 12 laboratories or fellowship training beyond the
 13 Royal College training et cetera. It's not an
 14 organized system. The Royal College and the
 15 Canadian Association of Pathologists have over
 16 the years had significant differences of
 17 opinion on the future of pathology and we
 18 continue to have those discussions. There's
 19 been a trend recently to go against the whole
 20 evolution of subspecialization, the Royal
 21 College feeling that they need fewer
 22 specialities and fewer subspecialties and we
 23 feel the opposite, that for good patient care,
 24 we actually need to specialize even more
 25 because the knowledge base required for

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1 generalists is so huge that they cannot keep
 2 up with everything, so that's something we've
 3 challenged the Royal College on on a number of
 4 occasions and we've had some positive response
 5 from them. They reversed some decisions
 6 recently, but they still haven't grasped the
 7 whole issue of quality assurance and lab
 8 medicine as their responsibility, unlike the
 9 British Royal College of Pathology and the
 10 Australian College of Pathology who are not
 11 just involved in education, but they actually
 12 have significant programs in quality assurance
 13 across the country.

14 COFFEY, Q.C.:

15 Q. I was going to ask you about that point,
 16 Doctor, because what the situation is to your
 17 knowledge or your understanding in, for
 18 example, the UK and Australia in that regard,
 19 in terms of the colleges. For example in the
 20 UK, the pathologists in the UK, are they part
 21 of the college at large or do they have their
 22 own college?

23 DR. BANERJEE:

24 A. They have their own college, as do the
 25 Australians.

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1 COFFEY, Q.C.:

2 Q. As do the Australians.

3 DR. BANERJEE:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. And your understanding is what then in terms
 7 of what sorts of activities are those colleges
 8 involved in, in comparison to the situation in
 9 Canada for pathologists.

10 DR. BANERJEE:

11 A. Well those colleges are involved in setting
 12 the curriculum for training programs, they're
 13 involved in setting the examinations,
 14 certification of pathologists and also running
 15 quality assurance programs which are
 16 mandatory, particularly in Australia. In the
 17 United Kingdom, I'm not sure whether it's
 18 entirely the role of the Royal College or
 19 their other NEQAS group is probably an
 20 independent, but same faculty involved in that
 21 effort. In the Australian Royal College, they
 22 do all of the quality assurance, licensing of
 23 laboratories across the country, so they are
 24 very much involved in that and that's
 25 mandatory. Americans have a similar system,

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1 the College of American Pathologists are
 2 involved in accrediting labs and inspecting
 3 labs, et cetera, so it's a national process
 4 which works very well.

5 COFFEY, Q.C.:

6 Q. In those three other countries.

7 DR. BANERJEE:

8 A. That's right.

9 COFFEY, Q.C.:

10 Q. And that's not true in Canada?

11 DR. BANERJEE:

12 A. No.

13 COFFEY, Q.C.:

14 Q. Now, Doctor, having sent out your letter, what
 15 happened?

16 DR. BANERJEE:

17 A. I got a few responses, some, I think just one
 18 in writing, a couple by telephone indicating
 19 an interest in the issue. There were quite a
 20 few that did not respond.

21 COFFEY, Q.C.:

22 Q. Doctor, I wanted to ask you about, perhaps if
 23 you could give a brief overview to the
 24 Commissioner of how the BC Cancer Agency
 25 operates in terms of its involvement

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1 throughout British Columbia, and particularly
 2 in relation to pathologists and pathologists'
 3 work, not only in the urban areas, but in the
 4 more rural or less urbanized areas, how does
 5 that work?
 6 DR. BANERJEE:
 7 A. So as you know, the British Columbia Cancer
 8 Agency is a provincial entity, it provides
 9 cancer care for patients throughout the
 10 province. They are predominantly designed as
 11 treatment centres, so radiation therapy,
 12 medical oncology, chemotherapy or systemic
 13 therapy as they call it, they are not really
 14 involved in the initial diagnosis or surgical
 15 procedures, those are done outside of the
 16 cancer agency. They don't have any
 17 jurisdiction over that, so they don't have any
 18 jurisdiction over the pathology quality in the
 19 various hospitals where the surgery is being
 20 done. However, as we have discussed earlier,
 21 the oncologists over a number of years have
 22 realized that there are significant problems
 23 with some of the reports and it's hard to
 24 predict which report has a problem by reading
 25 the report, by looking at the slide, so we now

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1 have a policy that requires some central
 2 review or review, not necessarily centrally,
 3 but by pathologists who are credentialed as
 4 consultants to the cancer agency that may be
 5 working out of other hospitals, like Vancouver
 6 General Hospital, et cetera. So those
 7 individuals are specifically credentialed and
 8 I have a role in selecting those individuals
 9 and credentialling them through the Medical
 10 Advisory Committee and the hospital board, et
 11 cetera. That means that we have jurisdiction
 12 over their practice, in terms of the review of
 13 pathology or signing out of pathology for
 14 cancer patients; however, we don't have any
 15 jurisdiction over pathologists in other
 16 hospitals and therefore, we have this policy
 17 of second opinion type review, take another
 18 look at the slides, the original slides from
 19 various hospitals and issue a review report
 20 which may or may not change the interpretation
 21 of a particular case or change the medical
 22 management of a particular case. Now we don't
 23 review every cancer patient in the province
 24 because, as I said, if they're presenting in
 25 fairly late stages, the initial diagnosis of

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1 it, at a stage where they already have
 2 metastatic disease, then we don't believe
 3 that we would provide any value to the
 4 management of that patient through the review
 5 process. So each tumour group, so there are I
 6 believe 14 different tumour groups in the
 7 cancer agency dealing with particular organ
 8 sites where cancers occur, and through those
 9 tumour groups, guidelines have been developed
 10 in terms of what happens when a patient is
 11 referred to a cancer centre for therapy and
 12 whether or not a pathology review is required
 13 and those are all posted on the website, it's
 14 publicly available. So for breast cancer they
 15 have particular rules; for lymphoma there are
 16 particular rules, et cetera.
 17 COFFEY, Q.C.:
 18 Q. So the cancer agency of which you're the head,
 19 you're involved in accrediting, did you use
 20 the word "accrediting" of certain
 21 pathologists?
 22 DR. BANERJEE:
 23 A. Credentialling.
 24 COFFEY, Q.C.:
 25 Q. I apologize, credentialling is the word, I

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1 thought I had it wrong.
 2 DR. BANERJEE:
 3 A. We don't accredit the labs.
 4 COFFEY, Q.C.:
 5 Q. No, I appreciate--so the credentialling of
 6 individual pathologists who--and the effect
 7 then of you credentialling them is what?
 8 DR. BANERJEE:
 9 A. Number one, that they are accountable to the
 10 cancer agency and if they are the primary
 11 pathologist who signs out a report after a
 12 surgical procedure, then we would accept that
 13 report without further review, unless an
 14 oncologist wishes to have it reviewed, for
 15 whatever reason and it's their right to ask
 16 for that review.
 17 COFFEY, Q.C.:
 18 Q. And if you receive a report from a pathologist
 19 that is not credentialed by your organization,
 20 then there is a second look -
 21 DR. BANERJEE:
 22 A. A second look as long as it follows the
 23 guidelines for that (unintelligible) group, we
 24 don't look at everything.
 25 COFFEY, Q.C.:

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1 Q. And this is pursuant to an understanding or an
 2 agreement you had with the oncologist groups.
 3 DR. BANERJEE:
 4 A. That's correct.
 5 COFFEY, Q.C.:
 6 Q. Doctor, I have one other actual question I
 7 wanted to ask you about, one other topic, you
 8 did indicate to us that, and certainly while
 9 you were involved in St. John's in 2005 and
 10 2006, you weren't aware of Ms. Wegrynowski's
 11 involvement.
 12 DR. BANERJEE:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. And I understand that yesterday, I believe you
 16 had the opportunity to receive a copy of her
 17 reports?
 18 DR. BANERJEE:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. And you have reviewed them?
 22 DR. BANERJEE:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. I appreciate at times it may be difficult to

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1 tell what one might have done in hindsight,
 2 but if you had been provided with copies of
 3 those reports back in 2005 and 2006, would it
 4 have made any difference to your approach?
 5 DR. BANERJEE:
 6 A. I don't think it would have made a difference
 7 to my conclusions, but I think I would
 8 certainly have preferred to have seen that
 9 report because perhaps some of my
 10 recommendations would have been in greater
 11 detail, particularly on the technical side.
 12 So it would have helped, but the overall
 13 impression of the problem would not have
 14 changed.
 15 COFFEY, Q.C.:
 16 Q. Would not have changed. Fixation, better
 17 education, internal controls -
 18 DR. BANERJEE:
 19 A. Right.
 20 COFFEY, Q.C.:
 21 Q. Optimization of stains.
 22 DR. BANERJEE:
 23 A. That is correct.
 24 COFFEY, Q.C.:
 25 Q. That whole approach. Commissioner, they are

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1 the questions I have.
 2 THE COMMISSIONER:
 3 Q. Thank you. Mr. Pritchett.
 4 MR. PRITCHETT:
 5 Q. Thank you, Commissioner, I don't have any
 6 questions for this witness.
 7 THE COMMISSIONER:
 8 Q. Mr. Simmons.
 9 MR. SIMMONS:
 10 COFFEY, Q.C.:
 11 Q. Thank you, Commissioner.
 12 DR. DIPONKAR BANERJEE, EXAMINATION BY DAN SIMMONS
 13 MR. SIMMONS:
 14 Q. Good afternoon, Dr. Banerjee. We met
 15 yesterday. I'm Dan Simmons, I'm the lawyer
 16 here for Eastern Health. I have a few
 17 specific things I want to follow up with you,
 18 but first I want to thank you for your
 19 detailed and thoughtful evidence that you have
 20 given so far, because I'm sure it's going to
 21 be of quite a bit of assistance to the
 22 Commission. When you came here for the first
 23 visit in the fall of 2005, you've told us how
 24 you reviewed about 20 of the slides or cases
 25 that had originally been tested using the DAKO

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1 autostain or technology and before your
 2 arrival had been retested on the Ventana
 3 technology. And I understand that you had the
 4 opportunity, went to explain to look at the
 5 original slide from the first test and then
 6 the subsequent slide.
 7 DR. BANERJEE:
 8 A. That's correct.
 9 MR. SIMMONS:
 10 Q. And the H&E slides also?
 11 DR. BANERJEE:
 12 A. Yes.
 13 MR. SIMMONS:
 14 Q. And from looking at your report, what you
 15 described in your report is that you were of
 16 the understanding that those cases originated
 17 in 2002, that the initial tests were done in
 18 the year 2002 and had then retested prior to
 19 your visit?
 20 DR. BANERJEE:
 21 A. I wasn't quite sure of the date of the
 22 original testing for some of those cases. I
 23 did look at the numbers or recorded the
 24 numbers.
 25 MR. SIMMONS:

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1 Q. Right, and we've seen other evidence here at
 2 the Commission to know which cases had been
 3 retested by the time of your arrival and the
 4 majority of them were in 2002, there were a
 5 small number that were from some other years.
 6 DR. BANERJEE:
 7 A. Uh-hm.
 8 MR. SIMMONS:
 9 Q. We also know that the time period for which
 10 retesting was later done at Mount Sinai
 11 covered from 1997 all the way up to 2005 and
 12 I'm just wondering if when you were here, if
 13 you made any effort or if you were asked to
 14 make any effort to review any larger time
 15 period other than that?
 16 DR. BANERJEE:
 17 A. No.
 18 MR. SIMMONS:
 19 Q. Okay. So that the conclusions that you drew
 20 regarding the reasons for the failure of the
 21 original test, would it be fair to say that
 22 those would be based on what you saw for the
 23 time period from which those particular 20
 24 cases came?
 25 DR. BANERJEE:

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1 A. That's correct.
 2 MR. SIMMONS:
 3 Q. And you've described for us how you were able
 4 to tell by looking at those cases that there
 5 were issues with the fixation of the tissue
 6 that had been used in the testing process that
 7 you were able to see when you reviewed those
 8 slides.
 9 DR. BANERJEE:
 10 A. That's correct.
 11 MR. SIMMONS:
 12 Q. So that tissue would have originated then at
 13 the time that the original tests were done in,
 14 largely in 2002 and if I understand correctly
 15 that same tissue was then used for the retests
 16 in 2005, that was your understanding as well?
 17 DR. BANERJEE:
 18 A. That is correct, yes.
 19 MR. SIMMONS:
 20 Q. And you also told us that aside from
 21 recognizing, from looking at the slides that
 22 there was issues with the fixation, you also
 23 determined that there was likely issues with
 24 the antigen retrieval and the optimization of
 25 the antibodies for the original tests done on

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1 the DAKO technology.
 2 DR. BANERJEE:
 3 A. That's correct.
 4 MR. SIMMONS:
 5 Q. And do I understand correctly that that was a
 6 conclusion you were able to make because there
 7 had been a change in test results when those
 8 same blocks were retested on the Ventana
 9 system?
 10 DR. BANERJEE:
 11 A. That's correct.
 12 MR. SIMMONS:
 13 Q. And so that was not--you couldn't look at a
 14 slide and say there was bad antigen retrieval
 15 here, you had to deduce that from the change
 16 in the results?
 17 DR. BANERJEE:
 18 A. Not entirely correct as a statement, because
 19 the fact that the internal control, benign
 20 epithelium of the breast were, the results
 21 were negative which would tell you that
 22 potentially two explanations or combinations,
 23 fixation, antigen retrieval or both.
 24 MR. SIMMONS:
 25 Q. Right.

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1 DR. BANERJEE:
 2 A. And when you switched platforms, it became
 3 clear that the staining protocol optimization
 4 was a significant factor because the Ventana
 5 machine could create a positive result and
 6 something was negative earlier on the other
 7 platform.
 8 MR. SIMMONS:
 9 Q. Would it be a fair inference to draw from your
 10 observations that either the antigen retrieval
 11 or the staining optimization or both in use
 12 when the tests were done on the Ventana, must
 13 have been improved or better in some way than
 14 the antigen retrieval and/or the staining that
 15 was used on the DAKO.
 16 DR. BANERJEE:
 17 A. Yes, yes, that's correct.
 18 MR. SIMMONS:
 19 Q. So we can conclude that whether it was the
 20 technology itself or the process that was used
 21 to implement and validate the newer system,
 22 something had made the test results better and
 23 more reliable?
 24 DR. BANERJEE:
 25 A. That's correct.

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1 MR. SIMMONS:
 2 Q. I believe you mentioned that there are
 3 different antigen retrieval methods that can
 4 be used and that are in use in semi-automated
 5 staining systems, like the DAKO autostainer
 6 that's in use in your lab?
 7 DR. BANERJEE:
 8 A. Yes.
 9 MR. SIMMONS:
 10 Q. And I believe you mentioned microwave heating
 11 in water or in liquids, I believe, we've heard
 12 that boiling the tissue or different
 13 varieties.
 14 DR. BANERJEE:
 15 A. Yes.
 16 MR. SIMMONS:
 17 Q. For that type of system, is there any single
 18 antigen retrieval method that's regarded as
 19 preferable or the best system to use?
 20 DR. BANERJEE:
 21 A. I think the microwave heating system has
 22 become a preferred technology, but there are
 23 still certain antigens that require enzymatic
 24 treatment, even if you're using the Ventana
 25 system. By the way, we have switched to

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1 Ventana not because it's a better system, but
 2 because for economic reasons and workflow
 3 redesign.
 4 MR. SIMMONS:
 5 Q. And we've heard as well that with the Ventana
 6 benchmark system, which is the one that's
 7 here, that the antigen retrieval is now done
 8 as part of the automated part of the process -
 9 DR. BANERJEE:
 10 A. That's correct.
 11 MR. SIMMONS:
 12 Q. Instead of being done separately as a manual
 13 step in the process.
 14 DR. BANERJEE:
 15 A. Yes, the variability has been removed in that
 16 process.
 17 MR. SIMMONS:
 18 Q. And that was going to be my next question, by
 19 automating it, that reduces the opportunity
 20 for variability in the performance of that
 21 step?
 22 DR. BANERJEE:
 23 A. That's correct.
 24 MR. SIMMONS:
 25 Q. You've told us about the different antibodies

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1 that have been used for ER testing, 1D5, 6F11
 2 and now SP1, over time have there been changes
 3 with the other reagents used in the test? As
 4 I understand there are buffers and in
 5 particular, there are what they referred to as
 6 detection kits, which are the chemicals used,
 7 I gather, to actually stain the antibodies and
 8 make them visible under the microscope?
 9 DR. BANERJEE:
 10 A. That's correct.
 11 MR. SIMMONS:
 12 Q. Have there been changes over time in the
 13 detection kits which may have enhanced the
 14 effectiveness of the testing?
 15 DR. BANERJEE:
 16 A. Oh definitely yes, major changes in the
 17 detection kits, they've become more sensitive,
 18 the background problem has been reduced, et
 19 cetera, so there's continuous improvement in
 20 that area.
 21 MR. SIMMONS:
 22 Q. You told us of your observations regarding the
 23 external control slides associated with the
 24 DAKO tests for those 20 cases that you
 25 reviewed and that you observed generally that

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1 you thought the intensity of the staining was
 2 weak, compared to what you would expect for a
 3 positive control?
 4 DR. BANERJEE:
 5 A. That's correct.
 6 MR. SIMMONS:
 7 Q. The slides that you looked at as part of those
 8 testing sets that have been run on the Ventana
 9 system, we know that at some point there was a
 10 step taken here which saw the control tissue
 11 being placed on the same slide as the patient
 12 tissue and I wonder if you observed any of
 13 those slides among the many cases that you
 14 did?
 15 DR. BANERJEE:
 16 A. Yes, I did.
 17 MR. SIMMONS:
 18 Q. And did you make any observations about the
 19 intensity of the staining of the positive
 20 controls on those slides that had been run
 21 using the Ventana system?
 22 DR. BANERJEE:
 23 A. Well on the Ventana system, clearly there was
 24 higher intensity of staining in the positive
 25 controls, as well as the test tissue.

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1 MR. SIMMONS:
 2 Q. Okay. Now you've commented on the idea of the
 3 reading of both external and internal controls
 4 by technologists and I believe you've told us
 5 that it's not a universal standard in Canada
 6 that technologists would read, read those
 7 controls?
 8 DR. BANERJEE:
 9 A. That is correct.
 10 MR. SIMMONS:
 11 Q. Where the technologists have received the
 12 training and acquired the knowledge and
 13 ability to be able to read those controls, I
 14 wonder can you tell me what effect that has
 15 then on the pathologist's responsibility in
 16 relation to both the internal and the external
 17 controls? Does it displace it or -
 18 DR. BANERJEE:
 19 A. No, it doesn't, it just--the pathologist is
 20 still ultimately responsible for signing out a
 21 particular case, so they have to accept their
 22 responsibility.
 23 MR. SIMMONS:
 24 Q. You've told us about how you would deal with a
 25 case where the internal control on an ER/PR

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1 test is negative and the tumour is negative
 2 and that that's one where it would be called
 3 into question and you would consider that a
 4 case where you could report a result?
 5 DR. BANERJEE:
 6 A. That's correct. We would report the case if
 7 there was no other tissue available to stain
 8 and there was--if there was tissue available
 9 and still was negative internal controls, we
 10 would issue a report that says this is
 11 uninterpretable, so no conclusions could be
 12 drawn, but you'd still have a report.
 13 MR. SIMMONS:
 14 Q. Yes, so in your laboratory with the level of
 15 optimization of staining and quality control
 16 that you have, do you still at times encounter
 17 cases where the internal controls do not
 18 stain?
 19 DR. BANERJEE:
 20 A. No.
 21 MR. SIMMONS:
 22 Q. No. Earlier this afternoon, when you were
 23 asked by Mr. Coffey some questions about what
 24 opportunities there might have been to have
 25 detected this issue with the ER/PR testing

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1 here earlier, one of the things you mentioned
 2 was the transition from the bioassay testing
 3 method to the IHC testing method. On your
 4 visits here, either first or second visit, did
 5 you do anything to investigate or determine
 6 what had been done here when that transition
 7 was made back in 1997?
 8 DR. BANERJEE:
 9 A. No.
 10 MR. SIMMONS:
 11 Q. You haven't seen any documentation or spoken
 12 to anyone about that?
 13 DR. BANERJEE:
 14 A. No documentation or correlation data, no.
 15 MR. SIMMONS:
 16 Q. So you don't know what kind of correlation was
 17 done?
 18 DR. BANERJEE:
 19 A. No.
 20 MR. SIMMONS:
 21 Q. My final question, you had made a
 22 recommendation regarding dedication of
 23 technologists to the IHC service so that they
 24 would not have other duties outside that, and
 25 you'd observed that there had been a rotation

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1 system in place here. In your experience with
 2 other laboratories that you've been involved
 3 with or know of, was that something that was
 4 unique to here or is it something that you
 5 find in other -
 6 DR. BANERJEE:
 7 A. No, it's a very common sort of process of
 8 rotation, cross-training people between
 9 different lab sections.
 10 MR. SIMMONS:
 11 Q. Yes.
 12 DR. BANERJEE:
 13 A. Which makes sense in certain lab sections, but
 14 this is an area that requires such detailed
 15 attention to the work that I think it's not a
 16 good idea.
 17 MR. SIMMONS:
 18 Q. Right. I believe you -
 19 DR. BANERJEE:
 20 A. But not everyone can achieve that, given the
 21 resources.
 22 MR. SIMMONS:
 23 Q. Right, and I believe you'd said this is a
 24 recommendation you would make to any lab, to
 25 achieve that?

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1 DR. BANERJEE:
 2 A. Yes.
 3 MR. SIMMONS:
 4 Q. Okay, good. Thank you very much. Those are
 5 all the questions I have.
 6 DR. BANERJEE:
 7 A. Thank you.
 8 THE COMMISSIONER:
 9 Q. Thank you, Mr. Simmons. Mr. Browne?
 10 MR. BROWNE:
 11 Q. Thank you, Commissioner. I have no questions
 12 for Dr. Banerjee. Thank you for your
 13 evidence, Dr. Banerjee.
 14 DR. BANERJEE:
 15 A. Thank you.
 16 THE COMMISSIONER:
 17 Q. Mr. Pritchett? Sorry, Mr. Eaton, you're here.
 18 EATON, Q.C.:
 19 Q. Don't sound so surprised. We have no
 20 questions.
 21 THE COMMISSIONER:
 22 Q. You are hiding behind Mr. Pike. That was what
 23 my problem was.
 24 EATON, Q.C.:
 25 Q. I'm glad I (unintelligible).

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1 THE COMMISSIONER:
 2 Q. Ms. Newbury?
 3 DR. DIPONKAR BANERJEE, EXAMINATION BY MS. JENNIFER
 4 NEWBURY
 5 MS. NEWBURY:
 6 Q. Good afternoon, Dr. Banerjee. My name is
 7 Jennifer Newbury and I represent the Canadian
 8 Cancer Society, Newfoundland and Labrador
 9 division, and I have just a couple of
 10 questions for you today. If we could bring up
 11 your report, P-0046, please, and turn to page
 12 five of the exhibit? Okay, recommendation
 13 number one, which I think is a bit lower
 14 there, you've indicated that "pathologists
 15 should subspecialize, if possible, covering
 16 two or more sites each with one designated
 17 leader for each major tumour site." And I'm
 18 wondering what your views are, if there are
 19 obstacles for a lab in implementing this,
 20 maybe on a temporary basis due to financial
 21 resources or pathologists are on leave, in
 22 that event, what are your views as to what the
 23 lab should do in terms of testing in a
 24 subspecialty area?
 25 DR. BANERJEE:

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1 A. I think obviously you can't do it overnight,
 2 shift from the generalist approach to
 3 subspecialization approach, so this requires
 4 planning and you have to work with the staff
 5 you have. If you have vacant positions, then
 6 you would recruit strategically into those
 7 positions. With the existing staff, you
 8 should have a plan to send individuals to very
 9 busy pure cancer pathology service to really
 10 bring them up to speed on and, you know,
 11 become comfortable with the content that is
 12 required in the reports for specific cancer
 13 types and you keep doing that until everyone
 14 has been trained and has one or two or even
 15 three different sites that they cover. You
 16 can't have one for each site because you need
 17 too many pathologists and of course, you have
 18 to cover the service when somebody is on
 19 vacation, etcetera. So there has to be cross
 20 coverage. So it takes time to build a system
 21 like that.
 22 MS. NEWBURY:
 23 Q. And once that's done, I guess, the concern is
 24 with problems that may be experienced with
 25 turnover of pathologists. Is the only option

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1 at that point for the lab to refer tests out
 2 to another laboratory?
 3 DR. BANERJEE:
 4 A. For--and this is what requires discussion with
 5 the oncology departments to set some
 6 priorities as to what types of cases need to
 7 be sent out to a reference lab or service and
 8 what could be handled in house, and you know,
 9 there's different levels of complexity so you
 10 can make that sort of judgment.
 11 MS. NEWBURY:
 12 Q. So it's something that you think should be
 13 thought out in advance?
 14 DR. BANERJEE:
 15 A. Yes.
 16 MS. NEWBURY:
 17 Q. To have a plan in place and how to deal with
 18 it, in the event that you have subspecialists
 19 on staff, but for some reason maybe -
 20 DR. BANERJEE:
 21 A. Yeah.
 22 MS. NEWBURY:
 23 Q. - not able to avail of their services for a
 24 particular period of time?
 25 DR. BANERJEE:

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1 A. Right. You sort of allow them to buy some
 2 time when they're getting into the strategic
 3 recruitment or expanding their program, they
 4 get funding and so on.

5 MS. NEWBURY:
 6 Q. Okay, and are there any circumstances, I
 7 guess, if other labs--you know, we hear from
 8 time to time that other labs are also
 9 operating at maximum capacity and if other
 10 labs are not able to respond quickly enough to
 11 the needs of a lab here, for example, who need
 12 some temporary services, is there a way that a
 13 general pathologist, general anatomic
 14 pathologist could safely sign out cases in a
 15 subspecialty area? Are there any extra
 16 mechanisms that could be in place, such as
 17 additional quality assurance or additional
 18 quality control to facilitate that?

19 DR. BANERJEE:
 20 A. Again, yes. The answer is yes, but it will
 21 take major effort in setting up the quality
 22 assurance processes to make sure inter
 23 observer variability is minimized, and since
 24 we know what the discrepancy rates are out
 25 there, it will be difficult to recommend that,

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1 that you just send it out to whoever is
 2 available. I think that would be a mistake.
 3 It's also true that across the country that
 4 capacity is saturated. So if, for instance,
 5 tomorrow you decided to send all the breast
 6 cancer cases to say the B.C. Cancer Agency, we
 7 would probably say no, because we can't handle
 8 any more work.

9 MS. NEWBURY:
 10 Q. Okay, and on page four of this report, it's
 11 actually four of the exhibit, under
 12 conclusions about the reasons for test
 13 failure, item number two, "Is the Ventana
 14 system too sensitive? There's no evidence
 15 that the Ventana system creates false positive
 16 results. However, the system still requires
 17 optimization to avoid non-specific cytoplasmic
 18 staining" and you've explained that in some
 19 detail this morning.

20 DR. BANERJEE:
 21 A. Um-hm.

22 MS. NEWBURY:
 23 Q. Did your review of slides, when you were here
 24 in October of 2005 and on your subsequent
 25 visit, did it include any positive test

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1 results or were they all negative?

2 DR. BANERJEE:
 3 A. No, they included samples that were positive,
 4 and in the first visit, we're comparing the
 5 two different platforms, so the same cases
 6 stained by the two different systems. So
 7 there were obviously those that had converted
 8 were definitely positive on the Ventana
 9 system. And the second visit, we essentially
 10 looked at the Ventana output, in terms of
 11 further optimization and they had done a very
 12 good job.

13 MS. NEWBURY:
 14 Q. So the test results that you looked at, they
 15 were all--were they all of the same category,
 16 initially ER negative -

17 DR. BANERJEE:
 18 A. Yes, that's right.

19 MS. NEWBURY:
 20 Q. - on DAKO and then converted to Ventana.

21 DR. BANERJEE:
 22 A. That's correct.

23 MS. NEWBURY:
 24 Q. Were any of the DAKO tested slides positive?

25 DR. BANERJEE:

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1 A. Oh yes, there were.

2 MS. NEWBURY:
 3 Q. Initially reported as positive?

4 DR. BANERJEE:
 5 A. Yes.

6 MS. NEWBURY:
 7 Q. You had a random sampling of both?

8 DR. BANERJEE:
 9 A. Yes, we had a random sample.

10 MS. NEWBURY:
 11 Q. Okay, and on either of the platforms for the
 12 slides that you looked at, and taking into
 13 account your observations, particularly with
 14 the Ventana there might have been some non-
 15 specific cytoplasmic staining, and also
 16 considering that there appears to have been no
 17 quality assurance in place at the time, do you
 18 have any concerns about the possibility of
 19 false positive results?

20 DR. BANERJEE:
 21 A. Not for estrogen receptors.

22 MS. NEWBURY:
 23 Q. And why is that?

24 DR. BANERJEE:
 25 A. It's highly unlikely. But for HER2, there's

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1 definitely risk of false positive stain.
 2 MS. NEWBURY:
 3 Q. And why would you not have any concern about
 4 false positive results, given the issue that
 5 you observed about the non-specific
 6 cytoplasmic staining?
 7 DR. BANERJEE:
 8 A. Because if you see the staining in the
 9 cytoplasm, you disregard that in your
 10 assessment. It has to be nuclear stain.
 11 MS. NEWBURY:
 12 Q. Okay. So in your view then, if the
 13 pathologist who reported various tests during
 14 the time period, either on the DAKO platform
 15 or the Ventana platform, was aware that you've
 16 got to be careful, you shouldn't interpret
 17 non-specific cytoplasmic staining to be a
 18 positive test, then you shouldn't have false
 19 positive results?
 20 DR. BANERJEE:
 21 A. That's correct.
 22 MS. NEWBURY:
 23 Q. What if that was not well known to the
 24 pathologists?
 25 DR. BANERJEE:

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1 A. I would be surprised if they didn't know that.
 2 MS. NEWBURY:
 3 Q. Okay.
 4 DR. BANERJEE:
 5 A. So it's more about optimization of the
 6 technique, as opposed to interpretation I was
 7 concerned about.
 8 MS. NEWBURY:
 9 Q. So your concern then, when you saw evidence of
 10 non-specific cytoplasmic staining, is that
 11 it's an indication that the test hasn't been
 12 optimized?
 13 DR. BANERJEE:
 14 A. Right.
 15 MS. NEWBURY:
 16 Q. As opposed to it being an indication that
 17 there might be false positive results?
 18 DR. BANERJEE:
 19 A. If there was a case, and I don't recall seeing
 20 such a case, that the nuclear staining
 21 intensity was the same as the cytoplasm, then
 22 I would definitely question that because then
 23 you don't know whether it's all non-specific
 24 staining.
 25 MS. NEWBURY:

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1 Q. Okay, right.
 2 DR. BANERJEE:
 3 A. It's the pattern of staining that's also
 4 important.
 5 MS. NEWBURY:
 6 Q. Okay, and there's nothing that caused you
 7 concern in the 20 slides, I guess, that you
 8 looked at?
 9 DR. BANERJEE:
 10 A. No.
 11 MS. NEWBURY:
 12 Q. About false positive results?
 13 DR. BANERJEE:
 14 A. No.
 15 MS. NEWBURY:
 16 Q. And to rule that out as a possibility, do you
 17 think that a larger review would be required
 18 of tests that had been initially reported as
 19 positive? Because you were focusing on those
 20 that had converted from negative to positive.
 21 DR. BANERJEE:
 22 A. Well, if they were reported as positive using
 23 the appropriate cutoffs, so anything that they
 24 were using maybe ten percent or 30 percent,
 25 would be in the upper range anyway, so in

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1 terms of the decision making about the
 2 individual patients that would have been
 3 appropriate, so I'm not concerned about that.
 4 I'm more concerned about the ones in the lower
 5 end of the scale that were called negative and
 6 didn't receive the therapy.
 7 MS. NEWBURY:
 8 Q. Right. In terms of the external quality
 9 programs, you've referenced this on page six
 10 of your report, page six of the exhibit. You
 11 said that "the laboratory should subscribe to
 12 external quality assurance programs, such as
 13 CAP or NEQAS, and should continue to monitor
 14 performance by interlaboratory comparisons
 15 with large--with appropriate large volume
 16 teaching hospital laboratories in Canada or
 17 the U.S." What do each of those three types
 18 of quality assurance programs, the CAP, the
 19 NEQAS and the interlaboratory comparisons,
 20 what do they assess and I guess, specifically,
 21 what do they each capture in terms of
 22 technical versus clinical skills or results,
 23 and in terms of pre-analytic, analytic and
 24 post analytic issues?
 25 DR. BANERJEE:

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1 A. Right. So the CAP is organized in that they
 2 will send out some unknown cases for the labs
 3 to stain and interpret, and then what they
 4 look at is the entire range of responses and
 5 see where the majority fell, and whether your
 6 lab was an outlier or not. So it's more like
 7 a consensus approach, as opposed to just
 8 saying that we're using one reference lab as
 9 the gold, you know, standard and then
 10 comparing everyone else against that. They
 11 don't do it that way.

12 MS. NEWBURY:
 13 Q. Right.

14 DR. BANERJEE:
 15 A. Now, the United Kingdom one is a bit of a
 16 hybrid in that they will do the same thing,
 17 but they actually look at your slides. So you
 18 have to submit your slides as well.

19 MS. NEWBURY:
 20 Q. Yes.

21 DR. BANERJEE:
 22 A. And also, they have, I think they have six
 23 teaching hospital labs that are their
 24 reference labs. So those are kind of the gold
 25 standard for them. So it's a different

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1 process, so that's why I think both have some
 2 value, but they're not equal. In terms of
 3 interlab comparisons, it's a sort of good
 4 habit for technologists and pathologists to
 5 get into, particularly when they're
 6 establishing a new assay with a new antibody,
 7 just to make sure that it's functioning as
 8 expected, to have another lab get additional
 9 slides from you from the same case and do
 10 their stain on that, and then you compare the
 11 two.

12 MS. NEWBURY:
 13 Q. Okay, and so that, what you've described, it
 14 would be good practice for technologists and
 15 pathologists, how long has that been
 16 something, a technique utilized by labs, by
 17 pathologists and technologists?

18 DR. BANERJEE:
 19 A. Some labs, it's always been done from the very
 20 beginning. Others, don't do it. It's not
 21 mandated by anyone, so it's really a voluntary
 22 thing.

23 MS. NEWBURY:
 24 Q. Okay, and are there any guidelines in terms of
 25 percentages? For example, if you're going to

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1 do interlaboratory lab comparisons on an
 2 ongoing basis versus if you're doing it at the
 3 time that you're implementing a new assay?
 4 For example, are there any percentages of
 5 tests that you might send out for comparison
 6 at those two different stages?

7 DR. BANERJEE:
 8 A. When you're first establishing a new assay,
 9 you should send every slide and additional
 10 slides for the other lab to stain and then
 11 look at both sets, and it's more for fine
 12 tuning. So if you're, you know, missing
 13 something or over staining, not staining
 14 issues, it would correct it. That's
 15 important. And also, if you were being
 16 reviewed because there was a central review
 17 process like we have in British Columbia, then
 18 all of that is automatically part of the
 19 review process, you look at the
 20 immunohistochemistry preparations. But in a
 21 situation like this when you are the reference
 22 centre in the province, then I think you have
 23 to look for some external reference point as
 24 well, because if you do everything just
 25 internally, your benchmark may be drifting and

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1 you wouldn't even know about it.

2 MS. NEWBURY:
 3 Q. Right. So on an annual basis even though
 4 you're not doing anything new in that
 5 particular year, you would still send out a
 6 certain percentage -

7 DR. BANERJEE:
 8 A. I think it's a good idea.

9 MS. NEWBURY:
 10 Q. And is there a figure that you would have, you
 11 know, is it two percent or ten percent?

12 DR. BANERJEE:
 13 A. No, I don't. But, you know, normally, you
 14 know, in audit systems they look at a ten
 15 percent retesting or review. In the United
 16 States they may be more specific sort of
 17 percentages that they would use. We don't
 18 have that in Canada, but I would say about ten
 19 percent random.

20 MS. NEWBURY:
 21 Q. Ten percent random audit?

22 DR. BANERJEE:
 23 A. Um-hm.

24 MS. NEWBURY:
 25 Q. And 100 percent when you're setting up a new

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1 procedure?
 2 DR. BANERJEE:
 3 A. That's right.
 4 MS. NEWBURY:
 5 Q. And again, back to the CAP and the NEQAS, do
 6 they both capture but the technical and the
 7 clinical aspects of testing, laboratory
 8 testing?
 9 DR. BANERJEE:
 10 A. I think CAP is they look at the end result.
 11 MS. NEWBURY:
 12 Q. Okay.
 13 DR. BANERJEE:
 14 A. So what are you saying, is the report.
 15 Whereas NEQAS actually needs your slides and
 16 they will look at it -
 17 MS. NEWBURY:
 18 Q. So they can more -
 19 DR. BANERJEE:
 20 A. - and evaluate it.
 21 MS. NEWBURY:
 22 Q. - likely get into the technical issues -
 23 DR. BANERJEE:
 24 A. Technical as well as the professional
 25 interpretation.

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1 MS. NEWBURY:
 2 Q. And the CAP is more the professional
 3 interpretation?
 4 DR. BANERJEE:
 5 A. That's right.
 6 MS. NEWBURY:
 7 Q. Now, on page 3 of your report there's a
 8 reference there to the incident problem case
 9 and I won't read through that again. But
 10 you'd indicated that it, that the incident
 11 case was invasive lobular carcinoma?
 12 DR. BANERJEE:
 13 A. Um-hm.
 14 MS. NEWBURY:
 15 Q. Which are frequently ER positive and the
 16 initial negative result should have been
 17 questioned. And you've indicated this
 18 morning, I believe, that both oncologists and
 19 pathologists probably ought have been alerted
 20 to this. Are there any basic programs for
 21 monitoring these types of trends that should
 22 be in place to look at, you know, what are we
 23 producing and does it match up with what we
 24 might expect in terms of the patient
 25 population? And perhaps you can give us an

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1 example by -
 2 DR. BANERJEE:
 3 A. No, I don't think there is such a process.
 4 And one could argue that in particular
 5 situations when we have perhaps less genetic
 6 variation of the population, you know, like
 7 small island populations, that you might see a
 8 difference skew. But I am not aware of such
 9 studies that have shown that there's some
 10 natural sort of difference in protein
 11 expression for estrogen receptors.
 12 MS. NEWBURY:
 13 Q. I guess -
 14 DR. BANERJEE:
 15 A. Population based.
 16 MS. NEWBURY:
 17 Q. I guess the question is there you've got a
 18 patient that's determined to be ER negative
 19 but the patient has invasive lobular
 20 carcinoma, so I guess there's still a chance,
 21 based on your statistics, that that's an
 22 accurate result for the patient because 92
 23 percent are positive, but eight percent are
 24 negative?
 25 DR. BANERJEE:

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1 A. Right. I think that the publication I've
 2 quoted has that number, but I would suspect
 3 that the eight percent that were negative were
 4 related to some technical issues.
 5 MS. NEWBURY:
 6 Q. Okay. So they might, in fact -
 7 DR. BANERJEE:
 8 A. It's not a true negative.
 9 MS. NEWBURY:
 10 Q. - truly have been positive?
 11 DR. BANERJEE:
 12 A. That's right.
 13 MS. NEWBURY:
 14 Q. Okay. And I think you've said earlier that
 15 from a clinical perspective it's 100 percent?
 16 DR. BANERJEE:
 17 A. We always see every case positive.
 18 MS. NEWBURY:
 19 Q. Okay. Are there any other types of cancers
 20 that might not be as strongly expected to be
 21 positive where keeping a look at what's being
 22 produced in your lab either by the oncologists
 23 or the pathologists or perhaps a cancer
 24 registry might be appropriate?
 25 DR. BANERJEE:

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1 A. Yeah, it would be hard to detect those
 2 patterns unless you deliberately sort of
 3 retrospectively reviewed, at the end of the
 4 year, what you've got and what is to be
 5 expected and so on.
 6 MS. NEWBURY:
 7 Q. And does the BC Cancer Agency have any sort of
 8 program in place where they -
 9 DR. BANERJEE:
 10 A. Not on an annual basis but once the question
 11 comes up, we do review that and we certainly
 12 keep an eye on the positivity rates and where
 13 it is and what's in the literature as an
 14 expected rate and so on. In some research
 15 protocols, like the papers published by Dr.
 16 Huntsman (phonetic), they've gone back and
 17 looked at 4000 patients and, you know, the
 18 immunohistochemistry procedures seem to
 19 correlate extremely well with the biochemical
 20 data, so we're very happy with that.
 21 MS. NEWBURY:
 22 Q. And that's more for research purposes or is
 23 that -
 24 DR. BANERJEE:
 25 A. Yes.

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1 MS. NEWBURY:
 2 Q. Yes, okay. Thank you very much, Dr. Banerjee.
 3 DR. BANERJEE:
 4 A. Thank you.
 5 MS. NEWBURY:
 6 Q. Those are my questions.
 7 COMMISSIONER:
 8 Q. Thank you. Yes, no questions, Ms. Russell?
 9 Mr. Pike?
 10 MR. PIKE:
 11 Q. No questions, thank you.
 12 COMMISSIONER:
 13 Q. Mr. Clark?
 14 MR. CLARK:
 15 Q. No questions.
 16 COMMISSIONER:
 17 Q. Anything arising, Mr. Coffey?
 18 COFFEY, Q.C.:
 19 Q. No, Commissioner.
 20 DR. DIPONKAR BANERJEE, EXAMINATION BY MADAM COMMISSIONER
 21 COMMISSIONER:
 22 Q. Dr. Banerjee, I have one or two small things.
 23 DR. BANERJEE:
 24 A. Certainly.
 25 COMMISSIONER:

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1 Q. If you, you might be able to help me with.
 2 And I think most of them you've addressed.
 3 But when you were discussing the role of the
 4 Royal College in standards and a role which
 5 your organization has, if you will, tried to
 6 assume, is it in your view the role of, the
 7 appropriate role for the Royal College and
 8 your organization has come in because there
 9 has been a vacuum or do you think that really
 10 is the role for the Canadian Association for
 11 Pathologists, it's the proper place for it to
 12 lie?
 13 DR. BANERJEE:
 14 A. Right. First of all, the Canadian Association
 15 of Pathologists is a voluntary organization.
 16 Pathologists are not obliged to be members.
 17 COMMISSIONER:
 18 Q. Um-hm.
 19 DR. BANERJEE:
 20 A. It's designed to provide some kind of annual
 21 educational experience for pathologists. It
 22 has not had the mandate to set policies,
 23 however it does set guidelines of practice.
 24 Over the years we have discussed and
 25 threatened to create our own college, royal

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1 college of pathologists, but that's a daunting
 2 task for most pathologists because it's a
 3 significant effort required given our fairly
 4 small membership, there won't be enough
 5 resources to do that. So one of our visiting
 6 professors from Australia was a member of the
 7 Royal College of Australia's accrediting
 8 process and I asked him how, they being the
 9 same kind of size population as Canada, how
 10 did they afford to have their own college of
 11 pathology, and he basically said all of the
 12 revenue that is generated from quality
 13 assurance and accreditation, on-site
 14 inspections is what drives the Royal College
 15 there. So it is possible to generate enough
 16 revenue to actually create a system whereby
 17 the Canadian Association of Pathologists could
 18 create their own royal college, but I think
 19 the energy levels amongst the profession right
 20 now are so low that they will probably not be
 21 galvanized into creating that process, so we
 22 are looking at alternatives. I think the
 23 Royal College has not responded to the
 24 pathology issues very well in the past and
 25 have not currently understood what needs to

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1 happen, so I'm not confident that they will
 2 take up this challenge and do something of
 3 value added. So we are stuck with either
 4 getting our Canadian Association of Pathology
 5 to another level of activity and require some
 6 kind of, some kind of authority to be the
 7 national body for quality assurance for
 8 laboratories and that's going to be a major
 9 battle. I mean, where is the money going to
 10 come from, who's responsible? If we look at
 11 how health care is delivered in the country,
 12 it's largely a provincial jurisdiction. There
 13 isn't really a national body that looks at
 14 funding health care activities in an organized
 15 sense. So we have some challenges because of
 16 the structure of how health care is provided
 17 in this country, how labs are funded in this
 18 country and how quality assurance activities
 19 are recognized by hospital administrators as
 20 important activities and therefore should be
 21 funded appropriately. Those are all of the
 22 challenges we are facing, so I'm not sure what
 23 the final answer is going to be. But I was
 24 hoping that the other societies that are
 25 involved in cancer patient care would see that

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1 this is a significant issue for them to
 2 address, as well, because, after all, they are
 3 dependent on what pathologists say for the
 4 individual patient in order to make a
 5 treatment decision, so if we are not doing a
 6 good job, then they are not doing a good job
 7 by default. And so have they truly understood
 8 that? And I'll take this moment to actually
 9 talk about something else that I feel very
 10 strongly about. There have been two major
 11 studies of the health care system in Canada,
 12 that was the Romano Report and the Kirby
 13 Report. I happened to read through those
 14 reports in great detail and did a word search
 15 for the word "pathology" in the two reports.
 16 In the Romano Report there was not a single
 17 hit; in the Kirby Report there were six hits,
 18 they're all related to speech pathology. Not
 19 a single word about labs in either document.
 20 So we are invisible to politicians, we are
 21 invisible to hospital administrators and we
 22 are invisible to the public until there's a
 23 scandal.
 24 COMMISSIONER:
 25 Q. To go back to the reality of your profession

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1 in rural areas and to bring it down to the
 2 level of ER and PR, one thing that's kind of
 3 puzzled me along the way is whether or not
 4 there is a place whereby a pathologist will
 5 see so little of a particular type of IHC
 6 test, in particular, that he or she should
 7 just not be doing it.
 8 DR. BANERJEE:
 9 A. I do believe that to be true. If you're
 10 asking me whether I can come up with a number,
 11 that is not possible. But I would say that
 12 there's no need for immunohistochemistry to be
 13 provided at every hospital because, number
 14 one, the turn around time requirements is such
 15 that it could easily be sent to a central lab
 16 within any province, secondly, you need that
 17 critical mass of not only pathologists who can
 18 interpret correctly, you need the
 19 technologists to understand how to
 20 troubleshoot this whole procedure, and in a
 21 small hospital lab that is not going to be
 22 possible. They'll have very limited menus,
 23 they won't have the experience to judge
 24 whether this is -
 25 COMMISSIONER:

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1 Q. Well what happened in our province was that
 2 they would be sent to a central location for
 3 the purpose of processing and then sent back
 4 to a rural location for reading and -
 5
 6
 7 DR. BANERJEE:
 8 A. Reading the slides?
 9 THE COMMISSIONER:
 10 Q. Reading the slides by the local pathologist
 11 who might see one or two a month.
 12 DR. BANERJEE:
 13 A. So, even the immunohistochemistry slides were
 14 being sent -
 15 THE COMMISSIONER:
 16 Q. ER/PR.
 17 DR. BANERJEE:
 18 A. Oh, I think that's inappropriate. It should
 19 be read at the lab that's doing the staining
 20 because they know what to look for. They
 21 should be able to troubleshoot.
 22 THE COMMISSIONER:
 23 Q. Okay. And then there's one final thing, in
 24 your report, you referred to the business of
 25 the reporting nature within the lab.

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1 DR. BANERJEE:
 2 A. Yes.
 3 THE COMMISSIONER:
 4 Q. And in our case, really the two divisions the
 5 lab did not meet until they got to the level
 6 of Dr. Williams, who, as you said today, that
 7 effectively made him the lab manager.
 8 DR. BANERJEE:
 9 A. Lab director.
 10 THE COMMISSIONER:
 11 Q. Lab director, thank you. So, do I assume your
 12 concern is that the place where these, if we
 13 do have this dual system, the place where they
 14 meet would be at a level where the person is a
 15 pathologist because the pathologist
 16 understands the working of the lab.
 17 DR. BANERJEE:
 18 A. That is correct.
 19 THE COMMISSIONER:
 20 Q. That's the basic principle.
 21 DR. BANERJEE:
 22 A. Yes, and that pathologist can report to the
 23 vice president.
 24 THE COMMISSIONER:
 25 Q. Because if you just leave it to the vice

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1 president level, the decisions are made by
 2 people who are really divorced from labs
 3 themselves.
 4 DR. BANERJEE:
 5 A. That's correct.
 6 THE COMMISSIONER:
 7 Q. And the many technical things that go on in
 8 labs that other physicians have come here and
 9 said they didn't really quite necessarily
 10 understand what was going on in the lab. It
 11 was that mystery behind the door that they
 12 were willing to leave to those who could go in
 13 -
 14 DR. BANERJEE:
 15 A. Well, having said that I would also have to
 16 say that that's not a unique situation. This
 17 is a model that's evolved across the country,
 18 dual management, separation of management from
 19 the medical staff. I personally think it's
 20 the wrong one, but I'm a minority as far as
 21 saying that publicly, I guess.
 22 THE COMMISSIONER:
 23 Q. Well, my thought process is whether it's that
 24 restructure that's required or whether it is
 25 the kind of relationship that's been developed

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1 with either model where due respect is given
 2 to the reviews of the other group or do you
 3 feel that it's just necessary that the final--
 4 if it comes to that point where a consensus
 5 could not be achieved and somebody has to make
 6 a recommendation within the system -
 7 DR. BANERJEE:
 8 A. That's exactly right.
 9 THE COMMISSIONER:
 10 Q. - it should be a pathologist.
 11 DR. BANERJEE:
 12 A. The structure should be independent of the
 13 personalities. So, if you have a have dual
 14 management model where the lab director and
 15 the program or lab manager gets along very
 16 well, then it works. But if they don't get
 17 along very well, the structure doesn't help
 18 the situation because when things go wrong,
 19 nobody is actually accountable because they'll
 20 say, well, it wasn't my problem; it was that
 21 person's problem.
 22 THE COMMISSIONER:
 23 Q. Okay. Well, thank you very much.
 24 DR. BANERJEE:
 25 A. Thank you.

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1 THE COMMISSIONER:
 2 Q. For me, I must tell you, it's been a really
 3 interesting day which I've enjoyed very much.
 4 DR. BANERJEE:
 5 A. Thank you very much, I really appreciate the
 6 comment.
 7 THE COMMISSIONER:
 8 Q. Thank you all. I'll see you at 9:30 in the
 9 morning. Oh, I think you've already been
 10 delivered of envelopes. If you haven't gotten
 11 one, there is one available for you. Thank
 12 you.
 13 Upon conclusion.

1
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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 30th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 30th day of July, A.D., 2008

Judy Moss

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