Reply Submission

By

Eastern Regional Integrated Health Authority

To

Commission of Inquiry

on Hormone Receptor Testing

December 15, 2008

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I. Introduction

1. Eastern Health responds to the submissions of several of the interested parties as follows.

II. Submission of the Canadian Cancer Society, Newfoundland and Labrador Division

2. The submission of the Canadian Cancer Society, Newfoundland and Labrador Division includes constructive recommendations that reflect the valuable contribution of the Society to the work of this Commission of Inquiry.

3. Regarding those recommendations Eastern Health responds as follows.

Monitoring of ER/PR Test Results and The Cancer Registry[1]

4. Since the reinstitution of ER PR testing in February 2007, and until it was temporarily suspended in the spring of 2008, the rate of positive and negative results has been monitored for trends.[2] 78% of the ER tests performed in that time period had positive results.

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[1] Submission of the Canadian Cancer Society, paragraph 9 and following, and paragraphs 300 to 301

[2] Exhibit P-2725
Evidence of Dr. Nebojsa Denic, September 12, 2008, page 229 line 2 to page 301 line 22

5. Eastern Health agrees with the recommendation for formal monitoring of ER PR test results. This activity falls under the mandate of the Pathology Quality Management Committee, which monitors the rate of positive ER and PR test results, among many other indicators of quality in the Pathology Division. ER negative, PR positive results will be tracked by the Committee.

6. The raw ER and PR data is also now collected in the Cancer Registry and could be used for similar trend monitoring, however Eastern Health suggests that trend monitoring should take place primarily within the Laboratory Medicine Program where the tests are performed, with communication of the results of trend analysis to the clinicians making use of the test.

Quality: National Standards and Occurrence Reporting[3]

7. Eastern Health has recognized the historical and current deficiencies in collection of data in the Cancer Registry. Sharon Smith gave evidence and made a presentation describing the functioning of the Cancer Registry and the need to continue work to resolve outstanding issues with death clearances and ascertainment. Substantial progress has been made to address these issues and diligent efforts will continue. As identified by the Cancer Society, resources must

[3] Submission of the Canadian Cancer Society, paragraphs 96 to 98 and 302 to 304

also be obtained to improve the capacity for analysis of information captured in the Cancer Registry.

8. Eastern Health shares the recommendation of the Canadian Cancer Society concerning the need for provincial and national agencies to work together to implement national standards for immunohistochemical testing and to provide for laboratory accreditation.

9. The Pathology Laboratory policy "Corrective Action for IHC Occurrences"[4] and the analysis of corrective action information gathered in the Pathology Laboratory is not intended to be a substitute for the reporting of occurrences that fall within the Eastern Health occurrence reporting policies. There will be corrective actions taken as part of the normal process of preparation of slides that will not meet the definition of occurrences, but there will be other occasions where both a record of corrective action and the reporting of an occurrence are required. These will include instances where there has been no actual impact on patient care. The Laboratory Medicine Program will undertake a process of continuing education of staff to ensure that it is understood that corrective action reporting is not a substitute for occurrence reporting and to encourage full compliance with occurrence reporting policies.

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[4] Exhibit P-2157 page 177

10. In relation to this, the development of a list of sample events that constitute occurrences that require reporting is a constructive suggestion that will be acted upon.

Patient Right to Effective Timely Communication and the Public Right to Know[5]

11. Eastern Health shares the goals for effective disclosure to patients and the public set out by the Canadian Cancer Society. Since the submissions of the Interested Parties have been filed with the Commission, the Task Force on Adverse Health Events has issued a report to Government also addressing disclosure issues.

12. Eastern Health has adopted policies for disclosure of adverse events to individual patients that are consistent with the CPSI Guidelines. Eastern Health looks forward to the recommendations of the Commission on this issue and anticipates that the implementation of new policies will follow from the work of the Commission and from the position taken by Government on the Task Force recommendations.

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[5] Submission of the Canadian Cancer Society, paragraphs 224 to 228 and 305 to 309

Hormone Positive Test Results and Retro-Conversions[6]

13. As presented in the submission of Eastern Health, work is underway to develop a comprehensive database of all ER PR tests performed between 1997 and 2005. The primary purpose of that work is to ensure that no tests that were originally reported to be negative have been missed in the retesting process. This work is being conducted in collaboration with NLCHI.

14. A secondary outcome of that project will be to allow an assessment to be made concerning the potential retesting of weak positive cases. That assessment will also be done in collaboration with NLCHI.

15. Development of the comprehensive test database will also facilitate assessment of potential rereading or retesting of a sample of all positive cases. A decision has not yet been made as to whether a review of positive cases will be carried out, or what form it would take. Eastern Health recognizes that the suggestions of the Canadian Cancer Society concerning the approach that might be taken, which are consistent with the position outlined in paragraph 462 of the submission of Eastern Health, have merit and they will be given full and careful consideration. In particular, Eastern Health has already taken steps to identify and engage an external consultant to assist with analysis of this issue.

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[6] Submission of the Canadian Cancer Society, paragraphs 295 to 297 and 310 to 313

Epidemiological and Psychological Study of ER PR Group[7]

16. The retesting of ER PR cases, the changes to treatment that have been made as a result and the impact on patients and their families present many opportunities for valuable research. While Eastern Health is primarily a deliverer of health care services, it does actively facilitate research by Memorial University and others. Eastern Health supports the objective of encouraging and facilitating appropriate research as suggested by the Canadian Cancer Society.

III. Submission from the Members of the Breast Cancer Testing Class Action

17. The participation in the Inquiry of the members of the class action added an important and necessary dimension to the public hearings. Many positive contributions resulted. Regarding the submission from counsel for the class members, Eastern Health will confine its reply to the matters raised in paragraphs 117 to 122 where counsel for the class members has made statements of opinion about the culture within Eastern Health regarding disclosure and patient safety.

18. A description of the 'culture' within an organization, or within parts of a multifaceted organization in transition, as Eastern Health has been since its

[7] Submission of the Canadian Cancer Society, paragraphs 314 to 316

inception in 2005, would require a more thorough analysis than has been presented. The Commissioner has heard the testimony of the people who were involved in decision making about retesting and disclosure and in the carrying out of the tasks decided upon, and of people involved in promotion of patient safety within the Health Care Corporation of St. John's, and then within Eastern Health.

19. The disclosure issues confronting those involved in decision making in 2005 and afterwards have engaged competing interests for which there were no clear precedents or standards dictating the course to be followed. The decisions made were made in good faith with what was judged to be in the best interests of affected patients. The "culture" was to find the right thing to do. There was no "culture" or "instinct" to "withhold, manage and spin information".

20. The submission makes a very serious allegation that there was a conspiracy among laboratory and clinical managers and top corporate managers to 'not get caught'. The thorough questioning of all witnesses by Commission counsel provided ample opportunity for discovery of any evidence to support such an allegation. Eastern Health submits that the testimony of the witnesses supports the opposite conclusion and that allegations of conspiracy or cover up are totally unfounded.

21. Regarding the specific allegations of a 'culture of cover up' in paragraphs 122 (a) to (m) of the submission, Eastern Health submits as follows, with reference to the

headings used in paragraph 122 of the submission of counsel for the class members.

(a) "Pathologists fail to investigate false negatives"

22. Mr. Purcell gave moving testimony concerning the retesting of his wife's ER PR sample in 1999 and her tragic death the next year. Her case may have been a missed opportunity to initiate inquiries into the reliability of the ER PR testing being carried out in 1999. Looking back, Dr. Cook considered it to have been a case that, had it come to his attention as Clinical Chief, might have caused him to inquire further.

23. None of the physicians involved in Mrs. Purcell's care testified about how they viewed the changed ER PR results or why no other actions were taken at the time. We do not know of any other similar cases from that time period, so it may have been regarded as an isolated case.

24. Dr. Brufsky testified about his experience with repeated ER PR tests. In his practice he is aware that at times they are repeated in the laboratory before results are reported, but he also has experience with reported tests being retested and changing from negative to positive. If he has a case that is reported to be negative but the clinical presentation suggests that it should be positive he will order a retest. He testified that a retest with a changed result every month or

two would not cause him to make any inquiry, but if there were a string of four or five changes, then he would bring it to the attention of pathology.[8]

25. The allegation of 'cover up' in relation Mrs. Purcell's case implies that there was a deliberate decision to not investigate so as to keep secret known problems with the test results. The evidence does not support such an allegation.

(b) "Clarenville abandons Eastern Health lab"

26. The Clarenville laboratory stopped sending specimens to St. John's for testing in 1999. In 2005 Dr. Cook asked Dr. Naghibi, who had been a pathologist at Clarenville before moving to St. John's, about the change and recorded that he was told that the reasons for it included slide quality, non-receipt of external control slides and cost, and also that St. John's had not been informed of these reasons at the time. The evidence from St. John's pathologists was that they had not been questioning the quality of the slides that they were seeing. Counsel for the class members is correct in stating that the fact that these reasons were not communicated to St. John's may represent a lost opportunity to make an inquiry, but there is nothing here to support any allegation of concealment of information that could have triggered investigation of test results.

[8] Evidence of Dr. Adam Brufsky, October 6, 2008, page 148 line 1 to page 154 line 21

(c) "CEO refuses offer of resources from Minister"

27. Counsel's allegation that Mr. Tilley declined the offer of additional financial resources in the summer of 2005 in order to keep knowledge within the organization is purely speculation that is completely unsupported in the evidence, and should be rejected.

(d) "CEO withholds information from Minister of Health"

28. On November 17, 2005 Minister Ottenheimer, Deputy Minister Abbott and Ms. Mundon met with Mr. Tilley and Dr. Williams.[9] After the meeting Mr. Tilley informed Ms. Bonnell that Ms. Mundon would be sending her questions that the Minister needed responses to before the opening of the House of Assembly.[10]

29. The questions arrived the next day.[11] Ms. Thomas asked for help with drafting answers from Ms. Predham,[12] who in turn asked for assistance from the Laboratory management.[13] Mr. Gulliver and Dr. Cook were unavailable, so Mr. Dyer asked the General Hospital Site Chief, Dr. Fontaine for assistance.[14] Dr. Fontaine provided information to Ms. Predham, including a statement in response to a question about the investigations that had been done to determine

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9 Exhibits P-0133 and P-0150
10 Exhibit P-0152
11 Exhibit P-0153
12 Exhibit P-0391
13 Exhibits P-2989 and P-2362
14 Evidence of Barry Dyer, July 23, 2008, page 83 line 19 to page 86 line 11

how there could have been inaccurate test results that had not been detected sooner. Ms. Predham added that text to her draft responses and sent them by e-mail to Ms. Thomas.[15] Late that afternoon Ms. Thomas sent draft responses to Mr. Tilley, Dr. Williams and Ms. Predham with a copy to Ms. Bonnell. That draft did not include the wording that had been provided by Dr. Fontaine.[16] Mr. Tilley edited the final version.[17]

30. By the conclusion of the public hearings the attachment to the e-mail from Ms. Thomas to Mr. Tilley with the draft responses was not available. Only the covering e-mail message was placed in evidence. Consequently counsel for the class members would not have been aware that it could not have been Mr. Tilley who made the edits that removed the exact text provided by Dr. Fontaine. That text had been removed before the draft was sent to Mr. Tilley. The testimony of the witnesses at the public hearing did not resolve the question of exactly how and by whom the edits that removed that text were made, however neither was there any testimony to support an inference that the editing was done for the purpose of withholding any information from the Minister.

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15 Exhibit P-1506

16 Exhibit P-1523. This exhibit is a printed copy of the e-mail message that did not include the draft responses that were attached. Since the conclusion of the pubic hearings, at the request of Commission counsel, Eastern Health has located a copy of the original e-mail message with the attachment and has provided it to the Commission.

17 Exhibit P-1524

(e) "CEO misleads the Board of Governors"

31. Counsel for the class members wrote that the CEO "mislead" the Board of Trustees by, "stating of the Ejeckam memos 'there was no indication of a results concern'", referring to Mr. Tilley's e-mail memo to the Trustees on May 31, 2007.[18]

32. That e-mail followed the release by the Premier of the June 19, 2003 memo written by Dr. Ejeckam to Mr. Gulliver and the press conference at which Eastern Health released other documentation concerning the 2003 suspension of staining. The phrase that "there was no indication of a results concern" appears in this passage from Mr. Tilley's message:

> The questions of the media were many including:
>
> - why was something not done about this in 2003. The answer was that the focus at that time was about tissue staining and there was no indication of a results concern, unlike in 2005 when there was an index case involving changed results which precipitated the review and subsequent retesting. We told them that the concerns and the memo were not shared at that time beyond the lab and the Surgical Pathology Review Committee (which consisted of pathologists, surgeons, and oncologists) a quality oversight committee.

33. Mr. Tilley was informing the Trustees that in response to the media question about why there had been no retesting in 2003 the media had been told that there had been no indication at that time of a concern about the results of the

[18] Exhibit P-0466

testing. This is consistent with the information available to Mr. Tilley. It is also consistent with the evidence of Dr. Ejeckam, reviewed in the Eastern Health submission, paragraphs 126 to 132, that he had no concern about the test results that had been reported. We know now that there had been three examples of changes in ER PR test results in 2003, but that was not known to Dr. Ejeckam or the laboratory leadership in 2003 and was not known to Mr. Tilley and Dr. Williams in 2005 when they first learned of the 2003 testing suspension, or in 2007 when Mr. Tilley wrote this memo to the Trustees.

34. Counsel for the class members also wrote that the CEO "mislead" the Board of Trustees by stating that, "there were no 'specific recommendations flowing from it'", referring to the June 19, 2003 memo.

35. Mr. Tilley had written in the e-mail message to the Trustees, again in relation to questions from the media, that:

> They asked as to why it was not shared with Administration at the time, we responded that it would not come to our attention unless there were specific recommendations flowing from it.

36. Earlier in the same memo he had also written:

> The points that were made include:
>
> - the 2003 memo was dealt with as a part of the ongoing lab quality control program;
> - the issues of concern related to the staining component though the pathologist did use language that was critical of the service;

- the actual follow up measures at the time were operational in nature and included:

- pulling the technologists together at a central location, ceasing the rotation of the technologists involved in this test to have them perform other related functions and finally bringing in a new piece of technology into the organization to further automate the process.

37. Mr. Tilley thus did describe to the Trustees the actions taken in response to the issues raised by Dr. Ejeckam. The statement that there were no "specific" recommendations was made in the context of explaining why the memos were not brought to the attention of the senior administration at the time. The Laboratory leadership had considered that the issues had been dealt with within the Program and that there were no issues that required that the memo be brought to the attention of the senior leadership of the organization for action at that level.

38. Counsel also wrote that Dr. Williams had argued, "as early as July 15, 2005 that the Board not be informed", referring to the July 15, 2005 e-mail message from Ms. Pennell to Ms. Bonnell.[19] The testimony does not support the statement that Dr. Williams argued against informing the Board, as explained at paragraph 263 of the submission of Eastern Health.

[19] Exhibit P-0070

(f) "Cloak of secrecy dropped over external reviews"

39. The terms of reference prepared for the use of the external reviewers set out the expectations of Eastern Health about how their reports would be treated, stating:

> The External Quality Review shall be in writing and include the team's recommendations. The recommendations will be shared with involved staff members.
>
> The Peer Review, its conclusions and the final report are protected under the *Evidence Act* and, as such, the final report will not be available to any third party and as well the final report is protected from any subsequent legal proceedings.

40. These terms of reference were prepared and communicated before the Eastern Health personnel involved in requesting the reviews had any knowledge of the outcome of the reviews, either from the exit interviews or receipt of the reports. They believed that the reports could be shared with "involved staff members", that the *Evidence Act* protections applied, and that the reports would not be available to third parties. After receipt the reports were treated in a manner consistent with that belief.

41. Judge Dymond found that belief to be mistaken, and for the reasons set out in his decision determined that section 8.1 of the *Evidence Act* did not apply.

42. The belief of Eastern Health personnel that the reports should be properly treated with an appropriate degree of confidentiality, for the purpose of more broadly encouraging the participation of health care personnel in such reviews and of encouraging the free expression of opinion by reviewers, guided their conduct

after the reports had been received. The evidence does not support a conclusion that anyone involved knew that the reports would not meet the requirements for such protection. Their conduct in treating the reports as peer review or quality assurance (the terms being often loosely used interchangeably) is consistent with their genuine belief about the status of the reports. There is no evidence that anyone anticipated that the *Evidence Act* would not apply to them.

43. A “cloak of secrecy” was not “dropped” over the reviews. They were regarded and treated in the way that any review properly meeting the criteria for recognition as protected peer review or quality assurance would have been.

44. At the outset of the investigation phase of this Inquiry, Eastern Health raised the issue of the external review reports with the Commission. Since section 8.1 of the *Evidence Act* operates to bar use of such reports in legal proceedings, but does not prohibit their disclosure to a body like the Commission, the full reports were disclosed by Eastern Health to the Commission. Nothing was withheld. The outstanding issue was whether the reports could be used in the public hearings and whether witnesses could be questioned directly about them. This involved important issues of principle that could affect the ability of Eastern Health and other health care providers to carry out effective peer review and quality assurance activities in the future. The court application was necessary to resolve uncertainties concerning whether section 8.1 applied to these reports and, if so, to determine the effect of section 12 of the *Public Inquiries Act, 2006*.

(g) "Misleading the public on rate of error"

45. Dr. Williams' statements to the media and the public in 2005 regarding the potential for changes in 10% of all ER PR test results have been addressed in the submission of Eastern Health, as has the difficulty of assigning a "rate of error" to the test results.

46. The only documentary reference to 3% is on notes from the meeting with Minister Tom Osborne on November 23, 2006. Eastern Health provided briefing notes and materials to government before and after that date without ever taking the position that the rate of change of test results would be, or had been, 3%. There is no evidence of any public or other statements by anyone on behalf of Eastern Health to the effect that there was a "rate of error" of 3%.

47. On November 23, 2006 Minister Osborne made a handwritten note of "3-4%" on his copy of retesting statistics provided by Eastern Health,[20] but in his testimony could not say where those numbers came from. He recalled that there was not much talk of numbers at that meeting.[21] His evidence was that his note of "3-4%" referred to a "margin of error" rather than a "rate of error", clearly understanding

[20] Exhibit P-0314, page 10
[21] Evidence of Tom Osborne, April 10, 2008, page 18 line 5 to page 20 line 20

there to be a difference between the two. He said that there was no discussion at the meeting about a rate of error.[22]

(h) "Court expert Dr. Gown was provided false information"

48. This allegation is without foundation. The statement in Dr. Gown's affidavit and the rate of positive ER test results shown on Exhibit P-3102 are the same, 74%.

(i) "Disclosure policies ignored"

49. There was no advertent decision to disregard the disclosure guidelines. Instead, as presented at paragraph 552 of the submission of Eastern Health, the guidelines had been developed with a different set of circumstances in mind and were not seen by those involved to be applicable to this case.

(j) "Pathologists investigate Deane conversion because of fear of complaint"

50. The investigation of ER PR results was triggered when oncologists Dr. Laing and Dr. McCarthy brought the Deane case to Dr. Cook, who quickly involved Dr. Carter. They proceeded out of concern for the quality of care provided to cancer patients and not in reaction to any potential complaint.

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[22] Evidence of Tom Osborne, April 10, 2008, page 58 line 1 to page 59 line 7

(k) "We have notified everyone"

51. This issue has been addressed in the submission of Eastern Health.

(l) "Ask the patients"

52. Patients are centrally involved with their health care providers in making decisions about their own health care. Developing a process to involve representative patients in decision making about disclosure to others, such as through the suggested focus groups, was not considered in this case and, given the circumstances prevailing in the summer of 2005, it is difficult to see how it could have been effectively organized and implemented in a timely manner. However, the idea merits exploration to assess how and under what circumstances it can and should be used in the future.

(m) "Eastern Health ethics consultant"

53. The circumstances of the ethics consultation of June 2006 were thoroughly explored in the examination of the witnesses who were present at that meeting. Dr. Singleton in his report to Dr. Williams wrote, in part:

> Important facts to the history and understand of this case include the following
>
> There were no mistakes or technical errors at the root of this problem;
>
> It is impossible to know in any specific case if the outcome for any individual patient would have been different;
>
> Intervention for post-menopausal women had positive impact by lengthening life in 47 % of patients treated.

54. Dr. Singleton testified that there had been relatively little discussion of causative factors at the consultation, which was focused on what to do about disclosure of results that had been obtained from retesting of specimens of deceased patients. In choosing the words that he did he intended to convey the idea that there was no easily identifiable single cause, and that the contributing factors were more systemic and complex. He said that he probably should have expressed it differently than he did in his report.[23]

55. Dan Boone was present at the consultation and had a clear recollection concerning the issue of whether anyone asserted that there were no technical errors at the root of the problem. The excerpt from the transcript of his testimony is as follows:[24]

> COFFEY, Q.C.:
>
> Q. Here, in this report, third paragraph, Mr. Singleton had written, "important facts to the history," and understand, which presumably is "understanding of this case include the following. There were no mistakes or technical errors at the root of this problem. It is impossible to know in any specific case if the outcome for any individual patient would have been different. Intervention for post-menopausal women have positive impact by lengthening life in 47 percent of patients treated." The second assertion, "is it [im]possible to know in any specific case if the outcome for any individual patient would have been different?" You've already referred to that.

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[23] Evidence of Dr. Rick Singleton, June 19, 2008, page 279 line 18 to page 283 line 8, and page 353 line 3 to page 353 line 17; September 25, 2008 page 60 line 12 to page 62 line 13, and page 79 line 2 to page 79 line 14

[24] Evidence of Daniel Boone October 29, 2008, page 185 line 4 to page 187 line 1

MR. BOONE:

A. That's definitely the conversation that I heard.

COFFEY, Q.C.:

Q. Do you recall anyone or any assertion during that meeting to the effect that there were no mistakes or technical errors at the root of this problem?

MR. BOONE:

A. I don't recall anything being said like that. I don't know what the root of the problem would be or what he would have been--Mr. Singleton would have been thinking was the problem. I really don't. I can't interpret the sentence, but I don't--if what he's saying is that somebody asserted that Eastern Health did nothing wrong here, I don't think I ever heard that.

COFFEY, Q.C.:

Q. And that's in the context, because if you look back, he says "the problems with the results was rooted in the test procedures used in the time period from 1997 through 2005" and he goes on to talk about it there, so presumably that's the problem he's talking about, and you certainly don't recall any reference to—or anybody asserting, "look, there were no mistakes -

MR. BOONE:

A. If that's what that assertion is intended to convey, nobody said anything of the sort.

56. Dr. Cook when presented with the same passage from the report testified:[25]

DR. COOK:

A. I wouldn't have made that statement. I don't know where that came from at that meeting.

COFFEY, Q.C.:

Q. Certainly your recollection of the meeting was you didn't offer that opinion yourself?

[25] Evidence of Dr. Donald Cook July 7, 2008, page 95 line 9 to page 96 line 9

DR. COOK:
A. No.

COFFEY, Q.C.:
Q. And I'm not suggesting you did at all.

DR. COOK:
A. No, I don't know where that came from.

COFFEY, Q.C.:
Q. Was the cause or causes of the problem discussed at the meeting, do you know?

DR. COOK:
A. We would have used a word like "system" describing concerns that we had, how the tissue was prepared, how it was tested, how it was interpreted. So we were looking in terms of discussion at system. This is what the -- I guess if anything, that would be the terms that we were using and probably discussing what was going on with the rest of Canada with the testing and the United States, and the problems with the testing in general.

57. Similar testimony was given by Dr. Denic[26], Dr. McCarthy[27] and Ms. Predham.[28] There is no evidence whatsoever to support the contention that Dr. Cook mislead those present at the consultation.

IV. Submission by Dr. Kara Laing et al.

58. Regarding the media briefing on December 11, 2006, in paragraph 269 of the submission by Dr. Kara Laing et al. it is stated that, "it has since been revealed that only a portion of the information known to Eastern Health at that time was

[26] Evidence of Dr. Nebojsa Denic, September 12, 2008, page 87 line 8 to page 89 line 23
[27] Evidence of Dr. Joy McCarthy, September 19, 2008, page 298 line 11 to page 299 line 16
[28] Evidence of Heather Predham, October 21, 2008, page 222 line 10 to page 227 line 13

actually released to the media for dissemination." That statement is incorrect. While not all retesting statistics were released to the media, the media were informed, understood, and reported to the public that information such as the total number of cases with changed test results had not been released.

59. The submission discusses the role of the Program Manager in the Laboratory Medicine Program with respect to a number of events and suggests a rigid division of responsibility between the Clinical Chief and the Program Manager.

60. While the Program Manager and Clinical Chief (and Discipline Chair if that position is separately filled) do have distinct areas of responsibility, the concept of program management requires them to work as a leadership team. Where matters have potential clinical implications there is a role for the Clinical Chief as part of that team.

V. Submission of Central, Western and Labrador-Grenfell Regional Integrated Health Authorities

61. In paragraph 7 of the submission it is stated that it was several months after officials at Eastern Health became aware of a problem with ER PR testing that requests were made to the Authorities to assist with compilation of patient samples to be sent for retesting.

62. The Authorities were informed and involved in the process earlier than is suggested in that passage. The memo from Dr. Cook requesting the collection of

cases for the year 2002 went to pathologists at all Authorities on June 14, 2005 at the same time that Eastern Health was collecting and retesting its own cases from that year.[29] By June 29, 2005 Dr. Dalton had sent his cases to St. John's.[30]

63. The decision to retest all cases from 1997 had been made at Eastern Health by late July, although it had not by then been decided to use Mount Sinai. The need to gather blocks from 1997 was known to Dr. Gallagher by July 24, 2005 when he e-mailed Dr. Carter for clarification of the criteria for selecting blocks.[31]

64. It was August 8, 2005 when memos with details for the retesting at Mount Sinai were circulated within Eastern Health.[32] On August 10, 2005 Dr. Cook began making phone calls to pathologists outside St. John's to ask them to send in cases.[33] As follow up to the calls he sent them a memo on September 6, 2005.[34]

65. The submission of the Authorities also addresses the observations of Dr. Mullen that a portion of the cases that were retested and reviewed by him exhibited signs of deficiencies in tissue fixation and processing. At paragraph 28 the submission states that the Authorities were never advised by Eastern Health of problems with the fixation or processing of the specimens submitted by them.

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[29] Exhibit P-0492
[30] Exhibit P-0494
[31] Exhibit P-2360
[32] Exhibit P-0412
[33] Exhibits P-1936, P-0576, P-0579 page 2, P-0581, P-0589
[34] Exhibit P-0590

66. Aside from the start-up phase for ER PR testing, when Dr. Khalifa read all slides, the specimens from the Authorities were sent to St. John's as paraffin-embedded tissue blocks. All fixation and processing was done by the Authorities. Slides were prepared in St. John's and returned to the pathologist who had requested the test for interpretation. The opportunity to discover issues related to fixation and processing that might have been apparent from those slides rested with the Authorities and not with Eastern Health, or its predecessor, the Health Care Corporation of St. John's.

Respectfully submitted this 15th day of December, 2008.

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