IN THE MATTER OF the Commission of Inquiry on Hormone Receptor Testing established under s. 3 of the *Public Inquiries Act, 2006* by Order dated July 3, 2007

SUBMISSION ON BEHALF OF THE MEMBERS OF THE BREAST CANCER TESTING CLASS ACTION

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Overview

1. The Members submit that there are four principal "sentinel" events which have given rise to this Inquiry:

    (i) the start up of ER/PR testing in 1997;

    (ii) the Ejeckam intervention;

    (iii) the index case; and,

    (iv) how middle and senior management dealt with information that affected patient care.

2. ER/PR testing began at Eastern Health in 1997. Those responsible for the technological side of the test were Terry Gulliver, the manager of the Histology lab, and the two technologists Mary Butler and Peggy Welsh, who actually performed the procedure. From the clinical side, the site chief Dr. Mahmoud Khalifa instigated the start up of ER/PR testing with the blessing of the pathologists at the General Hospital and the members of the Managers and Site Chiefs Committee. Dr. Khalifa provided no technical instruction in the performance of the test. Mr. Gulliver denies having anything to do with setting up the ER/PR testing, so Ms. Butler and Ms. Welsh were left to their own devices to adapt the Peroxidase Anti-Peroxidase (PAP) procedure they had been using in IHC, since the mid 80's for over 70 other antigens. The new ER/PR procedure called for antigen retrieval by a heat method and validation of the antibodies for ER and PR.

3. Six years later in early 2003 Dr. Gershon Ejeckam, one of the staff pathologists at the General Hospital and the only one with extensive experience in IHC, shut down IHC procedures for 8 antigens including ER/PR because of "erratic" and "unreliable"

staining.[1] Those responsible for responding to this alarm were the lab manager Mr. Barry Dyer, the site chief Dr. S. Parai, and the clinical chief Dr. D. Cook. Indirectly, the program director Mr. Terry Gulliver was responsible for the overall operations of the pathology lab on the technical side. Nobody in authority did anything to investigate Dr. Ejeckam's concerns. In any event, Dr. Ejeckam over the next month validated the antigen retrieval method and validation the antibodies with the technologists. Dr. Ejeckam reinstated the ER/PR procedure on May 2, 2003.[2]

4. Two years later in the spring of 2005, the index case was uncovered. Peggy Deane, a patient who had tested negative for ER in 2000, was retested on the new Ventana platform and found to be positive for ER. Several others were retested and also found to have converted from negative to positive. It was decided to retest all negative cases performed in 2000 in-house (St. Clare's and General. No records were kept on out-of-town results). On retesting a false negative rate of 67% was found on 38/57 samples. This set off alarm bells all the way up to the Vice President of Medical Affairs Dr. Williams. It was thought the new Ventana platform was over-reading the cases. This was proved not to be the case when the manufacturer of Ventana did an inspection and declared the machine functioning perfectly. Finally it was decided to shut down ER/PR testing as of August 2005. All current cases were referred out to Mount Sinai for consultation. Eventually, Mount Sinai was asked to review all negative ER cases from 1997 to August 2005 in a retrospective study adjusted for cut point.

[1] P-0113, p. 1
[2] P-0113, p. 2

5. While the powers to be were waiting for the results from Mount Sinai, risk management and quality assurance groups went to work to look into what happened, and the enormity of the problem became apparent. No quality assurance. No paper trail or documentation. The public relations group were trying to contain the problem and stall public statements until the facts were known. Then The Independent broke the story on October 2, 2005.[3] In the meantime, two external consultants issued "fairly damning" reports in the fall of 2005 showing the pathology lab, in general, was poorly organized and lacked the rudiments of quality assurance and documentation. Dr. Cook, the clinical chief, characterized the lab's performance as that of a Community hospital rather than that of an Academic Teaching Centre.[4] The recrimination and finger pointing started. Disclosure became a hot topic, although an ethics consult was not sought until mid 2006. Answers to inquiries from the Department of Health were softened. Information was withheld from patients and the public. The Commission heard from a parade of witnesses in middle management, quality assurance experts, deputy ministers of health, ministers of health, and even Premier Williams. Who knew what and when, became the issue. All this is irrelevant as to the cause and effect on patient care except the publicity caused a great deal of anxiety in the patients and relatives of breast cancer survivors and deceased.

6. We will address the Terms of Reference.

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[3] P-0086
[4] Evidence of Dr. Cook, July 7, 2008, p. 303, lines 1-11

(a) *inquire into why the estrogen and progesterone hormone receptor tests done between 1997 and 2005 in the Newfoundland and Labrador health system resulted in a high rate of conversions when re-tested;*

7. ER/PR testing was performed exclusively at the General Hospital (later on known as the Health Care Corporation and currently Eastern Health). The lab performing ER/PR testing was the histology section in the Anatomical Pathology Division of Laboratory Medicine, and was the reference centre for ER/PR testing and in fact the only laboratory performing immunohistochemistry assay for over 100 other tumor antigens in Newfoundland.

8. So as to avoid repetition of facts, a brief history of the Immunohistochemistry (IHC) lab at the General Hospital is in order.

9. Dr. Wong, the Chair of Pathology at MUN Medical School, started IHC procedures in the early 80's and taught Mr. Terry Gulliver, who had joined the Histology lab in 1980, how to perform IHC procedures starting with only a few antigens. Peggy Welsh, another technologist at the time (joined the lab in 1977), was taught the procedure by Mr. Gulliver, and when Mr. Gulliver was made supervisor of the lab in 1989, Peggy Welsh took over the procedures in IHC. Mary Butler, who joined the Histology lab in 1970 as a lab assistant, wrote her R.T. in histology in 1981. In 1988 she was taught IHC procedures by Peggy Welsh. By 1997 the number of antigens had grown to 70. So by 1997, Mary Butler and Peggy Welsh were experienced technologists in the performance of IHC procedures. The procedure they had started in the early 80's was the Peroxidase

Anti-Peroxidase (PAP) method and was still used up to the time of the changeover to the Ventana system in April 2004. The antibody they were using for estrogen receptors was ID5. Both the PAP method and ID5 are still used by labs across North America today.

10. In 1997 Dr. Khalifa first introduced or requested the lab to set up ER/PR testing using the monoclonal ER antibody 1D5 and for PR the IA6 antibody.[5] The antigen retrieval method used in the PAP procedure was Trypsin a proteolytic enzyme which essentially reverses formalin fixation. Trypsin works well with many surface antigens but not so well on nuclear antigens where they are well hidden in the cell. Antigen retrieval for ER/PR testing has always been a problem for ER/PR testing by IHC methods using paraffin sections until Shi published a landmark paper in 1991 proposing the use of controlled heat in a microwave oven. In the ensuing years other authors proposed heat sources from rice steamers, pressure cookers, autoclaves and water baths. It had been clearly established by the mid 90's that with careful attention to heat control and time of exposure of the tissue in a controlled pH environment that antigen retrieval of nuclear antigens were greatly enhanced. ER/PR are nuclear antigens[6].

11. Antigen retrieval has been identified by Allred as the single biggest contributor to false negatives in the IHC assay for ER/PR.[7] This opinion is also echoed by Rhodes in their

[5] P-1852, p. 5
[6] P-1568, p. 3, para. 3.
[7] P-0526, p. 3, para. 2

study of the frequency of estrogen and progesterone positivity in 7016 cases of breast carcinomas.[8] Also, Dr. Banerjee in his review of October 17, 2005 identified as one of the principle causes of false negatives, the antigen retrieval procedure.[9]

12. When ER/PR testing was first introduced in 1997, the PAP method had to be modified with the addition of antigen retrieval (A.R.) by a heat method. Mary Butler and Peggy Welsh were running the IHC lab, alternating on a weekly basis. It is not clear who gave them the antigen retrieval procedure, but both technologists said they followed the "manufacturer's (Dako) specs".[10] According to Peggy Welsh, they received no instruction, just followed the inserts (manufacturer's spec sheet).[11]

13. However this is not good enough, to blindly follow the manufacturer's specs. Just like the antibodies where you have to titrate the optimal concentration that give you crisp staining on the external positive control, you have to see what is the best exposure time to whatever heat source you are using that gives you crisp staining on the external positive control. We have reviewed the transcripts of Mary Butler, Peggy Welsh, Ken Green and Les Simms, the technologists who actually performed the ER/PR testing, and nowhere in the transcripts is there any reference to performing this refinement until Dr. Ejeckam intervened in 2003 (to be discussed further on in this brief).

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[8] P-1851, p. 9, second last para.
[9] P-0046, p. 4, Conclusions, item 1, line 3
[10] P-3050, p. 2, item (c)
[11] Evidence of Peggy Welsh, July 8, 2008, p. 137, lines 3-7

14. Basically a kitchen pot was placed on a hotplate and water brought to a boil. A Coplin jar with antigen retrieval solution was placed in the boiling water and when the antigen retrieval solution reached 90-95°C, a tray of slides with patient sections and controls were placed in the retrieval solution and intubated for 30 minutes. The temperature of the retrieval solution was controlled by a thermometer. This rather crude method was used during 1997-1998 and changed to a water bath method in October 1999.[12] This gave the user better control of heat. This method continued on up until the installation of the Ventana platform in April 2004. The Ventana platform performs antigen retrieval and eliminates the manual method completely.

15. The Predham statistics disclose that the false negative rate was 44% before the Ventana system was installed and then the false negative rate dropped to .05%.[13] This conforms with the opinions of Allred and Rhodes in separate articles that the root cause of a high conversion rate is likely to be poor antigen retrieval.[14]

16. The next most likely cause for the high conversion rate in the opinion of Allred, Rhodes and Banerjee is the choice of antibody and obtaining the best concentration of that antibody that gives crisp staining in a known positive control and no staining in a negative control. The procedure is outlined for the PAP method by Dabbs.[15] It is a complicated procedure but critical to the performance of IHC. If the concentration is too low, the process will miss the low expressers. If the concentration is too high, you will

[12] Evidence of Peggy Welsh, July 8, 2008, p. 137, lines 6-17
[13] P-1841
[14] P-0526, p. 3, para. 2 & P-1851, p.9
[15] P-1569, p. 3, Table I-3.

get over-staining of the tumor cells and non-specific staining of the other normal tissues, which will lead to a false positive interpretation by the pathologist.

17. In 2003 Dr. Ejeckam stressed the importance of allowing technologists practice time to hone their skills for antibody titration.[16]

18. According to the Gulliver summary[17], from the beginning of 1997 through to November 1997, an ER/PR kit system was used. The antibodies were pre-diluted and did not need validation (Chaytor quote from P-2150).[18] After that time, Peggy Welsh and Mary Butler did their own validation at different dilutions against a known positive control as per the spec sheets. A pathologist would read the controls and select the appropriate dilution giving the best result. Initially Dr. Khalifa read the positive external controls and the controls for validation of a new batch of ER and PR antibodies. When he left in June of 1999, the technicians chose any pathologist available, or Dr. Parai, the site chief (see Figure 1 below). Essentially for 39 months there was no direct oversight of IHC by a pathologist.

[16] P-0113, p. 6
[17] P-2150, p. 1
[18] Evidence of Peggy Welsh, July 8, 2008, p. 126, line 6

Figure 1

	1997	1998	1999	2000	2001	2002	2003	2004	2005
								Dako	Ventana
Clinical Chief	Dr. David Haegert ('91 – Oct 2002)				Acting and then Clinical Chief Dr. Donald Cook → 2005 (1986 – Present)				
Site Chief	Dr. M. Khalifa (1995 – June 1999)		Dr. P. Wadden Acting (1998-Present)		Dr. S. Parai → March 2005 (1993 – 2008)				
Manager	Terry Gulliver (1987 – Oct 2001)					Barry Dyer October 2001 – Present			
Lab Techs	Mary Butler, Peggy Walsh, Ken Green, Les Simms (started March 2003)								
Direct Pathology Oversight	Dr. M. Khalifa		No direct oversight (39 months)				Dr. G. Ejeckam September '02 - 2006		

19. Several other areas as a cause for the high rate of conversion were put forward by the various experts giving evidence at the Inquiry. Dabbs opined that any breach in technique in the pre-analytic phase can cause degradation of receptors which include delay in fixation, under-fixation or over-fixation, tissue processing and paraffinization. The fixation issue seems to be the most prominent cause of false negatives after antigen retrieval and antibody titrations. Undoubtedly fixation issues did contribute to some of the false negatives. If the tissue is not fixed optimally (8-24 hours) then no matter how well the analytical phase of the IHC procedure is performed, there will be a negative result.[19] If one looks at the Predham performance data as summarized at P-1841, there were 884 ER negative cases reported from 1997 to July 31, 2005. Of these, 372 were false negative on retesting and 512 confirmed negative by Mount Sinai. Therefore, if one advances the theory that poor fixation is a cause of false negatives then an unknown percentage of the confirmed negatives are in fact false negatives. The actual false

[19] P-0046, p. 4

negative rate is higher than the retesting results are capable of revealing. As Dr. Banerjee opined "no amount of antigen retrieval would have any effect if the protein (ER/PR) has been completely lost during processing."[20]

20. We submit a significant cause of the high rate of conversion was the substandard performance of ER/PR testing at Eastern Health.

21. There were four persons directly involved in the performance of the ER/PR testing. On the technical side, Mr. Terry Gulliver, the lab manager, and the two senior technologists Mary Butler and Peggy Welsh, and on the clinical side, Dr. Mahmoud Khalifa.

Mr. Terry Gulliver

22. Mr. Gulliver graduated from trade school with an R.T. in 1979 and joined the staff of the Histology lab at the General Hospital in 1980. He learned IHC procedures from Dr. Wong, the university chair, and was appointed as supervisor of Histology in 1989 (later called manager). He taught Peggy Welsh IHC procedures. Peggy had been a histology tech since 1977. She in turn taught Mary Butler IHC procedures. By 1997 when ER/PR testing was introduced, he admits he did not have the technical skills to go back to the bench and do IHC testing.[21] He was aware that the PAP procedure had to be modified for antigen retrieval but denies having anything to do with setting up ER/PR testing. He

[20] P-0046, p. 4
[21] Evidence of Terry Gulliver, October 3, 2008, p. 57, lines 16-20

relied on Mary Butler and Peggy Welsh to perform the tests under the guidance of Dr. Khalifa.[22]

23. When questioned by Ms. Chaytor on his role as manager in overseeing the staff and quality of the stain – What role did you play? Mr. Gulliver replied that he relied on feedback from the end-user of the service, the pathologists. Dr. Dabbs testified that this is another good layer of quality assurance. In his laboratory all repeat testing reprocessing or complaints are documented and reviewed monthly. When they reach 2% of total tests, then there is an investigation.[23] Unfortunately, as in many areas of the lab, there was no such documentation and really nothing to review. The overall impression is that the complaint is ignored and if there is no second complaint, there is an assumption made that the first complaint had been solved (i.e. the Khalifa "sensitivity" memo and the Ejeckam memo).

24. There was a serious complaint from the Dr. G. B. Cross Hospital in Clarenville (Peninsula Hospital) which did not receive due attention until it was decided to retest all negative ER receptors from 1997 to 2005.[24] In 1999, they moved their ER/PR testing to Mount Sinai because of the poor quality and lack of controls, and they were paying for the service. [25]

[22] Evidence of Terry Gulliver, October 3, 2008, p. 159, lines 22-25 & p. 160, lines 1-8
[23] Evidence of Dr. Dabbs, September 16, 2008, p. 206, lines 21-25 & p. 207, lines 1-18
[24] P-1604
[25] P-2141, p. 1

25. In Exhibit P-3100 the Mount Sinai statistics from 1999 to 2005 for the Peninsula Hospital (Dr. G. B. Cross Hospital in Clarenville) show a 78.3% ER positivity compared to 63% at the General Hospital lab for the same time period. As you know Commissioner, Mount Sinai were using the Dako machine, the 6F11 ER antibody (comparable to ID5) and a pressure cooker for antigen retrieval.

26. It would be fair to say that Mr. Gulliver, as manager of the Histology lab in 1997, had limited knowledge or insight regarding ER/PR testing, either in the technological performance of the test or its clinical prognostic significance. All these points were made in a letter to Mr. Gulliver from Dr. Khalifa on February 27, 1997.[26] When asked if he received this letter, he replied "I can't say that I did not. I can't say that I did." [27]. Ms. Chaytor took him through the letter anyway. He admitted he did not know the "delicacy" of the test. He knew it was a new test and that antigen retrieval was being used for the first time. He did not know the clinical significance of the test. He delegated the performance of the test to his two senior technicians Mary Butler and Peggy Welsh. The above is a summary of Mr. Gulliver's evidence from October 3, 2008, pages 160-175. When Mr. Gulliver was asked a simple question that could be answered by a simple yes or no, he leaned to prolix.

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[26] P-1889
[27] Evidence of Terry Gulliver, October 3, 2008, p. 161, lines 10-11.

Dr. Mahmoud Khalifa

27. Dr. Khalifa was a graduate in medicine (Cairo 1978), attaining his M.B., Bch (Bachelor of Medicine and Bachelor of Surgery). Following a rotating internship, he obtained his Masters in Pathology and then his PhD in pathology, 1989 in Cairo. Following five years of training in Maryland, the University of Oklahoma and George Washington University, he passed his American Boards in Anatomical Pathology in 1994. He obtained his Canadian Fellowship in 1995, FRCP(c) in anatomical pathology. He has an impressive C.V. of some 36 pages with many publications and abstracts over the 17 years since his graduation in 1978. He joined the staff of MUN Medical School in April 1995 as Assistant Professor of Pathology. This was his first university appointment, ie. his first full-time year round job in the 17 years since graduating in medicine.

28. In his testimony before the Commission as related to the IHC lab at the General: "The lab (IHC) was up and running – I was really impressed by the number of antibodies available, the quality of work done."[28]

29. In his testimony before the Commission he related how he became involved in ER/PR testing. With the blessing of Dr. Haegart, the chair at MUN Medical School and clinical chief, and the other pathologists at the General, he was asked to explore the idea of setting up ER/PR testing in IHC, in consultation with the site chief of Biochemistry where the test was being performed by a biochemical method. Most labs in North America were moving in this direction by the mid 90's.

[28] Evidence of Dr. Khalifa, July 24, 2008, p. 54, lines 1-3.

30. During 1997 and early 1998 Dr. Khalifa reported his progress in setting up ER/PR testing to the monthly meeting of the Site Chiefs and Managers, which included representatives from St. Clare's and the Grace, where the majority of breast surgery was performed. In the meantime he read and reported the current cases in parallel with the biochemistry method. In other words, the oncologist would receive two reports. According to the Predham data, he reported 137 cases in 1997.[29]

31. By early 1998, the other pathologists wanted to report their own cases. This was arranged and in 1998 an additional 147 cases were reported. In 1999 the biochemical method was discontinued and the IHC service for ER/PR was offered to all the pathologists in the other hospitals around the island. In 1999, 360 cases were reported.[30]

32. It is difficult to ascertain what role Dr. Khalifa played in setting up ER/PR testing. According to Dr. Khalifa, there were no job descriptions and the Pathology Department was run by consensus and collegiality. He knew he reported to Dr. Haegert, the chair at MUN, from the academic side of his work and as site chief reported to the clinical chief, who was also Dr. Haegert. Nobody reported to him. The closest thing to a job description was some musings of Dr. Khalifa dated April 19, 1999 entitled "Some of My Chores as Site Chief (1996-1999)", which included "preparing controls for immunohistochemistry, trouble shooting with failed tests" among the duties.[31]

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[29] P-1841
[30] P-1841
[31] P-1898

33. Mr. Coffey explored Dr. Khalifa's role in training Ms. Butler and Ms. Welsh[32]: "I was involved with them in troubleshooting and just explaining things as we go."[33]. Mr. Coffey asked, did you ever give them any training. Dr. Khalifa gave a long answer – he didn't feel they needed any training and if they did, he was not qualified to do it. Further in his testimony when asked how they started up the testing, he replied "so the IHC lab was up and running and this was just one more antibody that they can work with". The recipes were already there. The procedure was there. We had personnel.[34] Further on Mr. Coffey asked him about antigen retrieval with heat and how many other stains needed heat induced retrieval. Answer – "I wouldn't be able to know that."[35] And further on: "Q. Heating the slides, was that common at the time? A. I wouldn't remember that. I don't know."[36] Further on he was asked about antibody dilutions, and it is necessary to summarize as his answer covers three pages.[37] Essentially what he answered is that you use the manufacturers spec sheet – "it advises you how to do the recipes – sort of a cooking recipe."[38]. He did say the technicians brought him slides and he picked out the antibody concentration giving the best reading on the positive control. In other words, he had no direct involvement in either instructing or advising on the performance of ER/PR testing – just follow the spec sheets.

34. All these points are corroborated by the evidence of Mary Butler and Peggy Welsh to be discussed further in this brief.

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[32]Evidence of Dr. Khalifa, July 24, 2008, p.58, line 7-19
[33] Evidence of Dr. Khalifa, July 24, 2008, p.258, lines 18-25, p. 259, lines 1-10
[34] Evidence of Dr. Khalifa, July 24, 2008, p.85, lines 4-8
[35] Evidence of Dr. Khalifa, July 24, 2008, p.91, line 6
[36] Evidence of Dr. Khalifa, July 24, 2008, p.91, line 20
[37] Evidence of Dr. Khalifa, July 24, 2008, pp. 94-96
[38] Evidence of Dr. Khalifa, July 24, 2008, p. 94, lines 11-15

35. When Mr. Coffey asked Dr. Khalifa specifically had he ever done this process before (set up ER/PR testing), his answer covered several pages. This answer should have been a simple no. When questioned on the workshops and seminars he had given on IHC over the years as outlined in his C.V., he admitted they were on "the theoretical background of the stain."[39]

36. On the clinical side Mr. Coffey explored Dr. Khalifa's input into teaching the other pathologists about reading ER/PR slides and how he decided on a 30% positivity cut point.

37. On the first point, teaching the pathologists, he replied "They (the other pathologists) were very knowledgeable, they were up to date with the literature and I counseled with them a lot on the fine details of ER/PR testing."[40] (This appraisal of the state of knowledge of the other pathologists is unreliable, given the fact (discussed below) that Dr. Khalifa himself was poorly grounded in the literature.) Also in testimony earlier he stated that he sent slides of cases to the pathologists at the Grace and St. Clare's to familiarize themselves with reading ER/PR testing.

38. Dr. Khalifa based his statement, that conventional thinking in 1997-1998 regarding cut off point was 30% positivity, on a publication by O'Keane et al 1990. We question this because the publication predated the Shi landmark paper of 1991, using heat induced antigen retrieval which revolutionized the use of paraffin sections in ER/PR procedures.

[39] Evidence of Dr. Khalifa, July 24, 2008, p. 104, line 1.
[40] Evidence of Dr. Khalifa, July 24, 2008, p. 118, lines 1-4

Secondly, O'Keane was using an anti-estrogen antibody and the article was comparing their procedure to other biochemical methods. There was no clinical validation on survival.

39. The basic principle on using cut points for a procedure in ER/PR testing is to determine at what level of positivity will a patient respond to anti-hormone therapy, in relation to the procedure the facility is performing. This can only be done by clinical trials prospectively, retrospectively or on archival material. If setting up the ER/PR procedure and not doing clinical trials, the lab must rely on the literature in which the methodology and antibody used is similar.

40. Mr. Coffey questioned Dr. Dabbs on the Khalifa memo of February 16, 1998 wherein Dr. Khalifa proposed a uniform reporting system for ER/PR expressed in a percentage and a cut off of 30% (less than 30% positivity would be clinically negative). Dr. Khalifa supplied references to support this 30% cut point.[41]

41. Dr. Dabbs spent 22 pages of testimony beginning at p. 229, September 15, 2008, explaining that if not doing clinical trials, a lab must rely on publications in the literature using the same methodology and antibody ID5, as used in Eastern Health labs. He stated that in the mid 90's the publications of Mascarelli 1995 and Perchuck in 1996 should have been used, where the ID5 antibody was used and validated by clinical trials. Both publications used 5 and 10% cut points. Dr. Dabbs explained that the O'Keane

[41] P-1850, p. 3

publication used a polyclonal antibody (antibody to estrodiole), not ID5, and compared IHC procedures against other biochemical method with no clinical validation.

42. When questioned by Commissioner Cameron, Dr. Dabbs reiterated and clarified his interpretation of the O'Keane paper and finally he said "and to me that's comparing apples and oranges because you're trying to take the sensitivity and specificity of one test and translate it to a different test, which is impossible to do in reality."[42] Also in the O'Keane paper they were using an antibody against estrodiole (estrogen) whereas ID5 is an antibody against estrogen receptors.[43] Finally, Dr. Dabbs told the Commissioner "this paper I think was largely ignored in the literature and for good reason."[44] In Mr. Crosbie's cross-examination of Dr. Dabbs he asked Dr. Dabbs whether adoption of the 30% cut off in 1997 was ill-advised and not reasonable, answer: "I would agree with it."[45]

43. Mr. Coffey explored quality assurance with Dr. Khalifa starting on p. 219 and his evidence extended for several pages. Our summary of his evidence is that there was none, except the Tuesday/Wednesday conference where slides and diagnoses were compared among the pathologists and residents. The cases discussed were diagnostic problems in general. He admits "I would not describe it as a full-fledged program."[46] When questioned about external proficiency testing, he agreed that this very essential

[42] Evidence of Dr. Dabbs, September 15, 2008, p. 247, lines 17-21
[43] Evidence of Dr. Dabbs, September 15, 2008, p. 250, lines 8-12
[44] Evidence of Dr. Dabbs, September 15, 2008, p. 248, lines 11-15
[45] Evidence of Dr. Dabbs, September 15, 2008, p. 241, lines 12-14
[46] Evidence of Dr. Khalifa, July 24, 2008, p. 220, lines 1-2

element was missing.[47] When asked were external proficiency programs available, he was rather vague on this point but the simple answer was none. As we see it, yes they were. Dr. Torlakovic gave evidence that UK NEQAS was "created to support external quality assurance" and started their module on immunohistochemistry in the early 1980s, and "since then large number of laboratories from outside of UK, that means European and globally have decided to participate".[48]

44. Asked why internal positive controls were not used, Dr. Khalifa incorrectly stated: "The issue of internal controls as an additional layer of validation, that was not available to us in '97, '98."[49] When questioned on the same point, Dr. Dabbs said he was exposed to utilizing internal controls in the mid 80's.[50]

45. Dr. Khalifa's response to the need for a Standard Operating Procedures manual was to shrug the question over to Mr. Gulliver.[51]

46. On proficiency programs and sending out random slides to other institutions, Dr. Khalifa's answer was "that didn't happen."[52]

47. Dr. Khalifa's role in the startup of ER/PR testing at the General Hospital in 1997 was confined to germinating the idea of setting up the test and reading external positive controls, much the same as occurred until the arrival of Dr. Ejeckam in 2002. His

[47] Evidence of Dr. Khalifa, July 24, 2008, p. 222, lines 21-24
[48] Evidence of Dr. Torlakovic, October 9, 2008, p. 14, lines 14-25
[49] Evidence of Dr. Khalifa, July 24, 2008, p. 224, lines 22-25
[50] Evidence of Dr. Dabbs, September 15, 2008, p. 198, lines 14-19
[51] Evidence of Dr. Khalifa, July 24, 2008, p. 258, line 8
[52] Evidence of Dr. Khalifa, July 24, 2008, p. 259, lines 22-25

knowledge of the technical part of the test was shallow and he had no idea of the pitfalls associated with this complex procedure. To say that he engaged in troubleshooting is an exaggeration since he did not have the bench knowledge to do troubleshooting.

48. On the clinical side, Dr. Khalifa's review of the literature was outdated and irrelevant in setting the cut point at 30%. He claimed to have read and reported all the cases in 1997 and part of 1998 in parallel with the biochemistry procedure. We can get a good idea how the lab and Dr. Khalifa performed in these two years. If we look at the Predham data as captured in P-1841, for 1997-1998 there were 284 cases reported with a ER positivity rate of 53% and a false negative rate of 50%. Not a stellar performance when the standard was 75% positivity and the false negative rate 2%. Dr. Khalifa set up the service on a wrong theoretical basis, and his personal interpretative performance was terrible.

49. Dr. Khalifa's setting the cut point at 30% however raises problems. The criteria set for cases to be retested at Mount Sinai were cases with 30% positivity or less from 1997-2000 and 10% thereafter. Should the criteria be lowered to 10% for the cases tested from 1997-2000 instead of using 30%? Perhaps Dr. McDonald and Dr. Rezza, the statisticians, should be asked to see how many cases would be involved. We respectfully request that the Commissioner give some consideration to this issue.

Mary Butler and Peggy Welsh

50. Mary Butler started working in the Histology lab in 1970 as a lab assistant and wrote her R.T. in Histology in 1981. She learned IHC procedures from Peggy Welsh in 1988.

51. Peggy Welsh graduated as an R.T. in 1974, and after three years in general lab work elsewhere, started working at the General Histology lab in 1977. She learned IHC procedures in the mid 80's from Terry Gulliver. When Mr. Gulliver was promoted to supervisor in 1987, Peggy Welsh was put in charge of IHC. She taught Mary Butler the procedures. The procedure used was the Perioxidase Anti-Peroxidase (PAP) which was used until the Ventana platform was installed in 2004. By 1997 the number of antibodies used grew from four or five in the mid 80's to seventy. The overall impression left by the evidence was that Mary Butler and Peggy Welsh had performed IHC stains competently on the other antigens.

52. However, there was insufficient volume of work in IHC procedures to dedicate a tech full time, so Mary Butler and Peggy Welsh alternated on a weekly basis and performed the IHC once a week. This practice continued on until the Ejeckam intervention in 2003. In order to improve turnaround time and with the growing number of antibodies, IHC was performed twice a week and finally daily after the Ejeckam intervention. However in 1997 alterations had to be made to the PAP procedure to accommodate ER/PR testing.

Antigen Retrieval

53. In 1997 when ER/PR testing was first introduced, Ms. Welsh and Ms. Butler thought they were just two more antibodies added to their growing numbers. They did know, however, that the two new antibodies called for a change in antigen retrieval from Trypsin to a heat retrieval method, and in October 1999 to a more sophisticated temperature controlled water bath.[53] This was more than Mr. Gulliver knew, who thought Trypsin was still part of the process.[54]

54. Both technologists testified they had no instruction on the performance of the two antigen retrieval methods – "just followed the manufacturer's specs."[55] It is unknown who handed them the specs, and with Dr. Khalifa saying he was not qualified to train techs in procedures, one has to assume antigen retrieval procedures were started by Mr. Gulliver. Mr. Gulliver on the other hand denied having anything to do with setting up ER/PR testing.

55. Peggy Welsh and Mary Butler had a reasonable knowledge of antigen retrieval by heat methods and described the methods reasonably well in their testimony which was basically to bring a pot to boil (95-99°C) on a hot plate and try to keep the antigen retrieval solution between 90-95°C. They were both relieved when they got a water bath in October 1999, in that they could control the temperatures more easily. Both methods clearly say to keep the temperature of the retrieval solution below 99°C. Exposure time

[53] P-1853, p. 9, item 1
[54] Evidence of Terry Gulliver, October 15, 2008, p. 225, line 20 to p. 227, line 1
[55] Evidence of Peggy Welsh, July 8, 2008, p. 137, lines 2-5

to heat in the kitchen pot – hot plate method – is 30 minutes and the water bath with controlled temperature is 20-40 minutes. Optimal timing of exposure (incubation) is to be determined by the user.[56] In their testimony, neither Peggy Welsh nor Mary Butler described optimization to determine the time of exposure. If using temperatures above 100°C then the length of exposure is decreased to 2-5 minutes in a pressure cooker or autoclave. With the microwave, specified exposure is two 5 minute cycles on full power for a total of 10 minutes.[57] In general the higher the heat, the less exposure time.

56. Dabbs also states "in general, major factors that influence the quality of results of AR-IHC include heating temperature and heating time and the pH value of the AR solution.[58]

57. In any event whether using super high (120°C), high (100°C), or medium high (90°C) temperatures, it is critical to follow the method used to the letter and optimize the exposure time. Improper performance of the antigen retrieval in IHC is the most frequent cause of false negatives. (Allred and Rhodes previously quoted.)[59] One might say that performance of antigen retrieval is the Achilles heel of IHC in ER/PR testing.

Antibodies

58. A second major change in procedure came in April 1998 when the ER/PR kit method was discontinued. With the kits, the antibodies were pre-diluted and were ready for use. In April 1998 the antibodies for ER and PR were purchased in bulk and while the

[56] P-1605, p. 2, Procedure, item 3
[57] P-3050, p. 1, items a & b
[58] P-1568, p. 3, para. 3
[59] P-0526 & P-1851

manufacturer suggested a dilution, good practice was to take a dilution above and below the suggested dilution and test them against a known positive control, with the pathologist deciding which dilution gave the best staining. Mary Butler and Peggy Welsh testified that they followed this practice.

59. Dr. Banerjee's report supports our submission that antigen retrieval or inadequate antibody detection system titration were the principle causes of test failure.[60] It is noted in the Wegrynowski report that she was told the antigen retrieval method was by a steamer.[61] This is misinformation. Mount Sinai were using a pressure cooker.

Summary

60. Immunohistochemistry is a complex biochemical procedure. Although the Histology lab had been performing the tests since the mid 80's for the exclusive use of the pathologists for histological diagnostic purposes, results of ER/PR testing are for the exclusive use of the oncologists for therapeutic and prognostic decisions. In other words, the results of ER/PR testing have a direct influence on patient care.

61. It is incumbent on any lab not to issue results until those results are accurate and reproducible. This can only be assured if the test is performed by trained technologists, quality reagents are used and the test passes the rigors of the checks and balances of a quality assurance program. There is no learning curve allowed.

[60] P-0046, p. 4, Conclusions, item 1
[61] P-0047, p. 3, 1.2 Background, lines 6-7

62. There was almost a complete absence of quality control. We say almost in that a positive external was used. There was no negative external control, which is mandatory (see para. 69, first question). There was no emphasis on internal positive controls. There was no monitoring of the performance of ER/PR testing, ie. daily documentation of controls or any system set up to collect complaints from the oncologist or pathologist, repeat reprocessing of blocks, etc. In other words, Mr. Gulliver, Dr. Khalifa and the techs had no idea whether the ER/PR testing was performing properly. Unfortunately these practices continued on until the Ejeckam intervention in 2003, some 6 years later. Tragically by 2003 there were 319 false negative cases, an unknown number of false positives, and as we suspect, an unknown number of false negatives in the conformed negatives.[62]

63. What Dr. Khalifa and the entire technology side of the lab did not "get" is that this was *not just another kit*. When ER/PR testing was first introduced in 1997 it added an entirely new dimension to IHC procedures.

(i) the target antigen was on the nucleus of the cells;

(ii) heat had to be was applied to induce antigen retrieval;

(iii) the antibodies had to be titrated to a proper concentration;

(iv) the mandatory use of negative controls (see para. 69, p. 25, lines 1-4);

(v) the results impacted directly on patient care.

64. Mr. Gulliver as manager/supervisor of Histology, though he had no written job description, was accountable for the development and quality of the product.

[62] P-1852

65. Dr. Khalifa also had no job description or assigned responsibilities except to introduce the ER/PR testing. Both Mr. Gulliver and Dr. Khalifa had only shallow knowledge of the pitfalls of ER/PR testing at the bench level.

66. The question begs who is accountable for the product? The two senior and experienced technologists Peggy Welsh and Mary Butler, who actually performed the ER/PR testing, had no instruction or supervision in performing this new test, or Dr. Khalifa and Mr. Gulliver. We submit Mr. Gulliver and secondarily Dr. Khalifa.

67. Perhaps the situation in 1997 and thereafter can best be summed up by Peggy Welsh in her testimony made on July 8, 2008, some 20 odd years from her first performance of IHC procedures. We paraphrase:

> I've learned a lot in the past month – that I never heard in all the time I was doing the work – that woman from Mount Sinai – Trish Wegrynowski – Things that she talked about, I had never heard about before.[63]

68. Peggy Welsh had been in charge of the IHC lab from 1989 to April 2003.

69. Dr. Dabbs provided a non-exhaustive but representative list of things the lab did not do but should have, and which resulted in the high rate of conversions when retested. Building on the previous testimony elicited by Commission Counsel Mr. Coffey, Mr. Crosbie obtained the following summary:

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[63] Evidence of Ms. Wegrynowski, July 8, 2008, p. 269, lines 9-24

CROSBIE, Q.C.:
Q. Would you say that it's mandatory to use a negative control?
DR. DABBS:
A. Yes.
CROSBIE, Q.C.:
Q. Would it have been so in 1997?
DR. DABBS:
A. Yes, it should have been.
…
CROSBIE, Q.C.:
Q. … The first one, I wrote these out last night, so the first one I have here is that in your view adoption of the 30 percent cutoff in 1997 was ill advised and not reasonable. Is that correct or incorrect?
DR. DABBS:
A. I think based on the information that I have that that antibody that was published in that paper was actually not in use here. If I'm correct in that, then the answer to your question would be correct, I would agree with it.
CROSBIE, Q.C.:
Q. And it seems that in 1997 the adoption of the IHC technique was probably not appropriately validated, is that correct?…
A. Yes, I agree with that.
CROSBIE, Q.C.:
Q. I believe you told us that IHC is now considered to be a component of general pathological or pathology practice, is that correct?
DR. DABBS:
A. Correct.
CROSBIE, Q.C.:
Q. It's part of your standard armormentarium?
DR. DABBS:
A. Yes.
CROSBIE, Q.C.:
Q. And has been so since 1997 or even before that?
DR. DABBS:
A. Before that, yes.
CROSBIE, Q.C.:
Q. And then you characterized one of the practices of Eastern Health, in particular, the absence of an SOP as a recipe for disaster?
DR. DABBS:
A. Yes.
…

CROSBIE, Q.C.:
Q. …But you would expect the pathologists themselves to undertake an investigation if they realized there was a dramatic change in result?
DR. DABBS:
A. Yes.
CROSBIE, Q.C.:
Q. I also understood that you were of the view that Dr. Ejeckam's … analysis of the problem in the lab failed to recognize the extent of what you characterized as a global problem?
DR. DABBS:
A. … Yes, I agree, right, I agree.
…
CROSBIE, Q.C.:
Q. I took it that the lab here would have been closed down if inspected during the subject period, 1997 to 2005 to standards prevailing in the United States. Is that a correct understanding?
DR. DABBS:
A. I think that's a correct statement.
CROSBIE, Q.C.:
Q. And when asked about acceptable error rate, your reply was that the lab, your lab is dissatisfied with anything two percent or greater of tests which have to be repeated and then you investigate the problem?
DR. DABBS:
A. Well, just to clarify that, the two percent cutoff is for just repeats in immunohistochemistry. This would be a result of tissues that need to be reprocessed or stains that come back and there's a part of the tissue that is not there. Usually these relate to tissue processing issues and not to false negatives or false positives. That goes into a whole new realm.
…
CROSBIE, Q.C.:
Q. Did you characterize the test failures here in your view as being largely technique failures?
DR. DABBS:
A. To the best of my knowledge, yes.
CROSBIE, Q.C.:
Q. You stated, as well, that a negative invasive lobular would provoke deep concern in your institution?
DR. DABBS:
A. That's correct. And that's the type of event that I would consider to be a serious or sentinel event, something that needs to be thoroughly investigated because of the rarity of that result. It would be cause for concern to look at the testing, the fixation and

how the specimen was handled and how the specimen, in fact, was interpreted.
CROSBIE, Q.C.:
Q. And I got an overall sense of validation as something that should be done in house, as it were?
DR. DABBS:
A. Correct.
CROSBIE, Q.C.:
Q. And I think you said that variability for this particular test should be no greater than for any other path lab procedure?
DR. DABBS:
A. The variability in ER testing?
CROSBIE, Q.C.:
Q. Um-hm.
DR. DABBS:
A. Correct.
CROSBIE, Q.C.:
Q. Is it mandatory for a lab to have QA when undertaking this kind of testing?
DR. DABBS:
A. Yes, it is.
CROSBIE, Q.C.:
Q. Would that be true in 1997?
DR. DABBS:
A. Yes, it would.
CROSBIE, Q.C.:
Q. Is constant optimization mandatory?
DR. DABBS:
A. Yes, it is.[64]

[64] Evidence of Dr. Dabbs, September 16, 2008, p. 233, line 16 to p. 251, line 7

(b) Inquire into why the problem with the Estrogen and Progesterone Receptor tests was not detected until 2005, and whether it could have been detected at an earlier date and whether testing protocols during that period between 1997 and 2005 were reasonable and appropriate.

Ejeckam Intervention

70. Dr. Ejeckam was appointed to the staff of the General Hospital in September 2002. Because of his considerable experience and impressive credentials he was given the rank of Clinical Associate Professor. The clinical appendage meant he was not academic staff but was expected to teach at the Medical School as well as to share the workload with the other pathologists (surgical and autopsy pathology).

71. As in all academic teaching centres pathology had weekly teaching rounds. These took place on Tuesday and Wednesday. Attending would be both academic and staff pathologists, as well as the residents in training. They sat around a table with a multi-headed microscope and discussed interesting and difficult cases. There was an exchange of ideas and opinions. Difficult cases where no consensus of opinion could be reached were sent out for external consideration. Dr. Khalifa referred to these sessions as a form of QA among the pathology staff.

72. During the fall of 2002 and extending into early 2003 it was noted by Dr. Ejeckam that cases that were using IHC stains, particularly those used for lymphoma, prostate cancer and breast cancer, were not crisp, lots of cytoplasmic staining, and some not staining positive when expected and had to be repeated. Early in 2003 Dr. Cook, the Clinical Chief at the time, recognized that Dr. Ejeckam had considerable experience in IHC and

suggested to the group that Dr. Ejeckam look into the problem. Dr. Ejeckam states his appointment occurred "during the tail end of 2002 going into 2003".[65] He did, and it was the consensus of the group that the 8 antibodies used for lymphoma, prostate cancer and breast cancer should be shut down until the problem of erratic staining could be solved.

73. Dr. Ejeckam sent a memo to all the pathologists in Newfoundland on April 4, 2003, with copies to Mr. Dyer, the manager, and all technical staff in IHC.[66] Essentially the memo says that 8 antibodies will not be performed because they were "unreliable, erratic and therefore unhelpful for diagnostic purposes". He would keep them informed.

74. Starting on page 224 of Dr. Ejeckam's testimony on June 3 and continuing on to page 231, Dr. Ejeckam explained to the Commissioner what he did to correct the problem. We will summarize:

(a) He chose new positive control blocks.

(b) He had the techs try different exposure times in the heat antigen retrieval time against the positive control. He would decide which exposure time gave the best positive control. (Unfortunately nobody remembers what exposure time they were using before this experiment or what exposure time was finally decided on. Nobody was documenting, which seemed to pervade the whole operation.)

[65] Evidence of Dr. Ejeckam, July 3, 2008, p. 203, lines 17-18
[66] P-0113, p. 1

(c) The techs were asked to recheck the antibody concentrations by titration using different concentrations against a positive control. He would decide which concentration gave the most crisp positive control.

75. In any event, after what is described as "tweaking the procedure" for ER and PR testing as well as the other antibodies, Dr. Ejeckam was confident that the test results were back on track and reinstated the antibodies by a second memo dated May 2, 2003. The results of Dr. Ejeckam's "tweaking" of the ER/PR are quite astounding. In 2003 the rate of positivity for ER rose from 57% in 2002 to 76% and in the first four months of 2004 to 84%.[67] That's an increase by 19% and 28% respectively.

76. The May 2nd memo was what Dr. Ejeckam referred to as a teaching/instructional type of memo to the pathologists to stress the importance of correct fixation, core biopsy cautions on ER/PR testing, cut points, internal positive controls, and general comments to the less experienced and infrequent users of the IHC service. Copies were made to site chiefs, Mr. Dyer, the manager and techs in IHC.[68]

77. Dr. Ejeckam wrote a third memo to Mr. Gulliver, the program director, on June 19, 2003. The memo could be summarized as follows: Although the problems of the past two months have been arrested, the state of the IHC lab is still unsatisfactory. Six areas have to be corrected, among which are space for an IHC lab, training of techs, and dedication of techs to IHC only. A reasonable explanation was given for each item. Finally, Dr.

[67] P-1841
[68] P-0113, pp. 2-4

Ejeckam warned that unless measures were taken to correct these deficiencies "diagnosis based on inappropriate immuno stain will surely jeopardize patient care and may even expose the HCCSJ to litigation." Copies were made to Dr. Des Robb, Chair of Discipline of Lab Medicine, Dr. D. Cook, Clinical Chief, Dr. S. Parai, Site Chief, and Barry Dyer, Manager Histology.

78. How these five gentlemen responded to Dr. Ejeckam's memos determined whether an investigation was commenced. By investigation we mean a retest of the negative cases in 2000, the year before Dr. Ejeckam rejuvenated ER/PR testing.

79. The pathologists at the Tuesday and Wednesday session were aware that something was wrong with IHC results and it was Dr. Ejeckam, who started going to these sessions in September of 2002, who confirmed their suspicions. However they had the luxury of being able to retest when a stain was considered unsatisfactory. The majority of the erratic staining was diagnostic antigens for lymphoma and prostate cancer and some breast cancers. Amazingly, it appears that nobody, including Dr. Ejeckam, thought of the clinical complication of having poor staining in breast cancer cases. A false negative would mean depriving a patient of anti-hormone therapy.

80. After seven months of observing the problems in the IHC lab, there was a consensus of those attending the Tuesday/Wednesday session to shut down testing for lymphoma, prostate cancer and ER/PR testing until the problems were resolved.

81. Unfortunately, nobody was tracking the numbers of repeats for statistical performance of ER/PR testing.

82. The pathologists and Dr. Ejeckam knew in September 2002 there was a problem with staining in the IHC lab. This was a general observation of those at the Tuesday/Wednesday sessions. For the diagnostic antigen users for lymphomas and prostate cancer, these could be repeated without directly affecting patient care.

83. We submit that at a minimum the negative ER/PR cases for 2002 should have been repeated and if so the retesting would have in all likelihood picked up and corrected the false negativity of the index case Peggy Deane.

84. The general excuse offered by those involved in ER/PR testing in 2002 and 2003, including Dr. Ejeckam, was there was no "index case" and therefore no need to do any retrospective studies. Ms. Chaytor and Mr. Coffey brought forth numerous cases from 1999 onward that were retested and had converted. Any one of those could be an "index case". In fact, if there had been any retesting in 2003 there were 319 "index cases" discovered in the 2005-2006 retesting by Mount Sinai. Unfortunately the lab records did not record, either the in-house or out-of-town test results of ER/PR testing. The only records kept were the slides and paraffin blocks in their archives.

85. The following are the five gentlemen who were most responsible to recommend any investigation or retesting in response to Dr. Ejeckam's findings:

(1) Dr. Ejeckam, resource person for IHC;
(2) Dr. Parai, site chief;
(3) Dr. Cook, clinical chief;
(4) Mr. Barry Dyer, the manager; and,
(5) Mr. Terry Gulliver.

(1) Dr. Ejeckam

86. Dr. Ejeckam testified he was only a resource person, or as Dr. Cook referred to him, our "point person" in IHC. Remarkably, Dr. Ejeckam was not involved in any of the numerous meetings between Dr. Cook, Dr. Carter, risk managers, an assortment of middle managers, Dr. Williams the Vice President of Medical Services, and finally Mr. Tilley the CEO when the index case was discovered in the spring of 2005.

87. When the enormity of the problem with ER/PR testing began to sink in after finding a 67% false negative rate in the resting of the 2000 ER negative cases, Dr. Cook was forced to disclose the Ejeckam memos of 2003 to Dr. Williams in July of 2005.

88. We agree with the sentiments expressed by Dr. Carter in her letter of resignation from the ongoing investigation of ER/PR testing dated August 2, 2005, wherein she stated:

> The meeting with Mr. George Tilley on August 1, 2005, showed, in my opinion, that Mr. Terry Gulliver and Mr. Barry Dyer do not have a good understanding of the limitations of automated immunohistochemistry, rigorous clinical and technical validation of antibodies against ER and PR and establishment of reliable and reproducible means of providing ER/PR results to our patients, using the substantial published, peer reviewed and accepted scientific literature on the development of and continuous monitoring of an immunohistochemical testing protocol.

> It also became clear to me during that meeting that the current administrative structure within Eastern Health and within the laboratory allows decisions regarding the development of a reliable and reproducible system for assessing hormone receptor status to remain in the hands of paraprofessional staff within the laboratory.[69]

89. In Dr. Ejeckam's testimony Mr. Coffey asked: "Q. in 2003 it didn't occur to you to go looking for such a case, to go back to 2002 or 2001, bearing in mind what you knew in '03, that you were seeing erratic staining? A. It didn't occur to me and I didn't think it was a proper way--work to do then."[70] He did not elaborate why.

90. Although Dr. Ejeckam gave directions to the technicians how to troubleshoot the ER/PR procedure in April 2003, he did not know exactly what was going on at the bench level. For example, he did not know what antigen retrieval method was used. He thought they were using a pressure cooker.[71] Further on cross-examination by Mr. Crosbie, he was asked about antigen retrieval and he answered: "We used microwave or heating in a pressured environment (cooker). I'm not aware of a water bath method. I'm not aware that we ever used that."[72] Over the next several pages (295 to 299) Dr. Ejeckam admitted that he never personally observed the method used by the technicians[73] and finally he stated "what the techs did were technical work that I didn't have anything to do with."[74]

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[69] P-0079, p. 1, paras. 2-3
[70] Evidence of Dr. Ejeckam, June 4, 2008, p. 254, lines 6-13
[71] Evidence of Dr. Ejeckam, June 4, 2008, p. 280, lines 7-10
[72] Evidence of Dr. Ejeckam, June 4, 2008, p. 295, lines 4-6
[73] Evidence of Dr. Ejeckam, June 4, 2008, p. 297, line 5
[74] Evidence of Dr. Ejeckam, June 4, 2008, p. 299, lines 6-7

91. Like the other pathologists testifying, they knew the theoretical concepts of antigen retrieval, that getting the correct exposure time to heat was as critical as getting the correct concentration of antibodies that give crisp staining against a known positive control.

92. As the Commissioner knows from the evidence of Mary Butler and Peggy Welsh, they had been using a non-boiling technique from 1997. First the kitchen pot on a hot plate, then a water bath (1999) method up to the time when the Ventana platform was installed.

93. We submit that while Dr. Ejeckam did wonders with improving the ER positivity rate, there is nothing given into evidence that the antigen retrieval method used by the technicians from 1997 to Dr. Ejeckam's intervention in 2003, had ever been validated for exposure time. Both Mary Butler and Peggy Welsh testified "They just followed the manufacturers specs". So for six years the technicians were using a non-validated antigen retrieval method. As previously quoted, antigen retrieval is the "Achilles heel" of ER/PR testing.

94. When questioned on external controls Dr. Ejeckam explained to Mr. Coffey the importance of having a good external positive control and a good external negative control.[75] He must have known they never ever used an external negative control.

[75] Evidence of Dr. Ejeckam, June 3, 2008, p. 229, lines 1-5

95. We summarize his testimony as follows related to negative controls.[76] Dr. Ejeckam testified that one could use non-breast tissue known to be negative for ER/PR staining or the breast tissue and omit adding the antibody during staining. The best negative external control is the patient's own tissue. Simply make two paraffin sections instead of one when using the microtome. Label one as the patient's section and one the negative control. The tissue used for the negative control has been treated exactly the same as the patient's sample – fixation, processing, imbedding – all areas identified as possible causes of false negatives. Then process the slides side by side through the analytic stage except no antibody is added to the negative control. Take both slides through antigen retrieval method, detection system (PAP), chromogen (DAB) and Hematoxylin counter staining. The negative control has to be completely negative for any staining except the Hematoxylin (blue staining of the nucleus). It is an excellent control to pick up non-specific staining in the tissues (background). When chromogen is too concentrated or the techs have over cooked the specimen in the antigen retrieval process, you get cytoplasmic staining. If the negative control is stained in any way except for blue nuclei, the test has to be repeated. This background staining and cytoplasmic staining is one of the main reasons for false positive interpretation by an inexperienced pathologist. Technicians on the bench can and should read the negative controls. By contrast, the positive control belongs to another patient which has been optimally processed. From the inception of ER/PR testing in 1997 to the start up of the Ventana platform in 2004, no negative controls were ever used.[77]

[76] Evidence of Dr. Ejeckam, June 3, 2008, pp. 229-230
[77] Evidence of Ken Green, July 9, 2008, p. 131, line 25 & p. 132, lines 1-3

96. Although Dr. Ejeckam worked wonders in improving the positivity rate for ER, he like many of the other pathologists including Dr. Khalifa, had no real appreciation of the technical performance of ER/PR testing at the bench level. This contributed to what Dr. Dabbs described as Dr. Ejeckam's failure to appreciate the global nature of the problem in the lab: see para. 69 above.

97. Although Dr. Ejeckam had an incomplete understanding of bench level problems, he documented what he thought was wrong with ER/PR testing and passed it up the line to Dr. Parai, who in turn passed it up the line to Dr. Cook, the person most responsible for reacting to Dr. Ejeckam's findings.

(2) Dr. S. Parai July 28, 2008

98. Dr. Parai, the site chief in 2003, reasonably corroborated Dr. Ejeckam's memory of events leading up to his three memos. Essentially it was noticed by the other pathologists at the Tuesday/Wednesday sessions that there was or they suspected something wrong in the IHC lab. He was a bit vague on dates but knew Dr. Cook put Dr. Ejeckam in charge of IHC.

99. He had no problems with the Ejeckam memo of April 4, 2003 as it was discussed at the teaching sessions. The only feedback he had was from Mr. Dyer who came to him and complained that Dr. Ejeckam had no authority to issue such a memo.[78] Mr. Dyer thought he should be consulted. Dr. Parai told Mr. Dyer that indeed Dr. Ejeckam did have the

[78] Evidence of Dr. Parai, July 28, 2008, p. 20, lines 18-23

authority from Dr. Cook, the clinical chief. Dr. Parai agreed with the contents of the April 4th and the May 2nd memos and both were discussed at the Tuesday/Wednesday sessions. It was the first time he was aware of positive internal controls.

100. The Gulliver June 19th memo he also agreed with except he thought the stains were good after the tests were reinstated in May 2003. He did not think he had to take any action as his superiors Dr. Cook and Dr. Robb knew about the memos which were discussed at the teaching sessions. Also Dr. Ejeckam was put in charge of the IHC lab by Dr. Cook.

101. It would appear that Dr. Parai's only role related to ER/PR testing was to read the external positive controls when asked.

(3) Dr. Donald Cook

102. Dr. Cook was the clinical chief in 2003 and responsible for the clinical side of the Pathology Department which was divorced from the technical side. However, the Ejeckam memos had sufficient clinical implications that he should have taken them seriously. When asked by Mr. Coffey if he had received any complaints about IHC results, he said no. Apparently he never attended the Tuesday/Wednesday sessions. His response to the first Ejeckam memo shutting down the IHC lab for ER/PR testing was:

> Well I was going to phone Dr. Ejeckam, I was a little bit irritated that I had received this memo without any consultations prior to that, but I looked at this at the time as a quality assurance activity. Here was somebody that I had put in place to oversee the IHC (lab) and had taken steps to stop the staining and was acting as a circuit breaker in the system.

> So, in many respects I got a comfort level out of this and in that now I had somebody overseeing and monitoring the IHC.[79]

103. Dr. Cook never discussed the matter with Dr. Ejeckam – "I gave him the ball and let him run with it."[80]

104. Further in his testimony Dr. Cook was asked by Mr. Coffey why Dr. Ejeckam's assertion that the stains were unreliable, erratic and therefore unhelpful for diagnostic purposes, didn't that involve any more enquiries by yourself? Dr. Cook replied – "Well, up to that time, I mean, we looked at this as being in the world of immunohistochemistry. At that time, immunohistochemical stains can vary from day to day, can vary in intensity, can vary in staining characteristics. So, we looked at immunohistochemistry as a variable event."[81] In other words, we were used to poor quality product.

105. The Members find Dr. Cook's response to Dr. Ejeckam's April 4, 2003 memo most extraordinary. Dr. Cook was the only person who could have instigated an investigation which undoubtedly would have uncovered the lab errors found two years later.

106. Dr. Cook did not even discuss the matter with Dr. Ejeckam. He seemed to accept the erratic staining as a normal occurrence associated with IHC staining. Dr. Ejeckam felt that erratic staining was not a normal occurrence, as did those present at the Tuesday/ Wednesday sessions. Dr. Ejeckam's concerns were further vindicated two years later by Dr. Banerjee and Dr. Mullen – their bottom line, a poor quality product.

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[79] Evidence of Dr. Cook, July 2, 2008, p. 231-231, lines 18-3
[80] Evidence of Dr. Cook, July 2, 2008, p. 232, lines 9-10
[81] Evidence of Dr. Cook, July 2, 2008, p. 240, lines 8-21

(4) Barry Dyer, Manager of the Lab

107. Mr. Dyer attained his R.T. in 1986 following two years at the University. He started at the Janeway in Hematology and in 1989 started in Anatomical Pathology to the present. He moved from the Janeway to the General in October 2001 and replaced Mr. Terry Gulliver as manager of Anatomical Pathology in March 2002. He had no experience in the IHC lab at the General. As related to antigen retrieval, he had never performed this procedure[82] and never used the Dako autostainer. Mary Butler and Peggy Welsh were the lead tech II. They would consult him on non-technical issues – administration.[83] In a word, he had little or no experience in IHC where heat for antigen retrieval was used. He relied on Ms. Butler and Ms. Welsh.

108. With regard to Dr. Ejeckam's involvement in the HSC lab, Mr. Dyer said "he ran the lab" and gave direction to the technical staff which he perceived as a good thing.[84] Like Mr. Gulliver in 2997 assuming Dr. Khalifa knew about the technical performance of the ER/PR testing, Mr. Dyer assumed Dr. Ejeckam knew the same. Both Dr. Khalifa and Dr. Ejeckam in their evidence said they were not involved in the "technical side". These assumptions proved to be disastrous.

109. He testified that Dr. Ejeckam called him to his office and gave him the April 4th memo, and discussed its contents. Mr. Dyer was taken aback as he had not had any complaints against the IHC lab staining. We consider repeats and complaints as one and the same,

[82] Evidence of Mr. Dyer, p. 30, lines 11-17
[83] Evidence of Mr. Dyer, July 21, 2008, pp. 51-52
[84] Evidence of Mr. Dyer, July 24, 2008, p. 211, lines 12-25

but nobody was counting. He immediately went to see Mr. Gulliver, the Program Director, his immediate supervisor. Mr. Gulliver was also surprised as he had heard no complaints. In any event neither Mr. Gulliver or Mr. Dyer thought Dr. Ejeckam would solve the problems in the IHC lab.

110. However to his credit he did discuss the memo with Mary Butler, the Tech II in charge of IHC. His only part in the revalidating the IHC procedures for the 8 antibodies under investigation was to phone the Dako representative Dan Belchowsky because he was the expert.[85] Mr. Belchowsky sent a memo to the IHC lab with certain recommendations which reasonably concur with Dr. Ejeckam's instructions to Mary Butler, that is check the timing of exposure in the antigen retrieval method and check the dilutions of antibody giving the best staining. In any event Mr. Dyer had passed this information on to Mr. Gulliver, his superior.

111. So it would seem at this point in time (the spring of 2003) that Dr. Ejeckam had passed the problem up the line to Dr. Parai, the site chief, who in turn passed it on to the clinical chief Dr. Cook. Mr. Dyer passed the staining problem along to Mr. Gulliver.

112. Thus the two persons responsible or accountable for assessing the staining problem and taking any further action would be Mr. Gulliver and Dr. Cook.

[85] Evidence of Mr. Dyer, July 24, 2008, p. 216

(5) Mr. Terry Gulliver, Program Director

113. Mr. Gulliver's response to the "erratic and unreliable" memo from Dr. Ejeckam is covered in his October 8, 2008 appendix, pages 11 to 39. We will summarize our interpretation.

114. Mr. Gulliver's stated attitude was "if the memo said that we are closing down the IHC lab, where we are doing 120-140 antibodies, that would be a huge event". But Dr. Ejeckam was saying "there are several I would like to review. No big deal."[86] Dr. Ejeckam solved the problem and opened the lab for service.

115. On the June 17th memo directed to him from Dr. Ejeckam, Mr. Gulliver's response was much the same. He said he had a long meeting with Dr. Ejeckam in his office where they discussed the six points brought out in the memo. Dr. Ejeckam said this meeting never happened. Dr. Ejeckam said he met Mr. Gulliver in the corridor and he said he would respond in writing. This response never happened.

116. It is fair to say that in 2003 Mr. Gulliver's knowledge of IHC testing had faded on the technical side and he had a shallow understanding of the clinical implications of a faulty ER/PR test. As he was in charge of the pathology lab and had overall responsibility for the quality of the product, then if he had any understanding of the clinical implication of the problem, he would have investigated the problems raised by Dr. Ejeckam. His lack of

[86] Evidence of Mr. Gulliver, October 8, 2080, p. 19, lines 6-16

action can reasonably be attributed to a laissez-faire attitude and his failure to educate himself on the basics of the new test.

(c) and (d) *appropriate and timely communication with patients, the general public, and internally concerning testing after the problem was detected in 2005.*

> The first rule of medicine is not "Do no harm." It's "Don't get caught."
>
> - Anonymous Surgeon

117. Eastern Health is not committed to a culture of disclosure. Its instincts were to withhold, manage and spin information about the testing fiasco. Laboratory and clinical managers engaged with top corporate management in a tacit conspiracy to not get caught.

118. Once the dimensions of the testing errors were understood, Eastern Health did decide to retest the negative results. No other decision was possible. But having embarked on the necessary retesting, Eastern Health adopted a sometimes tacit, sometimes explicit strategy of damage containment. The damage this strategy has caused to public confidence in Eastern Health probably would have driven a private sector organization into bankruptcy, as betrayed patients flocked to competing alternatives. Eastern Health exists today because consumers of health services in this province have no alternative.

119. Anyone who wants to succeed in crisis management could study what Eastern Health did, and do the opposite. A timely illustration arrived with this week's mail in the form of a story about how CEO Michael McCain handled the response of Maple Leaf Foods to last August's listeriosis outbreak. McCain was quoted in a press conference (Report on Business, December 2008, p. 62):

> "Going through the crisis, there are two advisors I've paid no attention to," he told reporters. "The first are the lawyers, and the second are the accountants. It's not about money or legal liability–this is about our being accountable for providing consumers with safe food."

120. According to Mr. McCain, Maple Leaf's response to the health crisis did not need to be thought out, it arose instinctively from the corporate culture (p. 62):

> "The core principle here was to first do what's in the interest of public health, and second to be open and transparent in taking accountability," McCain told me. "For the team, this was almost not a decision–it was obvious. It's just what we are."

121. Eastern Health does not have a culture of safety and does not have a culture of disclosure. If it had a culture of safety, investigations would have been launched after the Ejeckam intervention or after one of numerous earlier "index" cases. If it had a culture of disclosure, there would not have been months of committee meetings, internal debate, consultations with government, memo writing and sputtering investigations without any conclusion in sight. There would have been immediate disclosure of what was known along with a plan of action and full apologies. The public sees anything less than full, frank and prompt disclosure by a healthcare institution as a cover up. Prompt disclosure should have been "almost not a decision", to quote Mr. McCain.

122. The terms of reference direct the Commissioner to inquire into communication "once detected", presumably referring to the case of the late Peggy Deane. We know now that there were numerous occasions on which problems with ER and PR testing were detected, but no investigative action taken. This submission will mention some examples of the culture of cover up at Eastern Health:

(a) *Pathologists fail to investigate false negatives – Christine Purcell* – Ms. Purcell was diagnosed with breast cancer in July 1998. The estrogen receptors were read as "positive, faint (5% of cells)" and progesterone receptors as "negative".[87] These were sent out to Boston where they were read as positive. When reread by Dr. Griffin at Eastern Health, the addendum was "estrogen receptors – weakly positive, approximately 50% of invasive tumor – progesterone receptors – weakly to moderately positive – 10-15% of invasive tumor." The addendum was signed July 15, 1999. Ms. Purcell was started on Tamoxifen in October 1999, and unfortunately died in March of 2000 at age 46. Ms. Purcell's husband Bryan Purcell testified before the Inquiry in March 2008. Mr. Crosbie asked Dr. Cook "was this a sentinel case?"[88] Dr. Cook testified that "it should have required a further investigation"[89], and that the responsible pathologist "should have notified the clinical chief".[90] Other potential index cases were brought up by Commission Counsel.

[87] C-0098, p. 2
[88] Evidence of Mr. Purcell, March 24, 2008, p. 210, line 3
[89] Evidence of Dr. Cook, July 8, 2008, p. 211, lines 23-24
[90] Evidence of Dr. Cook, July 8, 2008, p. 212, lines 15-16

(b) *Clarenville abandons Eastern Health lab* – Dr. Cook's note of March 6, 2006 recorded that Clarenville discontinued sending slides in due to "poor quality and to lack of external controls plus the fact they were paying for this."[91] No notification was given to the St. John's lab, but the lab ought to have noticed when these referrals ceased in 1999 and made enquiries to discover the reason. A lost opportunity.

(c) *CEO refuses offer of resources from Minister* – At a meeting with Mr. Tilley in July 225, Minister Ottenheimer asked if Eastern Health needed any extra resources to deal with the ER/PR situation. Mr. Tilley declined, and never did seek extra resources.[92] In light of all the other evidence of Eastern Health's cover up efforts, it is a reasonable inference that Mr. Tilley's refusal of help was motivated by a desire to keep knowledge of the extent of the errors within the organization where it could be managed and kept under control.

(d) *CEO withholds information from Minister of Health* – In November 2005, Eastern Health prepared a briefing paper in question and answer format, intended to inform the Minister of Health.[93] CEO Tilley personally made extensive alterations and deletions to this document.[94] Perhaps the most egregious was the deletion of the brief but reasonably accurate (and unflattering) summary of investigative findings provided by Dr. Fontaine,[95] which was too honest for Mr.

[91] P-2141, p. 1
[92] Evidence of George Tilley, April 17, 2008, p. 33
[93] P-1506
[94] P-1524
[95] P-1506, p. 3

Tilley. He sent bland, vaguely exculpatory statements to the Minister instead. Another cover up.[96]

(e) *CEO misleads the Board of Governors* – In his memo to Trustees dated May 31, 2007[97] the CEO misled the governing body by stating of the Ejeckam memos "there was no indication of a results concern" and there were no "specific recommendations flowing from it". Chair of the Board Joan Dawe admitted this advice was misleading when pressed in cross-examination.[98] Even this misleading advice was unduly delayed, with Dr. Williams arguing as early as July 15, 2005 that the Board not be informed.[99]

(f) *Cloak of secrecy dropped over external reviews* – Eastern Health ordered the external reviews to find out what had gone wrong and when the reviewers did what was asked, the findings were so explosive that a conspiracy of secrecy arose. The Banerjee and Wegrynowski reports had very restricted circulation under tight control, so tight that Dr. Cook read the Banerjee report to the pathology group but would not allow individual pathologists to have a copy. This surprised Dr. Ejeckam, who was "point main" for the IHC lab, and who thought that most of what Banerjee was saying was what he had been saying earlier. Mr. Tilley placed the reports in an envelope to send to the Deputy Minister of Health at his request, but then departed his post. Louise Jones then took the reports intended for the

[96] Ms. Chaytor examined Ms. Predham on these changes on October 20, 2008, pp. 365-375, who admitted that the earlier wording which contained Dr. Fontaine's information, was to be preferred: p. 371, line 20
[97] P-0112
[98] Evidence of Joan Dawe, March 28, 2008, p. 35, lines 14-25
[99] P-0070

Deputy Minister and locked them away. The techs who could have benefited from knowledge of the reports were never told of them or instructed in their lessons. This obsession with secrecy arose only after the reports with their damming conclusions were received, because as Judge Dymond found, "the External Reports were never intended to be confidential."[100] Eastern Health capped the campaign of secrecy by brazenly resisting production of the reports on grounds of "peer review" and "quality assurance". We say brazenly, because "it did not resemble, in any way, a Peer Review"[101], and "there was no Quality Assurance Committee in place at the time"[102], so Eastern Health's decision to fight production of this essential evidence must be seen as a last desperate attempt to obscure the truth and not get caught.

(g) *Misleading the Public on Rate of Error* – Eastern Health tried to spin a 3% error rate to some government officials (Tansy Munden: "Certainly, the impression … 3 percent margin of error"[103]; Darrell Hynes: "so the margin of error was only three percent, which was within an acceptable range".[104]) They decided to give 10% to the press. This occurred when Dr. Williams called Dr. Cook: "there was pressure on Dr. Williams to put some sort of number in the media. So, as best as I could tell him, we were certainly thinking around maybe 10 percent or so, possible conversion rate."[105] This was wishful thinking at best, because by

[100] *Eastern Regional Integrated Health Authority v. Commission of Inquiry on Hormone Receptor Testing*, 2008 NLTD 27, para. 112
[101] *Supra*, para. 44
[102] *Supra*, para. 82
[103] Evidence of Tansy Munden, June 18, 2008, p. 97, lines 4-7
[104] Evidence of Darrel Hynes, June 19, 2008, p. 87, lines 15-17
[105] Evidence of Dr. Cook, July 4, 2008, p. 333, lines 1-5

August 4, 2005, in-house retesting had revealed a 67% ER false negative rate on the 58 cases retested.[106]

(h) *Court expert Dr. Gown was provided false information* – The Commissioner does not need reminding that the privilege of giving expert opinion evidence is granted on the premise of assisting the tribunal in discovering the truth. Dr. Gown swore an affidavit in defence of the class action certification motion.[107] At para. 6, he stated "I have been advised that the seven year average was 74% ER positivity." This advice came from Mr. Gulliver. The actual positivity rate was 53%. Both figures are shown on P-3108, p. 2.

(i) *Disclosure policies ignored* – Eastern Health had reasonable disclosure policies in effect in 2005.[108] Counsel asked many witnesses if they had reviewed disclosure policies to determine if they were applicable, and if they were aware of anyone who did review disclosure policies and who stated the result of that review. Nobody did.

(j) *Pathologists investigate Deane conversion because of fear of complaint* – Dr. Ford Elms did his pathology residency at Eastern Health. His conduct is an illustration of the culture of "don't get caught". This pathologist had to sign the addendum of changed results in the Deane case, which became referred to as the

[106] P-0940
[107] P-0375
[108] P-0056, p. 18

index or sentinel case. He went to Clinical Chief Dr. Cook because *he thought "this might result in a complaint*."[109]

(k) *We have notified everyone* – Eastern Health knew early on that "we will not be able to notify everyone,"[110] but insisted time and again that every affected patient had been notified.

(l) *Ask the patients* – It never occurred to anyone at Eastern Health that they should ask the patients how they thought disclosure should be handled. One technique for exploring this would be a focus group. This would be a natural response in an organization with a patient centered culture instead of a preoccupation with protecting itself.

(m) *Eastern Health misleads ethics consultant* – A neutral onlooker might think that an ethics consult was an obvious early recourse. No such consult occurred until Dr. Cook wrote Dr. Williams in May 2006[111] to ask how to retire files of deceased patients. When the consult took place in June 2006, an "important fact" was stated to be "there were no mistakes or technical errors". At the date of this statement, the damming reports of Banerjee and Wegrynowski were known to the inner circle, particularly Dr. Cook, who attended. It must be inferred that Dr. Cook misled the consultants.

[109] Evidence of Dr. Ford Elms, September 2, 2008, p. 133, line 17
[110] P-0308
[111] P-1369

Recommendations

1. Eastern Health needs a new beginning and a true commitment to a culture of openness, accountability and frank disclosure. It also needs to regain the trust and confidence of the public. The Members strongly recommend that a series of town hall style meetings be organized around the province within a reasonable period of time after the submission of the Commissioner's report, for the purpose of explaining the findings and the response to the findings.

2. Hire a CEO who has no ties of loyalty to the present management of Eastern Health, and give him or her the authority to put in place an executive team with the executive ability to follow through on changes. This executive team needs a mandate to establish Eastern Health in a patient-centered culture of safety and disclosure.

3. Healthcare workers are not trained in disclosure and an extensive program of training should be put in place from medical school through to ongoing training at all levels.

4. One of the challenges for this Inquiry has been to determine which actors were responsible for what decisions. This is a result of the practice of not having position descriptions, not having clear written mandates (eg., Khalifa, Ejeckam), not having clear reporting lines, and making decisions "collegially" by committee, frequently without adequate or any minutes of committee deliberations and decisions. This is another organizational area that would benefit from review.

5. New testing procedures involving new equipment should not be adopted without formal written analysis of whether and to what extent the financial and human resources are available to perform to the desired standard. If this analysis had been done in 1997, that answer may have been that the resources were not available to undertake ER/PR testing by IHC and the testing should be outsourced. At least a decision would be made, instead of wandering blindly into a woefully under-resourced testing program.

6. The House of Assembly has introduced legislation providing for a public interest disclosure ("whistleblower") program, designed to encourage persons within government to report instances of behavior that are considered improper, unethical or wrong. The terms of the proposed legislation would presently protect only members of the public service, including an officer of the House of Assembly, but not employees in the healthcare sector. The whistleblower protections should be extended to protect any employee in the healthcare sector who reasonably believes that they have information that could show that a wrongdoing has been or is about to be committed and who makes disclosure in the appropriate manner. Whether whistleblower protection should be extended through the existing intended legislation, or by separate legislation, may be left to the authorities to decide.

7. At least three jurisdictions in Canada have now introduced "apology legislation" which will allow a party an opportunity to offer their regrets while having the protection of statute that an expression of sympathy will not be admissible in court as evidence of fault or liability. It is not clear that any Canadian court has ever relied on evidence of an apology as a ground for finding liability, so while an apologies act may make little or no

change in substantive law, its proclamation may have value in giving social and legal reinforcement to the perception that apologies are a good thing. For a healthcare institution, apologies are a condition precedent to the re-establishment of the trust and confidence which must characterize the relationship between the institution and its patients.

8. The institution should have a crisis management plan, including a plan for the management of communications about the crisis, and if sufficient skill, expertise and surge capacity is not available within the institution, then there should be a mechanism for calling in outside help.

9. Just as the lab now engages in external proficiency testing as a form of quality assurance, so should the institution's policies involving communication and disclosure be subject to quality assurance. This would involve periodic review to ensure compliance with current standards, but much more important than this is periodic audit to ensure that the policies currently in place are actually known about and are being followed in practice. Follow up is required to ensure that perfectly good policies are not left on the shelf to gather dust and never be seen again.

10. The Inquiry hearings revealed a pervasive tendency of clinical staff to ignore institutional policies and to fail or refuse to file incident reports or request investigation of untoward events. Examples would include the failure to investigate when false negatives were discovered in the late 1990s, and the failure to file incident reports. In other words, a culture of non-reporting. A behavioral organizational review should be conducted,

probably by outside consultants, with a view to establishing effective reporting and a quality assurance response to reporting which is effective and is seen to be effective.

11. This province should consider adopting a Provincial Day of Remembrance for the Victims of Healthcare. This has been done on a national basis for the victims of road crashes, and a national day is now observed on November 19 each year. The needless toll of death and injury from hospital care is even greater than that caused by our highways and our provincial government's proclamation of such a day would mark a serious start down the road to hospital safety. For further information, see Newfoundland Injury Law Blog.[112]

12. Eastern Health should post on its website all its policies and procedures. The days when anyone could plausibly argue the need for secrecy over these is gone. Transparency and accountability should rule.

13. Much of the damage to trust was caused by communications specialists whose lack of understanding of the issues was exceeded only by their zeal to put a positive spin on the story and contain damage. Direct access to the CEO gave these people too much influence. Communications staff should be given training in their ethical responsibilities and they should not report above the vice president level. The need for these positions should be reviewed.

[112] http://www.chescrosbie.com/blog/if-a-national-day-of-remembrance-for-road-crash-victims-is-such-a-good-idea-what-about-the-victi.cfm

14. Heather Predham's position as manager of Quality Assurance and Risk Management implies a potential conflict of interest. A quality assurance manager's loyalty should be to patients and patient safety. A risk manager who must liaise with the insurer must arguably be loyal to the insurer. These functions should be separated.

RESPECTFULLY SUBMITTED this 1st day of December, 2008.

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