SUBMISSIONS

OF

CENTRAL, WESTERN AND LABRADOR-GRENFELL REGIONAL INTEGRATED HEALTH AUTHORITIES

COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING

TO

The Honourable Justice Margaret A. Cameron Commissioner

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I Introduction

1. In his first Interim Report in the SARS Commission of Inquiry, Mr. Justice Archie Campbell, Commissioner, stated:

> Everything said in this report is said with the benefit of 20-20 hindsight, a gift not available to those who fought SARS or those who designed the system that proved inadequate in the face of a new and unknown disease.
>
> It is important to distinguish between the flaws of the public health systems and the skill and dedication of those who worked within them.[1]

2. The evidence is clear that this Province has highly skilled and dedicated professionals in the health care system. It is equally clear that in pathology/laboratory medicine, there is a lack of human resources, equipment, physical space[2], and sufficient budgets for necessary professional development. Yet the laboratories, as they must, carry on, providing previously unrecognized essential services.

3. As we look back on the ER/PR testing that occurred in this Province from 1997 to 2005, the problems that occurred with the testing, and the response of the Health Authorities as the problems were understood, we must be mindful that the people dealing with the many issues did not have the benefit of any precedent to guide them. What went wrong in the testing process was not then understood, and, it seems there is still no universal agreement.

4. Never before had any of the Health Authorities been required to review its paper and electronic files to identify patients who had received a particular laboratory test. Never

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1 The SARS Commission Interim Report, April 15, 2004; http://www.health.gov.on.ca/english/public/pub/ministry_reports/campbell04/campbell04.html

2 As indicated by the review of Charles S. Curtis Memorial Hospital Pathology Laboratory conducted by Bryan R. Hewlett. See: CIHRT Exhibit Number P-3368.

before had any of the Health Authorities faced the task of communicating to such a large number of patients, province wide, and to members of the public.

5. What took place from the discovery of the problem with the ER/PR test results was unprecedented. The Health Authorities did not have the benefit of hindsight or the benefit of precedents. Dedicated professionals became engaged and used their best efforts to deal with the problem in the best way they knew how. To the extent that mistakes were made, it was not for a lack of dedication or effort.

6. The Western, Central and Labrador/Grenfell Regional Integrated Health Authorities (the "Authorities") have elected to file joint submissions to the Commission of Inquiry into Hormone Receptor Testing (the "Commission"). The positions of the Authorities in respect of certain evidentiary issues, potential findings, and/or future recommendations that may be made by the Commissioner are outlined below.

II Identification of Patients and Communication of Results

(a) Patient Identification

7. It was not until several months after officials at Eastern Health became aware that a problem with ER/PR testing had occurred that requests were made of the Authorities to assist in the compilation of patients samples to be sent to Mt. Sinai for re-testing. The general task was to: (a) identify all patients who had an ER/PR IHC test performed between 1997 and 2005; and, (b) assemble the necessary tissue blocks and test slides for the Mt. Sinai retrospective review. Since Eastern Health did not, at that time, maintain independent records of ER/PR tests which had been completed at its St. John's facility,

the task of identifying patients was reduced to a search and review of individual Pathology reports and records.

8. In some cases, the identification of recent test subjects was relatively straightforward. By 2005, most facilities had adopted an electronic method of recording test results. Test results recorded in such a fashion could be electronically searched by keyword, and a list of perspective patients could be obtained in relatively short order. Unfortunately, in the earlier years of the ER/PR testing era, most facilities outside St. John's utilized either paper records or non-searchable electronic records. This technological limitation necessitated a physical search and review of pathology records.

9. At the time that the list of retest subjects was compiled, the leadership of Eastern Health's Laboratory Medicine Program and Pathology Division compiled a list of all patients (that they could identify) who had an ER/PR test performed between 1997 and 2005. Unfortunately, this information was never offered to the Authorities[3]. Had this information been offered, it may have helped minimize the delay associated with a physical review of the Pathology Reports (as was the case with Labrador-Grenfell, see below). This information could also have been used to cross reference the results of all the local searches done in each of the Authorities to further minimize the chance that a patient be improperly excluded from the re-test group.

10. An excellent summary of the actual patient identification efforts undertaken by the Authorities can be found in a spreadsheet compiled by the Newfoundland and Labrador

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[3] Evidence of Terry Gulliver 9/10/08, from Page 350, Line 20 to Page 356, Line 25.

Centre for Health Information ("NLCHI")[4]. Some specifics of the identification efforts are further outlined below.

11. In the Central Health Authority, different methods were undertaken in Grand Falls and Gander. Because most of the ER/PR testing was done when these two labs were functioning under separate predecessor organizations (the former Central West and Central East Authorities), different record-keeping systems were in place. At the Grand Falls site, logbooks had been kept which identified all Pathology tests performed on patient samples. Accordingly, a manual search of the logbook was performed. Once this was completed, a Meditec database search was done for post-2001 "breast" and "carcinoma" to produce a list of cases for cross-referencing against the logbook[5].

12. In Gander, various Meditec searches were performed, for: (a) "breast"; (b) "breast" + "carcinoma"; and, (c) "breast" + "carcinoma" + "hormone receptor". All of the reports identified through these various search mechanisms were printed. The resulting reports were then individually reviewed to ensure completeness[6].

13. Ultimately, personnel in both Gander and Grand Falls had to perform a physical review of pathology reports to ensure that as many cases as possible were identified for the purposes of retesting.

14. Western Health utilized a variety of different methods to identify patients for retesting. First, a search was done of all requisition forms where ER/PR tests were ordered between 1997 and 2005. Second, a request was made of the Newfoundland Cancer

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4 CIHRT Exhibit Number P-3555, at pages 3–6.

5 Evidence of Dr. Maurice Dalton, 18/07/2008, from Page 248, Line 12 to Page 250, Line 16.

6 Evidence of Dr. Barry Gallagher, 25/07/2008, from Page 116, Line 9 to Page 117, Line 9.

Treatment Research Foundation for the production of list of all cancer cases reported from the Western region between 1997 and 2005. Finally, an electronic search was made of the Meditec database from 1999 onwards. (The system was only implemented for pathology in 1999.) The relevant reports were all printed and physically reviewed as part of the identification process[7].

15. The Labrador-Grenfell Health Authority faced a particularly onerous task in searching its records. Having not implemented an electronic means of entering pathology reports and records until 2003, much of the data required for retesting was only available in old paper records. After a manual search was done for all pathology cases reported in St. Anthony for 2002, it was recognized that a manual search of all records from 1997 – 2001 would be a massive undertaking (between 2,000 and 3,000 records per year). To deal with this problem, officials at Labrador-Grenfell enlisted the help of Eastern Health to obtain a list of all breast specimens that went to St. John's for testing between 1997 and 2001. This information was ultimately provided and utilized in assembling the list of patients for retest. Ultimately, to ensure that all patients possible were found, every single Pathology Report generated at the Labrador-Grenfell, between the years of 1997 and 2005, was physically reviewed. This amounted to the manual review of between 13,000 and 15,000 pathology reports[8].

16. In the circumstances, the Authorities submit that the best possible efforts were made to compile the appropriate patient list. The Authorities suffered from the profound disadvantage of having not performed the actual tests, and thus not having access to a comprehensive database of all patients who had received the tests. This limitation,

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7 Evidence of Dr. Paul Neil, 10/07/2008, from Page 225, Line 9 to Page 228, Line 3.

8 Evidence of Dr. Kweku Dankwa, 11/07/2008, from Page 242, Line 18 to Page 254, Line 2.

combined with the enormity of the search, and the limited personnel available, placed a considerable strain on each of the Authorities.

17. The scope of the respective reviews and the overlapping levels of technology in patient recordkeeping made this an all but impossible task to do in such a manner as to create a fool-proof list of patients for retesting. The Authorities submit that, even with the benefit of hindsight, it is difficult to see what more could reasonably have been done to ensure the proper identification of all patients once the problem with testing was reported by Eastern Health.

(b) Communication of Results

18. The Authorities were placed in a difficult position with respect to the notification of affected patients. First, the Authorities were not responsible for the actual performance of ER/PR testing. Second, the Authorities were never advised of the factors which contributed to ER/PR testing errors (as they were identified by Dr. Diponkar Banerjee and Ms. Trish Wegrynowski). In the circumstances, the Authorities lacked the ability to advise patients of the reasons for the test failures. The only information that the Authorities could offer was first that re-testing was taking place and then the actual results of the re-test for a given patient.

19. Irrespective of the information advantage held by Eastern Health, the Authorities submit that it was prudent for Eastern Health to take a lead role in patient notification. The ER/PR matter was, and remains, an extremely complex issue. The management of patient communications, and the provision of a consistent, accurate message, was clearly challenging, even when Eastern Health was taking a leadership role in this regard. The Authorities submit that communication through a common voice, under the direction of Eastern Health was the best available strategy. The presence of additional

messengers, and messages, would only have served to obfuscate the already confused communication channels between patients and their care-givers.

(c) Conclusion

20. The Authorities submit that each of them, along with their individual representatives and employees, exercised the utmost diligence in fulfilling their respective roles in the notification of patients. Each individual exercised their obligations in an appropriate manner, and in a timely fashion, whenever they were called upon to contact affected patients and/or the families of deceased patients.

III ER/PR Testing Outside of St. John's

21. In the years when Eastern Health was performing ER/PR Testing via the IHC method, samples were being processed by pathology laboratories in each of the Authorities. In these situations, tissue samples were removed from patients by local surgeons. The tissue was then fixed and processed by pathologists and technologists in Corner Brook, St. Anthony, Grand Falls, and/or Gander, as the case may be. Once the tissue had been fully processed, the parafinized blocks were shipped to Eastern Health for the completion of ER/PR Testing.

22. Upon receiving samples from the Authorities, the technologists at Eastern Health would prepare sections from the tissue blocks, and create and stain tissue slides in accordance with their IHC testing protocol. The net result of this process was a slide which was to be interpreted by a pathologist. When the test had been requisitioned by a pathologist within one of the Authorities, the prepared slides were returned to the original pathologist for interpretation.

23. In summary, the role of the out of town labs was to take the raw tissue recovered in surgery and convert it into usable tissue blocks through the fixation and tissue processing stages. From these blocks, ER/PR slides were created by Eastern Health and those slides were interpreted by pathologists in out of town hospitals.

24. In the course of his consultative work for Eastern Health, and for the Commission, Dr. Brendan Mullen of Mount Sinai Hospital had occasion to review a significant number of the original slides generated by Newfoundland Health Institutions. In his review, Dr. Mullen stated as follows:

> There are very few cases in which there was a significant difference in my observation compared to that recorded on the original report. Some of my observations were higher than those recorded and some lower[9].

25. Accordingly, it does not appear that the interpretation of the slides was a significant factor in creating the number of testing errors observed. Firstly, Dr. Mullen notes that a small minority of cases exhibited variance in interpretation. (It is noteworthy that such discrepancies do not of necessity impact patient care, in that a variation in percentage positivity may not affect an oncologist's treatment recommendations.) Secondly, Dr. Mullen notes that his observation of interpretive variance was not consistently biased in one direction. His results were neither consistently higher nor consistently lower than those reported originally. As such, there does not appear to have been a tendency to over-call or under-call the level of positivity exhibited in the original slides. This conclusion is further supported by the evidence of Dr. David Dabbs, who testified that

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9 CIHRT Exhibit Number P-1840, at page 2.

the type of inter-observer variability described by Dr. Mullen was well within acceptable parameters[10].

26. The Authorities submit that the evidence of Dr. Mullen illustrates that the reporting of false (negative) results in cases originating from the Authorities did not arise from interpretation errors by reporting Pathologists.

27. Aside from interpretation, the only remaining involvement of the out of town labs in the ER/PR process was the fixation and preparation of tissues blocks for analysis in St. John's. In the external review commissioned by Eastern Health, it has been noted that fixation procedures were less than optimal throughout the Province[11]. That said, there is ample evidence to illustrate that the process of fixation, while likely a contributing factor to some test failures, was not the sole, or even leading, cause of poor results.

28. The Authorities were never advised by Eastern Health that there was a problem with the fixation and/or processing of any of the tissue blocks sent for ER/PR testing.

29. An illustration of this can be found in Dr. Mullen's analysis of the original slides, particularly his spreadsheet generated from a review of original slides[12]. In this document, Dr. Mullen details his observations regarding original slides prepared by Eastern Health. His analysis includes a comment, under the heading "F/P", for fixation and processing. He either notes that fixation and processing were adequate ("A") or

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10 Evidence of Dr. David Dabbs, 16/09/2008, from Page 17, Line 24 to Page 20, Line 12.

11 As indicated in the External Review Report of Dr. Diponkar Banerjee. See: CIHRT Exhibit Number P-0046, at page 3.

12 CIHRT Exhibit Number P-1837, at pages 1-30.

poor ("P"). In perusing this data, it is clear that a significant majority of slides reviewed by Dr. Mullen were adequately fixed and processed. While Dr. Mullen did state that he applied a low standard in assessing the adequacy of fixation, he did testify that:

> It's a standard that, very - as I mentioned yesterday, it was basically, ***is there anything that I can interpret with comfort, and that's a moving target but given the size of the original section of the H & E Section, given what I perceive to be the tumour, given what I perceive to be the internal control, is there enough there on the ER slide and the PR slide that, as we discussed yesterday, we prepared and that we are discussing today that were prepared in Newfoundland, is there enough there that gives me reasonable comfort that I can make an interpretation.*** Again, this is all material that was - that I can't go back, I can't change anything after case one. It is not something, it's not a prospective, it's all retrospective so...[13]
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> [Emphasis added]

30. Perhaps the most compelling reason for the assertion that fixation was not the fundamental cause of the ER/PR testing errors is the undeniable fact that Dr. Mullen took the entire body of tissue samples, prepared by pathologists throughout Newfoundland and Labrador and conducted retests on those same samples. Whatever deficiencies may have existed in those tissue samples at the time of the original tests were necessarily still evident at the time of the retest. Interestingly, Dr. Mullen appears to have still been able to generate interpretable, reliable results for all cases. Indeed, the validity of Dr. Mullen's results is the very basis for asserting that testing errors took place at all.

31. The Authorities submit that the original testing errors could not have been principally caused by poor fixation if Dr. Mullen was able to overcome any deficiencies and obtain valid results. Rather, some other factor(s) must have caused these errors in testing. If neither interpretation nor fixation were principal causative factors, then those factors must have occurred in the actual processing of the IHC slides.

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13 Evidence of Dr. Brendan Mullen, 27/06/2008, from Page 102, Line 24 to Page 103, Line16.

32. Again the Authorities point to the testimony of Dr. David Dabbs:

> Q: Doctor, the Commission has heard evidence, of course, about – much evidence about what has been phrased "conversions" here in this matter. Doctor, several questions in this regard. From your perspective, ***what could account for*** or what might potentially account for a patient who was originally – upon originally being tested, okay for ER and PR, in particular we will use ER right now, ***a patient who when originally tested for ER was classified as a no expressor, 0%, and on retesting became what I will refer to as a high expressor***, which as I say, I'll pick a figure, 80% or 90%, using the same block, albeit done in two different laboratories, what could account for that difference?
>
> A: ***I think that it is probably safe to say that the one thing that would not account for it would be tissue fixation*** because if you are going from a negative to – would be a strong positive result, it most certainly – ***almost certainly not tissue fixation, but rather technique, and by technique, I mean, this could be anywhere from all the steps that I demonstrated. Initial – the concentration, the tighter [sic] of antibody, if that is not done correctly, you are going to end up with a negative result...***
>
> Q: In the original...
>
> A: In the original lab, which when properly done in another lab will show up as strongly positive. It is not going to be related to antibody clone because the clones that are out there are all fairly robust and comparable, so that is not going to be a cause for it.
>
> Q: It wouldn't account for a low – no expressor to a high expressor.
>
> A: Correct, no, it would not. So here we're talking about the technique. ***We are talking about probably, you know, tighter [sic] of antibody would be a crucial component, again, a proper dehydration and de-parafinization, and, of course, antigen retrieval is crucial there as well. If antigen retrieval techniques are comparable in this situation that you are telling me, then we are really pointing all fingers towards antibody dilution being improper and giving an original negative result, which when then properly diluted would give you the appropriate result.***
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> Q: And that, of course, assumes that the antigen retrieval methods....
>
> A: Are comparable.
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> Q: And if they're not, if there are any one or more deficiencies in the original laboratory, it could account for a no expressor to a high expressor in the retest lab?

> A: Yes, correct, and you know, it's not just about heat and duration, but it's also about buffers. So if the buffer calls for a basic pH, but it as being done at an acetic [sic] pH, that would obviously be a huge defect that could account for a false negative.[14]
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> [Emphasis added]

IV Budgetary Considerations

33. Throughout the process of the evidentiary hearings conducted by the Commission, there have been discussions around initiatives which could serve to improve the quality of pathology/laboratory medicine services, and health care generally, in the Province. In many cases, this discussion has also pointed to deficiencies in the current system. While the following list is by no means exhaustive, some of these issues are:

(i) The need for improved recruitment and retention of pathologists;

(ii) The need for more and better trained technicians;

(iii) The need for increased staffing throughout all levels of the laboratory medicine system;

(iv) The need for more comprehensive and frequent continued medical education;

(v) The need for robust quality assurance and quality control programs for laboratories throughout Newfoundland and Labrador;

(vi) The possible need for standardized laboratory accreditation processes for pathology services generally, and for immunohistochemistry ("IHC") services in specific;

(vii) The need for expansion and upgrades to laboratory premises and laboratory equipment throughout Newfoundland and Labrador; and

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14 Evidence of Dr. David Dabbs, 15/09/2008, from Page 209, Line 19 to Page 212, Line 17.

(viii) The need for an integrated, comprehensive and robust electronic patient record system that does more than hold data but rather provides valuable information.

34. In most, if not all, of these cases, the Authorities would welcome these developments, if properly implemented. Indeed many of these items have been goals of the Authorities for some time. However, it is critical to note that each and every one of these items would require significant resources, both financial and otherwise, before it could be implemented. A strong commitment of resources by the Provincial Government must be in place before any such initiatives can be pursued. The Authorities submit that, in the eventuality that any or all of the above-listed items are incorporated into the Commissioners official recommendations arising from this Inquiry, it is imperative that the recommendation(s) be tied to a recommendation for additional government funding. At current funding levels, there is little chance that any meaningful attempt could be made to implement such initiatives. The Authorities therefore request that the Commissioner remain cognizant of this issue in the midst of her deliberations and her preparation of the Commissions' final report.

V Pathology Services Beyond the Boundaries of Eastern Health

35. Another issue which is of profound importance to the Authorities is the long-term future of the provision of Pathology Services outside the St. John's region. The Commissioner has heard direct evidence from a number of pathologists practicing outside the City of St. John's. Pathologists from Corner Brook (Dr. Paul Neil), St. Anthony (Dr. Kweku Dankwa), Grand Falls (Dr. Maurice Dalton), Gander (Dr. Barry Gallagher) and Carbonear (Dr. Gary Baker) have all testified. These individuals all offered their unique

insights into the benefits and challenges of practicing pathology in a smaller centre with a limited number of colleagues.

36. The Commission has also heard considerable evidence about the frequency with which pathologists perform certain procedures, and the difficulties of generalists when faced with an increasingly complex set of practice demands. ER/PR IHC testing is a particular example of this phenomenon, as none of the pathologists practising with the Authorities were faced with a sufficient volume of breast cancer cases to see more than an occasional ER/PR test.

37. Such discussions inevitably lead to the topic of increased sub-specialization, which would greatly increase the relative exposure of a given pathologist to those specific procedures that he/she is charged with performing. Taken to its extreme, the goal of sub-specialization and focussed caseloads could call into question the very need for "general" pathology services being performed on an as-needed basis in smaller hospitals. The Authorities submit that the Commissioner should not only resist any such arguments but also strongly re-iterate the vital need for pathology services in rural health care settings.

38. In support of their position, the Authorities refer to the testimony of Dr. Kenneth Jenkins, the Vice-President of Medical Services for Western Health. Dr. Jenkins offered the following commentary when questioned by counsel on the need for pathology services outside the City of St. John's[15]:

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15 Evidence of Dr. Kenneth Jenkins, 22/09/2008, from Pages 266, Line 22 to Page 268 Line 20.

Q: Just one area to touch on generally, Dr. Jenkins, and that is something that really hasn't come up specifically yet, and that is the need for pathology generally in the regional systems, I guess, or the regional health authorities. We have heard a fair bit of evidence to date about very specialized areas of pathology, but nobody has spoken or indicated about ***the need for pathology in the regional health authorities.***

A: Right.

Q: ***Can you comment on that?***

A: Sure.

Q: Perhaps give the Commissioner some idea how it works on a regional basis, just in a general way.

A: Sure. So in terms of looking at our, you know major health centres in the Western Region which will be located in Corner Brook and Stephenville where our two hospitals are located, ***any time there is a provision of speciality service and particularly for surgical programs***, but also in some other areas, you know, pathology – excuse me, dermatology would be one that comes to mind. You know, ***there is a fair amount of demand for general pathology service***, in particular, and there is a need to have ready access and availability between colleagues, you know, to be able to deal with samples that may need some immediate attention and for colleagues to converse directly on aspects of patient care. So certainly it is very important, from our perspective, that we have access to general pathology supports, and I think you would find that in secondary centres, which basically everything outside of St. John's in hospitals is considered a secondary centre, for the most part. Yeah, there certainly is a need to provide some of those types of services, particularly in support of the surgical program that I mentioned, particularly significant.

[Emphasis added]

39. A similar perspective was offered by Dr. Lawrence Alteen, former Vice-President of Medical Services for Central Health[16]:

Q: Thank you. Dr. Alteen, I am just going to ask you about the – ***your views on the necessity of having pathology within the Regional Health Authority*** at, I think you called it level 2 hospitals?

A: Right.

Q: Do you have any thoughts on that?

A: I think, as I talk to pathologists and Dr. Dalton, like I said, has worked with us and I have worked with him since in my capacity as the VP since 1998 and with Dr. Gallagher and Dr. Somers since 2005. We've had numerous conversations and ***there has been a concern when it comes to a regional site that perhaps some of these services could be done elsewhere, i.e., all centralized so that all pathology goes to a central location***. When you have these conversations,

16 Evidence of Dr. Lawrence Alteen, 23/09/2008, from Page 171, Line 5 to Page 173, Line 24.

> I think you have to bear in mind that it depends on what your perspective, pathologists do more that sit all day and look at a microscope or do autopsies. Obviously the general functioning of the lab when it comes to general pathology, they are involved in haematology, blood bank and there's lots of other issues that go on. At the same time there are numerous conversations that go on, certainly at our organization whereby there is contact between the surgeons, the dermatologists, even I as a family practitioner there's times I have gone and met with a pathologist about a particular patient who you have some questions about because the history that would give the pathologist and generally for most of us a physicians you tend to have busy lives, sometimes what you put on a particular form that goes with the specimen is very limited, you know, maybe a one liner, sort of thing. And sometimes the pathologist, to provide a consultation service, they need more information, and sometimes that dialogue has to occur. They could argue, I guess, that that dialogue can occur, you know, we all have telecommunication, all kinds of access points, but sometimes that one on one conversation, ad there is lots that they do in terms of education. They had been doing for a period of time now sort of reviews with the radiology department in terms of breast cancer or breast biopsies that may be done as needle localizations and the correlation between that and the final pathology. So there's lots of interactions that go on. ***And my fear, personally, is that if this service gets removed from an organization, have you lost something because of that, irrespective and understanding the issues around the quality that we all have to be concerned about and how do you assure appropriate quality at the same time as maintaining some of these other services, those linkages, and it's a challenges. And I think at some point you have to come to the conclusion that there are certain things you will do at a secondary level service and there are other things that should be done at a tertiary care level.***
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> [Emphasis added]

40. We submit that the views of Drs. Jenkins and Alteen, given their extensive experience as Vice-Presidents of their respective Authorities, should be given considerable weight. It is clearly their view that pathology is a necessary component when providing even a basic level of service in rural areas. While there may well be a clear definition between 'usual' services and those services which are too specialized to be performed in such a setting, we submit that the ongoing quality of care of patients outside of St. John's demands the maintenance of a wide range of pathology services at secondary level facilities.

VI Inter Laboratory Communication

41. Throughout the course of the Inquiry, many witnesses have testified about the series of three memos written by Dr. Gershon Ejeckam in the spring of 2003[17]. It is clear that these memos were not circulated as widely as Dr. Ejeckam had intended, particularly within the Authorities[18,19,20,21]. In any event, Dr. Ejeckam, an expert in the area of IHC testing, provided what should have been an invaluable resource to pathologists throughout the Province. Unfortunately, not all pathologists were able to receive the benefit of Dr. Ejeckam's knowledge and expertise.

42. The Authorities submit that the failure to circulate Dr. Ejeckam's memo is indicative of a larger problem which should be addressed in the Commissioner's recommendations. It is easy to foresee situations where enhanced communication amongst the Province's pathologists would be highly beneficial. Some sort of established system whereby items like Dr. Ejeckam's memos could be widely and reliably circulated to all pathologists would be profoundly helpful. If the system was well established, and well advertised to staff, one could avoid the disconnect seen here whereby Dr. Ejeckam intended on circulating the memos to all pathologists in the Province, but most pathologists outside St. John's did not receive them.

43. An organized system of communication is particularly important to the continued operation, and maintenance of quality patient care, outside St. John's. By establishing

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17 CIHRT Exhibit Number P-0113, at pages 1-7.

18 Evidence of Dr. Paul Neil, 10/07/2008, from Page 131, Line 18 to Page 132, Line 21

19 Evidence of Dr. Kweku Dankwa, 11/07/2008, from Page 218, Line 7 to Page 220, Line 19.

20 Evidence of Dr. Maurice Dalton, 18/07/2008, from Page 216, Line 13 to Page 223, Line 14.

21 Evidence of Dr. Barry Gallagher, 25/07/2008, from Page 85, Line 18 to Page 87, Line 20.

such a communication system, the unique and particular expertise which is present in the tertiary care centre can be spread throughout the Province. As such, pathologists who are functioning on their own, or as part of a very small team, could have had immediate (possibly electronic) access to other pathologists who may have more experience in a particular area. This could only serve to benefit patient care.

44. In the particular case of ER/PR, there is considerable evidence to the effect that pathologists outside of St. John's were seeing very few cases of ER/PR tests per year. For example, Dr. Dankwa in St. Anthony was viewing approximately one to two cases per month[22]. Drs. Neil (10 cases per year)[23], Dalton (one case every 10-14 days)[24], and Gallagher (10 cases per year)[25] all testified that similarly small volumes was seen by the pathologists in Corner Brook, Grand Falls and Gander, respectively. In a situation such as this, where specialized testing is occurring on a very rare basis in smaller labs, the system could be greatly improved if those pathologists in the larger centre, who are more familiar with these special cases, were readily able to share their knowledge throughout the Province.

VII PART II

45. Part II of the Inquiry was dedicated to the exploration of patient disclosure after the discovery of adverse events, particularly in cases involving more that one patient. The

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22 Evidence of Dr. Kweku Dankwa, 11/07/2008, from Page 194, Line 11 to Page 196, Line 6.

23 Evidence of Dr. Paul Neil, 10/07/2008, from Page 86, Line 11 to Page 87, Line 25.

24 Evidence of Dr. Maurice Dalton, 18/07/2008, from Page 158, Line 11 to Page 159, Line 5. Dr. Dalton's evidence related to the number of cases referred to the Pathologist(s) in Grand Falls. While Dr. Dalton testified that he has often been the sole Pathologist in Grand Falls, a second position exists, and it has been periodically filled by a qualified Pathologist at various points in the last 11 years. During the periods when there were two Pathologists in Grand Falls, each Pathologist would see a case every 3-4 weeks, a level similar to that reported by Dr. Dankwa (see note 22).

25 Evidence of Dr. Barry Gallagher, 25/07/2008, from Page 78, Line 13 to Page 79, Line 7.

examination of this topic drew on the fundamental principles of patient care, medical ethics and the legal obligations of health care professionals. The Authorities believe that the conduct of Part II was an important investigation into an area of medical practice and health administration that remains ill-defined.

46. One of the most striking realizations to come out of Part II was the fact that medical professionals around the world have struggled for many years to establish generally accepted protocols for (individual) patient communication upon the occurrence of an adverse event. Indeed it was not until 2008 that the Canadian Patient Safety Institute released its ***Canadian Disclosure Guidelines.***

47. Part II also demonstrated that insofar as adverse events occur to a large number of patients, there is still no generally accepted protocol as to how such information should be communicated to the patients.[26] While some of the principles applied in individual patient events may be relevant, there is simply no formal guidance for an institution considering an issue of public disclosure.[27] With the possible exception of case law which speaks to how mass disclosure should not occur, the institution contemplating public disclosure of an event, or series of events, is faced with a potentially unsolvable conundrum.

48. It is clear that public disclosure has many complex, and occasionally conflicting, issues that have yet to be resolved. Foremost among there are, or course, patient safety, quality of care and the privacy rights of individual patients. While it may be beyond the scope of this Inquiry to fill the void in this area of medical practice and health

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26 Dr. Peter Norton, 22/04/2008, Transcript page 150, line 22 to 152, line 12.

27 Dr. Thomas Gallagher, Closing Panel Discussion, 23/04/2008, Transcript page 92, lines 11 to 21.

administration, it is hoped that this Commission will provide some guidance so that in the future, should another widespread event such as the ER/PR testing matter occur, health authorities will not be left to their own devices to struggle through disclosure issues.

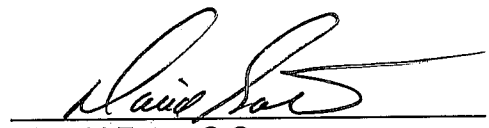
VIII Conclusion

49. The Authorities acknowledge that the failures in ER/PR testing over the last decade represent a dark period in the history of health care in this Province. Public confidence in the health care system has eroded. This state of affairs has caused a great strain, not only on those who rely on health care services, but also on the professionals who dedicate themselves to providing a high quality of patient care. As serious as this problem is, however, it pales in comparison to the tragic – and potentially irreversible - consequences faced by breast cancer patients and their families. The aggravation of illness and/or loss of life are outcomes that forever change the affected families. The Authorities hope that this Inquiry can play a vital role in restoring public confidence and in providing much deserved answers to patients and their families.

50. There can be no doubt that IHC testing, pathology laboratories and practices, laboratory medicine, and the provincial health care system in general, will benefit greatly from the recommendations to be made in the Commission's final report. In fact, many meaningful improvements have already been made as a result of evidence given as a part of these hearings. Many other important changes are in progress.

51. However, as noted above already, the recommendations will only be valuable if the resources are available to implement them. It is hoped that the Report will emphasize this need.

All of which is respectfully submitted this 1st day of December, 2008.



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